



**ASX ANNOUNCEMENT**

**26 July 2023**

## **CardieX files with the SEC for IPO & dual listing on Nasdaq**

CardieX Limited (ASX: CDX) ("CardieX" or "the Company") is pleased to announce the public filing of a registration statement on Form F-1 with the U.S. Securities and Exchange Commission (the "SEC"). The filing relates to a proposed initial public offering (the "Offering") of American Depositary Shares ("ADSs") representing CardieX's ordinary shares and the subsequent listing of those ADSs under the ticker symbol "CDEX" on the Nasdaq Capital Market® ("Nasdaq"). The registration statement is also being lodged with the ASX as part of this announcement.

A registration statement on Form F-1 is filed with the SEC by non-US companies seeking to undertake an IPO in the United States and list on a U.S. exchange. It is similar to a prospectus for an Australian IPO but is more comprehensive.

The Offering is subject to the Company obtaining shareholder approval for the issue of ordinary shares under the Offering, which will be sought at an Extraordinary General Meeting of shareholders to seek shareholder approval (which the Company expects to provide notice of imminently), as well as general market conditions, and there can be no assurance as to whether, or when, the Offering may be launched or completed, or as to the actual size or terms of the Offering. The number of ADSs to be sold, the issue price per ADS under the Offering, and the number of ordinary shares represented by each ADS have not yet been determined.

Roth Capital Partners is acting as lead book-running manager for the Offering. The Offering will be made only by means of a prospectus. When available, copies of the preliminary prospectus related to the Offering may be obtained from:

Roth Capital Partners  
888 San Clemente, Newport Beach, CA 92660  
Attn: Prospectus Department  
Telephone: 800-678-9147  
Email: [rothecm@roth.com](mailto:rothecm@roth.com)

CardieX's ordinary shares are currently listed on the ASX under the symbol "CDX" where those securities will continue to trade throughout and, if completed, upon completion of the Offering. The proposed Nasdaq listing of ADSs is not intended to involve a delisting of ordinary shares from ASX, and if successful it would mean that the Company will be dual listed on both ASX and Nasdaq.

A registration statement on Form F-1 has been filed with the SEC but it has not yet become effective. Accordingly, no securities may be sold, nor may offers to buy be accepted, prior to the time the registration statement becomes effective.

This announcement does not constitute an offer to sell, or the solicitation of an offer to buy, any securities in any jurisdiction, nor shall there be any sale of these securities in any state or jurisdiction in which such an offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction. Any offer or solicitation of any sale of securities will be made in accordance with the registration requirements of the US Securities Act of 1933.

**Craig Cooper**  
**Chief Executive Officer**

**Approved by the Board of Directors and Released by the Company Secretary**

**- ENDS -**

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**About CardieX**

CardieX is a medical technology company focused on developing vascular biomarkers. Its ATCOR subsidiary is a leader in medical devices and vascular biomarkers for hypertension, cardiovascular disease, and other vascular health disorders based on the Company's SphygmoCor® central blood pressure technology. CardieX's CONNEQT subsidiary develops and markets medical devices, digital solutions, and wearables for home health, primary clinician, and other healthcare channels. CardieX is listed on the Australian Stock Exchange (ASX:CDX).

### **Forward Looking Statements**

This announcement contains forward looking statements, including statements of current intention, statements of opinion and predictions as to possible future events. Forward looking statements should, or can generally, be identified by the use of forward-looking words such as “believe”, “expect”, “estimate”, “will”, “may”, “target” and other similar expressions within the meaning of securities laws of applicable jurisdictions, and include but are not limited to the expected outcome of the acquisition. Indications of, and guidance or outlook on, future earnings or financial position or performance are also forward-looking statements. Such statements are not statements of fact and there can be no certainty of outcome in relation to the matters to which the statements relate. These forward-looking statements involve known and unknown risks, uncertainties, assumptions and other important factors that could cause the actual outcomes to be materially different from the events or results expressed or implied by such statements. Those risks, uncertainties, assumptions and other important factors are not all within the control of CardieX and cannot be predicted by CardieX and include changes in circumstances or events that may cause objectives to change as well as risks, circumstances and events specific to the industry, countries and markets in which CardieX operates. They also include general economic conditions, exchange rates, interest rates, competitive pressures, selling price, market demand and conditions in the financial markets which may cause objectives to change or may cause outcomes not to be realised.

None of CardieX or any of its subsidiaries, advisors or affiliates (or any of their respective officers, employees or agents) makes any representation, assurance or guarantee as to the accuracy or likelihood of fulfilment of any forward-looking statement or any outcomes expressed or implied in any forward-looking statements. Statements about past performance are not necessarily indicative of future performance.

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM F-1**  
REGISTRATION STATEMENT  
*Under*  
*The Securities Act of 1933*

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**CARDIEX LIMITED**  
(Exact name of Registrant as specified in its charter)

Not Applicable  
(Translation of Registrant's name into English)

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**Australia**  
(State or other jurisdiction of  
incorporation or organization)

**3845**  
(Primary Standard Industrial  
Classification Code Number)

**Not Applicable**  
(I.R.S. Employer  
Identification Number)

55 Lime Street, Suite 301  
Sydney, NSW, 2000  
Australia  
Tel: +61 2 9874 8761  
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

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Craig R. Cooper  
Chief Executive Officer  
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Tel: (630) 228-8871  
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the

extended transition period for complying with any new or revised financial accounting standards<sup>†</sup> provided pursuant to Section 7(a)(2)(B) of the Securities Act.

<sup>†</sup> The term “new or revised financial accounting standard” refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission acting pursuant to said Section 8(a), may determine.**

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED JULY 25, 2023**

**Preliminary Prospectus**

**American Depositary Shares representing Ordinary Shares**

**CARDIEX**

**CardieX Limited**

This is an initial public offering in the United States of American Depositary Shares (“ADSs”) representing of ordinary shares, no par value, of CardieX Limited (“CardieX”), deposited with JPMorgan Chase Bank, N.A., as depository. The estimated initial public offering price will be between US\$ and US\$ per ADS.

Our ordinary shares currently trade on the Australian Securities Exchange under the symbol “CDX.” On , 2023, the closing price for our ordinary shares on the ASX was A\$ per ordinary share (US\$ per ordinary share, based on an exchange rate of A\$1.00 to US\$ as published by the Reserve Bank of Australia as of such date). We have applied to list our ADSs on the Nasdaq Capital Market under the symbol “CDEX.” We will not consummate this offering unless our ADSs are approved for listing on the Nasdaq Capital Market.

**Investing in our securities involves a high degree of risk. Before buying ADSs you should carefully read the discussion of the material risks of investing in our securities in “Risk Factors” beginning on page 12 of this prospectus.**

**We are an “emerging growth company” as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.**

	<u>Per ADS</u>	<u>Total</u>
Initial public offering price	US\$	US\$
Underwriting discounts and commissions <sup>(1)</sup>	US\$	US\$
Proceeds before expenses, to us	US\$	US\$

(1) See “Underwriting” for a complete description of the compensation payable to the underwriters.

In addition to the underwriting discounts and commissions referred to in the table above, we have agreed to issue, upon closing of this offering, warrants to the representative of the underwriters to purchase 5.0% of the total number of ADSs sold in this offering at a per ADS price equal to 100% of the public offering price (the “Representative’s Warrants”). The registration statement of which this prospectus is a part also covers the Representative’s Warrants and the ADSs issuable upon the exercise thereof. See section entitled “Underwriting” on page 186 for more information.

We have granted the underwriters, for a period of thirty (30) days after the date of this prospectus, the right to purchase up to an additional ADSs from us at the public offering price less the underwriting discounts and commissions.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

The underwriters expect to deliver the securities to purchasers on or about , 2023.

**Roth Capital Partners**

, 2023

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You should rely only on the information contained in this prospectus and any related free-writing prospectus that we authorize to be distributed to you. We have not, and the underwriters have not, authorized any person to provide you with information different from that contained in this prospectus or any related free-writing prospectus that we authorize to be distributed to you. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state where the offer or sale is not permitted. The information in this prospectus speaks only as of the date of this prospectus unless the information specifically indicates that another date applies, regardless of the time of delivery of this prospectus or of any sale of the securities offered hereby.

No action is being taken in any jurisdiction outside the United States to permit a public offering of the securities or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of the prospectus applicable to that jurisdiction.

Until \_\_\_\_\_, 2023 (the 25<sup>th</sup> day after the date of this prospectus), all dealers that buy, sell or trade in our securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer’s obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

## STATISTICAL AND OTHER INDUSTRY AND MARKET DATA

This prospectus includes statistical and other industry and market data and contains estimates and information concerning our industry and our business, including estimated market size and projected growth rates of the markets for our product candidates. Unless otherwise expressly stated, we obtained this industry, business, market, medical and other information from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources.

This information involves a number of assumptions and limitations. Although we are responsible for all of the disclosure contained in this prospectus and we believe the third-party market position, market opportunity and market size data included in this prospectus are reliable, we have not independently verified the accuracy or completeness of this third-party data. In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in “Risk Factors.” These and other factors could cause results to differ materially from those expressed in these publications and reports.

## TRADEMARKS

We own or have rights to trademarks and trade names that we use in connection with the operation of our business, including our corporate name, logos, product names and website names. A list of our trademarks can be found in “Business – Intellectual Property.” Other trademarks and trade names appearing in this prospectus are the property of their respective owners. Solely for your convenience, some of the trademarks and trade names referred to in this prospectus are listed without the ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks and trade names.

## CONVENTIONS THAT APPLY TO THIS PROSPECTUS

Except where the context requires otherwise and for purposes of this prospectus only:

- “ADSS” refers to our American depository shares, each of which represents ordinary shares, and “ADRs” refers to the American depository receipts that evidence our ADSS.
- “ASX” refers to the Australian Securities Exchange, where our ordinary shares are listed.
- “A\$” or “Australian dollar” refers to the legal currency of Australia.
- “CardieX,” “we,” “us” or “our” refer to CardieX Limited and its subsidiaries.



- “FDA” refers to the United States Food and Drug Administration.
- “FY2020” refers to the fiscal year ended June 30, 2020.
- “FY2021” refers to the fiscal year ended June 30, 2021.
- “FY2022” refers to the fiscal year ended June 30, 2022.
- “FY2023” refers to the fiscal year ended June 30, 2023.
- “GAAP” refers to the Generally Accepted Accounting Principles in the United States.
- “HY2022” refers to the six-month period ended December 31, 2021.
- “HY2023” refers to the six-month period ended December 31, 2022.
- “IFRS” refers to the International Financial Reporting Standards as issued by the International Accounting Standards Board, or IASB.
- “US\$” or “U.S. dollars” refers to the legal currency of the United States.
- “U.S.” or “United States” refers to the United States of America.

Unless otherwise indicated, the consolidated financial statements and related notes included in this prospectus have been presented in U.S. dollars and also comply with IFRS, which differs in certain significant respects from GAAP. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Certain Differences Between IFRS and GAAP.” For us and our subsidiaries that use a functional currency that is not U.S. dollars, the assets and liabilities have been translated at the closing exchange rate, while the income and expenses have been translated at the average exchange rate for the financial year as published by the Reserve Bank of Australia. The resulting exchange differences are recognized in our consolidated statement of comprehensive income. See note 1 in the notes to our consolidated financial statements and the related notes included elsewhere in this prospectus for more information.

Unless otherwise indicated, all amounts presented in this prospectus are presented in U.S. dollars. Our reporting and functional currency is the Australian dollar. Solely for the convenience of the reader, this prospectus contains translations of certain Australian dollar amounts into U.S. dollars at specified rates. Except as otherwise stated in this prospectus, all translations of income, expenses and compensation from Australian dollars to U.S. dollars are based on the average exchange rate for the financial year of A\$1.00 per US\$0.7468 for financial year 2021 and A\$1.00 per US\$0.7258 for financial year 2022, each as published by the Reserve Bank of Australia. All translations of assets and liabilities from Australian dollars to U.S. dollars are based on the financial year end closing rate for the financial year of A\$1.00 per US\$0.7518 for financial year 2021 and A\$1.00 per US\$0.6889 for financial year 2022, each as published by the Reserve Bank of Australia. No representation is made that Australian dollar amounts referred to in this prospectus could have been or could be converted into U.S. dollars at such rates or any other rates. Any discrepancies in any table between totals and sums of the amounts listed are due to rounding.

In February 2022, we completed a consolidation of all of our issued securities on a 1 for 10 basis as approved by our shareholders at the General Meeting of shareholders held on February 16, 2022. Unless otherwise indicated, all amounts in this prospectus are expressed on a post-consolidation basis.

## PROSPECTUS SUMMARY

*This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and audited consolidated financial statements and the related notes thereto included elsewhere in this prospectus. This summary does not contain all the information you should consider before investing in our securities. You should read this entire prospectus carefully, including “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and our audited consolidated financial statements and the related notes thereto included elsewhere in this prospectus, before making an investment decision. Unless the context requires otherwise, references in this prospectus to “CardiX,” “we,” “us” and “our” refer to CardiX Limited and its subsidiaries.*

### Overview

We are a commercial-stage digital healthcare company using our medical devices to redefine the way hypertension, cardiovascular disease (CVD), and other major vascular diseases are clinically diagnosed and managed. Our SphygmoCor XCEL is a vital signs and vascular biometric monitoring device that offers non-invasive assessment of the central aortic pressure waveform, including both pressures and indices of arterial stiffness, providing noninvasive measurement of arterial pressure that the heart, brain, and kidneys actually experience.

Our pioneering SphygmoCor vascular biosensing technology uses novel sensors that have been clinically validated and FDA-cleared to collect digital vascular biomarkers. These biomarkers represent key indicators of vascular health including, but not limited to, central blood pressures (cBP), vascular stiffness, vascular age, and heart stress. SphygmoCor technology has been deployed in multiple clinical trials sponsored by pharmaceutical companies and healthcare systems to measure arterial health. When combined with cloud-based data analytics, we believe that our patient-friendly desktop and wearable devices built using our SphygmoCor technology enable key stakeholders throughout the healthcare ecosystem to obtain valuable health information from our digital vascular biomarkers not available from standard blood pressure devices. We believe that our consumer-facing solutions are creating a new paradigm in the diagnosis of vascular disease that is well aligned with the evolution of the healthcare industry as delivery of services becomes increasingly decentralized, patient-managed and consumer-oriented.

Our vision is to be the leading provider of home, wearable, healthcare, clinical trial, and remote patient monitoring solutions for common health disorders related to high blood pressure including hypertension, CVD, Alzheimer’s disease, chronic kidney disease (CKD), and other major vascular health conditions. Our two subsidiaries, ATCOR Medical (ATCOR) and CONNEQT Health (CONNEQT), are focused on separate, but complementary, sectors of our target healthcare market. ATCOR pioneered the SphygmoCor technology and continues to focus on servicing specialist health care providers, on-site clinical trials, research programs, and hospital networks with a variety of proprietary vascular biomarker solutions, such as our SphygmoCor XCEL system and the SunTech Oscar 2<sup>TM</sup> Ambulatory Blood Pressure Monitor with “SphygmoCor Inside”. Launched in 2021, the CONNEQT business is introducing a suite of new devices and digital solutions strategically targeted to consumer health, general health care providers, remote patient monitoring, decentralized clinical trials, and home health.

Our first two products under the CONNEQT brand are our CONNEQT Pulse and CONNEQT Band (together, our “CONNEQT Products”). Our CONNEQT Products incorporate our SphygmoCor vascular biosensing technology to obtain biomarkers representing vascular health. The CONNEQT Pulse is a vascular biometric monitor we co-developed with blood pressure manufacturer Andon Health Co. Ltd. (“Andon”). It offers dual blood pressure (central and brachial) and other advanced measures of vascular health not available with traditional blood pressure monitors. The CONNEQT Band is a “medical grade” wearable device (as proposed to be designated by the FDA through its clearance process) we are co-developing with LifeQ B.V. (“LifeQ”), a developer of general health biometrics, and Shenzhen Fenda Smart Technology Limited (“Fenda”), a contract manufacturer for wearables. It captures vascular health data in patients as well as to provide general health insights to consumers using a wristband form factor. See “Business – Manufacturing, Supply and Operations” for a more detailed discussion of our relationships with LifeQ and Fenda and related agreements. We anticipate that the CONNEQT Pulse will be commercialized in the second half of 2023, having recently received FDA 510(k) clearance from the FDA in April 2023. The CONNEQT Band wearable is targeted for commercialization in the second calendar quarter 2024, subject to obtaining 510(k) clearance from the FDA.

We have incurred operating losses each year since our inception in 1994, including net losses of US\$8.6 million and US\$3.9 million for FY2022 and FY2021, respectively, and net losses of US\$5.9 million and US\$4.8 million for the six months ended December 31, 2022 and December 31, 2021, respectively, and may continue to incur net losses in the future. Additionally, because we do not have proven marketing or sales strategies with our CONNEQT Pulse and CONNEQT Band, nor do we know if customers will accept our CONNEQT Pulse and CONNEQT Band, we do not know how the introduction of the CONNEQT Pulse and CONNEQT Band will affect our business. Our revenue growth may slow or our revenue may decline for a number of reasons, including reduced demand for our products and services, increased competition, a decrease in the growth or reduction in size of our overall market, or if we cannot capitalize on growth opportunities.

### Our Market Opportunity

Patient blood pressure is generally monitored either in a healthcare facility or in a patient’s home to diagnose, guide, and manage hypertension, the leading cause of cardiovascular disease and premature death worldwide. Recent studies suggest that the use of digital vascular biomarkers including cBP in hypertension management may be more cost-effective and require less use of medications than current methods of hypertension management.

We believe we are at the forefront of a paradigm shift where blood pressure measurement, one of the four key vital signs, will increasingly refer to cBP now that technologies that measure it noninvasively can be accessed outside of healthcare facilities. We further believe that the use of digital vascular biomarkers will become part of the standard practice in the management of cardiovascular health, patient monitoring, and ensuring patient safety during clinical trials.

### Clinical Trials and Healthcare Research

With rising geriatric populations worldwide and the growing burden of chronic disorders, there has been increased demand for the development of novel noninvasive therapies that can increase patient monitoring with the goal of improving health outcomes and reducing the burden on health care systems. The increased demand for novel noninvasive therapies that can increase patient monitoring is further fueled by the increasing number of biologics on the market and the demand for contract research organizations (CROs) to manage clinical studies. According to *Precedence Research*, the global clinical trials market was valued at US\$48 billion in 2020 and is projected to reach US\$84 billion by 2030.

The increasing prevalence of wearable devices and remote patient monitoring spurred on by the COVID-19 pandemic has resulted in rapid growth to embrace out-of-the-box thinking for clinical trial alternatives that may be more efficient and effective, including decentralized clinical trials (DCT). With just 5% of eligible patients participating in clinical research according to a study lead by researchers at THREAD Research, trial decentralization broadens trial sponsors' access to a larger and a more diverse pool of patients. Decentralization can also reduce the workload for trial investigators, since traditional site activities (such as vital signs measurements) can be performed remotely by trial participants themselves.

Remote vital signs data collection can capture the same parameters as conventional on-site trials while offering the opportunity to increase the volume of data collected in order to facilitate a deeper physiological characterization of the efficacy of interventions being studied while also maintaining the quality of data, and most importantly, ensuring that the collected data reflects the real-world patient experience. Respondents to a *Ernst & Young-Parthenon* survey estimate that 50% of clinical trials will be hybrid or decentralized by 2024 and *MarketResearch* projects the DCT market to reach US\$14.2 billion by 2026.

#### *Patient Monitoring Market*

According to the CDC, Americans made 860 million physician office visits to seek health care in 2018. Blood pressure measurements are almost always captured as a routine procedure during these visits. The American Heart Association (AHA) Task Force on Clinical Practice Guidelines recommends office-based BP measurement as a screening method for the diagnosis of hypertension followed by out-of-office BP measurement (ambulatory or home) as a diagnostic method. Outside of the clinic, AHA also recommends home monitoring for all people with hypertension in order to better manage their condition. With hypertension impacting nearly 1 of every 2 of U.S. adults, there are 104 million people in the U.S. alone that can benefit from having a blood pressure device in their home, according to an article published by the American Heart Association News.

The current patient journey for hypertension is broken as it is narrowly focused with limited health data and patient education. Traditional blood pressure devices are constrained by one or more of the following:

- Single diagnostic output. A 130-year-old technology that provides a single diagnostic data point based on blood pressure at the arm (systolic/diastolic pressure), which may be insufficient to understand the daily (and nightly) overall vascular health of an individual;
- Single diagnostic focus. No determination for risk of other vascular disease apart from hypertension and limited guidance as to appropriate medications to prescribe; and
- Absence of reimbursement structure. Office-based blood pressure readings are not separately reimbursable to the physician by public or private payers.

*Fortune Business Insights* estimating the global blood pressure device market reaching US\$3.2 billion by 2028, with *Markets and Markets* estimates the global remote patient monitoring market to reach US\$175 billion by 2027. In addition, *Grand View Research* forecasts the health wearables market to reach US\$104.4 billion by 2027 and the digital health market to reach US\$809.2 billion by 2030.

### *Our Outlook*

As both the patient monitoring and the clinical trials markets increasingly rely on the remote collection of vital signs such as blood pressure, we believe that our focus on creating cloud-enabled devices under the CONNEQT brand will enable us to commercialize a compelling solution for those markets. While the market for remote patient monitoring, both in healthcare and clinical trial settings, is highly competitive with frequent new entrants, and we have no history of marketing or sales execution with our CONNEQT Products, we believe the clinical evidence that have been generated from our SphygmoCor technology over the past two decades enables us to create a unique and competitive value proposition.

Although we also recognize there may be some challenges to remote vital signs collection, whether as part of a remote patient monitoring program or decentralized trial, we believe the benefits outweigh such challenges. For example, although there is an advantage to our patients having access to a smartphone with either WiFi or a cellular data connection to access the internet, our products do not require such access. The health data collected by our devices is stored on the device, making it so a smartphone is not required to support the product's functionality and the collection of data. Access to a smartphone with internet access would also enable secure remote transmission of the health data to a patient's physician or care provider. However, a patient can download all data at a doctor's office if he or she does not have access to a smartphone with internet connection. Similarly, although patients using our products outside of their doctor's offices need to learn how to properly use our products, we believe that they can learn how to do so as the usage instructions are similar to home blood pressure monitors and fitness trackers currently available on the market. Furthermore, our user manuals include graphical illustrations to ensure that the instructions are easy to follow.

### *Our Success Factors*

We believe the following factors differentiate our company and will continue to be significant components of our success and growth:

- Pioneering technology. Our patented SphygmoCor vascular biosensing technology non-invasively extracts high fidelity arterial signals at the heart and other major organs and has supported studies that have resulted in over 2,000 peer-reviewed clinical publications.
- Industry trusted actionable data. Our patented algorithms extract actionable medical and consumer health parameters not available from traditional blood pressure devices and wearables. Our SphygmoCor technology is deployed in more than 4,500 installations worldwide, and it has been used in clinical trials sponsored by pharmaceutical companies, in trial areas as diverse as pregnancy, diabetes, kidney disease, cardiovascular disease, heart failure, and the impact of cigarette smoking.
- Track record of innovation. Our track record in developing new products that leverage the SphygmoCor technology will continue to differentiate us. The current SphygmoCor XCEL is the third generation of this device.
- Versatility of CONNEQT ecosystem. Through the CONNEQT cloud we are expanding our existing proven technology into significant new markets including complete arterial health remote patient monitoring, home health and wearable devices and decentralized clinical trials. We have additional CONNEQT devices in development that we believe will put us in a position to capture a portion of the growing global remote patient monitoring market.
- Management. Proven management team with diverse sector expertise and world recognized scientific expertise and research pioneers.

### *Our Growth Strategies*

Our goal is to be the leading provider of home, wearable, healthcare, clinical trial, and remote patient monitoring solutions for common health disorders related to high blood pressure including hypertension, CVD, Alzheimer's disease, chronic kidney disease (CKD), and other major vascular health conditions. To achieve our growth plan, we expect to employ the following growth strategies:

- Expand CONNEQT through our existing partner ecosystem. We plan to capture a significant untapped opportunity with CONNEQT by incorporating the SphygmoCor vascular biosensing technology in wearables, in-clinic patient monitoring solutions for general practitioners, remote patient monitoring, and decentralized clinical trials.

- Regulatory progress. We are the only company with an FDA-cleared technology capable of providing a non-invasive cBP reading with full pulse waveform output features and analysis in all adult populations. CONNEQT Pulse is the fourth generation of our device to receive FDA clearance and FDA clearance of the CONNEQT Band is anticipated in the first quarter of calendar year 2024. However, there is no guarantee that the FDA will grant clearance to the CONNEQT Band or that it will do so on the timeline currently indicated.
- Building a health ecosystem and brand. In addition to our SphygmoCor vascular health parameters, the CONNEQT Band will also be a comprehensive lifestyle wearable incorporating a suite of features and health insights, derived from a wrist-based PPG sensor, thereby enabling users to obtain a complete 360-degree view of their health and fitness status. When paired with the CONNEQT App, the CONNEQT Band will continuously track users' heart health, support 24/7 practitioner monitoring and apply advanced intelligent analytics (our Arty Heart Health platform) to evaluate their health data in order to provide actionable insights regarding their unique vascular and health status.
- Expand payor coverage and reimbursement. A key component in ensuring whether the appropriate payment amount is received for physician and other services, including those procedures using our products, is the existence of a Current Procedural Terminology (CPT) code to describe the procedure in which the product is used. To receive payment, health care practitioners must submit claims to insurers using these codes for payment for medical services. CPT codes are assigned, maintained and annually updated by the American Medical Association and its CPT Editorial Board.
- Continue to scale our operations in the United States to accelerate the growth of ATCOR and CONNEQT Products. We expect to continue to scale our business in the United States by hiring additional U.S.-based managers as well as sales and marketing and end-user support personnel to enhance our ability to acquire customers and retain and grow these relationships. We expect that by expanding our U.S. team, we will acquire additional commercial expertise that will enable us to grow our customer and revenue base by continuing to cultivate satisfied customers and building key relationships with U.S. medical societies, which we believe will position us to create the value and tools required to win in an evolving competitive healthcare landscape.
- Growth through partnerships and acquisitions. While we continue to accelerate our internal organic sales growth we will also monitor opportunities to expand our business through select partnerships and acquisitions, especially as we look to drive value through a more vertically integrated product offerings in our target markets.

### *Risk Factor Summary*

Our business and the successful execution of our strategies are subject to certain risks and uncertainties related to our business and our industry, regulation of our business and our corporate structure, doing business in Australia and ownership of our securities, our trading market and this offering. The risks and uncertainties related to our business and our industry include, but are not limited to:

- We have incurred operating losses in the past, may incur operating losses in the future, and may not achieve or maintain profitability in the future.
- We have disclosed that there is substantial doubt about our ability to continue as a going concern. We may require additional capital in order to execute our business plan and continue the operations of our business. Any capital-raising transaction we are able to complete may result in substantial dilution to our existing shareholders.
- We currently derive the majority of our revenue from our SphygmoCor technology enabled products. If these products do not continue to achieve market acceptance, our business, financial condition and results of operations would be adversely affected.
- Some of our products are in development and may not achieve market acceptance, which could limit our growth and adversely affect our business, financial condition, and results of operations.
- We may be unable to attract and retain users, which could have an adverse effect on our business and rate of growth.
- If we are unable to anticipate consumer preferences and successfully develop and introduce new, innovative, and updated products and services in a timely manner, or effectively manage the introduction of new or enhanced products and services, our business may be adversely affected.
- The health wearable market is relatively new and, if the general market and specific demand for our products and services does not continue to grow, grows more slowly than we expect, or fails to grow as much as we expect, our business, financial condition, and operating results may be adversely affected.
- We have a limited operating history with certain of our products from which to predict our long-term performance, and our past financial results may not be indicative of our future performance.
- We have limited control over our suppliers and contract manufacturers, which may subject us to significant risks, including the potential inability to produce or obtain quality products and services on a timely basis or in sufficient quantity.
- Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.
- If we fail to comply with healthcare and other governmental regulations, we could face substantial fines and penalties and our business, results of operations and financial condition could be adversely affected.
- We are significantly dependent on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to our rights or the rights of others may result in our payment of significant monetary damages and/or royalty payments, negatively impacting our ability to sell current or future products.
- Our products could infringe or appear to infringe the intellectual property rights of others, which may lead to patent and other intellectual property litigation that could itself be costly, could result in the payment of substantial damages or royalties, prevent us from using technology that is essential to our products, and/or force us to discontinue selling our products.
- If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, and our business could be harmed.
- The market price and trading volume of our ordinary shares, and that of the ADSs, may be volatile and may be affected by economic conditions beyond our control.

- Our issuance of additional ordinary shares in connection with financings, acquisitions, investments, or otherwise will dilute all other ADS holders.
- The public offering price will be determined by negotiations between us and the representatives of the underwriters and set by our board of directors and does not necessarily indicate the actual or market value of our ADSs.
- As a foreign private issuer, we are permitted and expect to follow certain home country corporate governance practices in lieu of certain Nasdaq Capital Market requirements applicable to domestic issuers and we are permitted to file less information with the Securities and Exchange Commission than a company that is not a foreign private issuer. This may afford less protection to holders of our ADSs.
- If we fail to establish and maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.
- ADS holders may be subject to additional risks related to holding ADSs rather than ordinary shares.

See “Risk Factors” and “Forward-Looking Statements” for a more detailed discussion of these and other risks and uncertainties that we may face.

#### **Our Corporate Information**

We were formed in 1994 as ATCOR Medical, an Australian company, by Dr. Michael O’Rourke. In November 2005, we completed an initial public offering of our ordinary shares and listing of these shares on the Australian Securities Exchange, or the ASX, under the symbol “ACG.” In May 2018, we changed our name to CardieX Limited, and began trading on the ASX under the symbol “CDX.” Our U.S. subsidiaries, ATCOR Medical, Inc. and CONNEQT Health, Inc., both Delaware corporations, are headquartered at 184 Shuman Blvd #515, Naperville, IL 60563.

Our principal executive offices are located at 55 Lime Street, Suite 301, Sydney, NSW, 2000, Australia. Our telephone number at this address is +61 (2) 9874-8761. Our office in the United States is located at 184 Shuman Blvd #515, Naperville, IL 60563. Our telephone number at this address is +1 630 228-8871. Our websites are [www.cardiex.com](http://www.cardiex.com), [www.atcormedical.com](http://www.atcormedical.com), and [www.conneqthealth.com](http://www.conneqthealth.com) (together, the “Websites”). Information contained on the Websites is not part of this prospectus. Our agent for service of process in the United States is our wholly-owned subsidiary, ATCOR Medical, Inc, located at 184 Shuman Blvd #515, Naperville, IL 60563.

#### **Implications of Being an Emerging Growth Company**

As a company with less than US\$1.235 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act (the “JOBS Act”), enacted in April 2012. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the “Sarbanes-Oxley Act”);
- reduced disclosure obligations regarding executive compensation in our periodic reports (if any), proxy statements (if any) and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenues exceed US\$1.235 billion or we issue more than US\$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in this prospectus and in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information in this prospectus and that we provide to our shareholders in the future may be different than what you might receive from other public reporting companies in which you hold equity interests.

#### **Implications of Being a Foreign Private Issuer**

We are also considered a “foreign private issuer” as defined in Rule 405 under the Securities Act of 1933, as amended (the “Securities Act”). In our capacity as a foreign private issuer, we are exempt from certain rules under the Exchange Act that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and “short-swing” profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act with respect to their purchases and sales of our ordinary shares. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. In addition, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information.

We may take advantage of these exemptions until such time as we are no longer foreign private issuer. We would cease to be a foreign private issuer at such time as more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (1) the majority of our executive officers or directors are U.S. citizens or residents, (2) more than 50% of our assets are located in the United States or (3) our business is administered principally in the United States.

As a foreign private issuer, we have taken advantage of certain reduced disclosure and other requirements in this prospectus and may elect to take advantage of other reduced reporting requirements in future filings. Accordingly, the information contained herein or that we provide shareholders may be different than the information you receive from other public companies in which you hold equity securities.



## THE OFFERING

### ADSs offered by us

ADSs.

### Representative's Warrants

The registration statement of which this prospectus forms a part also registers the Representative's Warrants that will be issued to the representative of the underwriters to purchase up to 5.0% of the total number of ADSs to be offered by the company in this offering, as a portion of the underwriting compensation payable in connection with this offering. The Representative's Warrants will be exercisable immediately upon issuance, and from time to time, in whole or in part, and will expire five years from the commencement of sales at an exercise price of US\$ (100% of the public offering price of the ADSs). Please see "Underwriting" for a more complete description of the Representative's Warrants.

### ADSs to be outstanding immediately after this offering

ADSs (or ADSs if the underwriters exercise the option to purchase additional ADSs in full) (assuming the sale of all ADSs covered by this prospectus, and no exercise of outstanding options issued under the CardieX Performance Rights and Option Plan (the "Performance Rights and Option Plan") and based on 129,984,144 ordinary shares outstanding as of December 31, 2022).

### Ordinary shares to be outstanding immediately after this offering

ordinary shares.

### Over-allotment option

We have granted the underwriters an option, which is exercisable within thirty (30) days from the date of this prospectus, to purchase up to additional ADSs from us at the public offering price less the underwriting discount to cover over-allotments, if any.

### The ADSs

Each ADS represents ordinary shares, no par value. The ADSs are evidenced by American depositary receipts issued by the depositary.

The depositary will be the holder of the ordinary shares underlying the ADSs and you will have the rights of an ADS holder as provided in the deposit agreement among us, the depositary and owners and beneficial owners of ADSs from time to time.

You may surrender your ADSs to the depositary to withdraw the ordinary shares underlying your ADSs. The depositary will charge you a fee for such an exchange.

We may amend or terminate the deposit agreement for any reason without your consent. If an amendment becomes effective, you will be bound by the deposit agreement as amended if you continue to hold your ADSs.

To better understand the terms of the ADSs, you should carefully read the "Description of American Depositary Shares" section of this prospectus. You should also read the deposit agreement, which is filed as an exhibit to the registration statement of which this prospectus forms a part.

### Use of proceeds

We anticipate that the net proceeds from this offering will be approximately US\$ , or approximately US\$ if the underwriters exercise their option to purchase additional ADSs in full, at an assumed initial public offering price of US\$ per ADS, the U.S. dollar equivalent of the last reported sale price of our ordinary shares on the ASX on , 2023, after giving effect to the Australian dollar/U.S. dollar exchange rate of as of , 2023, and an ADS-to-ordinary share ratio of -to-1, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents for: (i) device manufacturing, marketing, and sales activities necessary to commercialize the CONNEQT Pulse in patient monitoring and clinical trials; (ii) device manufacturing, marketing, and sales activities necessary to commercialize the CONNEQT Band in the health wearable market; (iii) supporting our commercial expansion, including scaling of our supply chain, order-fulfilment, and customer care operations in support of our business growth; (iv) market access initiatives (regulatory clearance and outcomes research) in support of our commercialization efforts into domestic and international geographies; (v) research and product development expenses to iterate CONNEQT Pulse and CONNEQT Band features and capabilities to further strengthen capabilities of our solutions; and (vi) funding working capital and other general operations and other corporate purposes. See "Use of Proceeds."

### Depositary

JPMorgan Chase Bank, N.A.

**Risk factors** See “Risk Factors” and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.

**Lock-up** We have agreed for a period of \_\_\_\_\_ days after the date of this prospectus not to sell, transfer or otherwise dispose of any of our ordinary shares, ADSs or similar securities. Furthermore, each of our directors and officers have agreed to a similar \_\_\_\_\_ day lock-up. See “Underwriting” for more information.

**Listing** We have applied to have our ADSs listed on the Nasdaq Capital Market. This offering will not be consummated until we have received Nasdaq Capital Market approval of our application. No assurance can be given that our application will be approved.

**Proposed trading symbol** “CDEX”

The number of ordinary shares to be outstanding following the offering is based on 129,984,144 ordinary shares outstanding at December 31, 2022, and excludes:

- the exercise of outstanding employee options under our Performance Rights and Options Plan outstanding at December 31, 2022 to purchase 7,280,000 ordinary shares issuable upon at a weighted average exercise price of A\$0.68 per ordinary share.
- the exercise of outstanding free-attaching placement options outstanding at December 31, 2022 to purchase 4,811,122 ordinary shares issuable upon at a weighted average exercise price of A\$0.45 per ordinary share.
- the exercise of outstanding options at December 31, 2022 to purchase 2,794,370 ordinary shares issuable upon at a weighted average exercise price of A\$0.46 per ordinary share.
- the vesting of outstanding performance rights under our Performance Rights and Option Plan outstanding at December 31, 2022 that will convert into 22,800,000 ordinary shares subject to the satisfaction of certain vesting conditions.

Except as otherwise indicated, all information contained in this prospectus assumes:

- no exercise of options after December 31, 2022;
- no exercise of the Representative’s Warrants issued as part of this offering; and
- no exercise by the underwriters of their right to purchase up to an additional \_\_\_\_\_ ADSs from us to cover over-allotments.

## SUMMARY CONSOLIDATED FINANCIAL DATA

The following summary consolidated financial data presented below as of and for the six months ended December 31, 2022 and 2021, and as of and for the years ended June 30, 2022 and 2021 have been derived from our unaudited consolidated interim financial statements as of and for the six months ended December 31, 2022 and 2021 and related notes and audited consolidated financial statements as of and for the years ended June 30, 2022 and 2021 and related notes included elsewhere in this prospectus. Historical results are not necessarily indicative of results to be expected in the future and the results for FY2022 are not necessarily indicative of the results that may be expected for any other period. The summary consolidated financial data should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes thereto included elsewhere in this prospectus.

Our financial statements are presented in U.S. dollars and have been prepared in accordance with IFRS.

	Year Ended June 30		Six-Month Period Ended December 31,	
	US\$ 2022	US\$ 2021	US\$ 2022	US\$2021
			(unaudited)	
	(in thousands except per share information)			
<b>Consolidated Income Statement Data:</b>				
Revenue:				
Sales revenue	1,695	1,573	486	682
Lease revenue	860	1,615	202	580
Other revenue	397	547	203	269
Revenue	<u>2,952</u>	<u>3,735</u>	<u>891</u>	<u>1,531</u>
Other income:				
Research & development tax incentive scheme	480	401	203	223
JobKeeper Covid 19 stimulus	-	47	-	-
PPP loan forgiveness	-	174	-	-
Foreign exchange gains	215	-	-	122
Interest income	314	192	87	178
Miscellaneous other income	7	5	115	4
Other income	<u>1,016</u>	<u>819</u>	<u>405</u>	<u>527</u>
Total revenue and other income	<u>3,968</u>	<u>4,554</u>	<u>1,296</u>	<u>2,058</u>
Expenses:				
Cost of goods sold	(705)	(676)	(224)	(381)
Research and development	(2,813)	(1,310)	(1,735)	(1,312)
Sales and marketing	(2,279)	(998)	(895)	(1,202)
Management and administration	(4,725)	(3,482)	(3,512)	(1,900)
Stock based compensation	(1,459)	(1,051)	(609)	(806)
Fair value loss on financial assets	(200)	(42)	67	(1,011)
Finance costs	(166)	(200)	(87)	(104)
Other expenses	(192)	(664)	(189)	(88)
Total expenses	<u>(12,539)</u>	<u>(8,423)</u>	<u>(7,184)</u>	<u>(6,804)</u>
Loss before income tax	<u>(8,571)</u>	<u>(3,869)</u>	<u>(5,888)</u>	<u>(4,746)</u>
Income tax expense	-	-	-	-
Other comprehensive income for the period, net of tax –				
Exchange differences on translation to the presentation currency	(128)	751	(156)	(199)
Loss attributable to the owners of CardieX Limited.	<u>(8,699)</u>	<u>(3,118)</u>	<u>(6,044)</u>	<u>(4,945)</u>
Losses per share attributable to the ordinary equity holders of the Group:				
Basic – losses per share (1)	(0.08)	(0.04)	(0.05)	(0.05)
Diluted – losses per share (1)	(0.08)	(0.04)	(0.05)	(0.05)

(1) Please refer to Note 6 to our consolidated financial statements included elsewhere in this prospectus for a calculation of basic and diluted losses per share.

	As of June 30,	
	Actual	As adjusted (1)
	US\$ 2022	US\$ 2022
<b>Consolidated Balance Sheet Data:</b>		
Cash and cash equivalents	1,003	
Total current assets	3,327	
Total assets	8,527	
Total current liabilities	3,524	
Total liabilities	3,973	
Total equity	4,554	

- (1) The unaudited as adjusted consolidated balance sheet data has been adjusted to reflect the issuance and sale of \_\_\_\_\_ ADSs by us in this offering and our receipt of the estimated net proceeds from such issuance and sale in this offering, each based on an assumed initial public offering price of US\$ \_\_\_\_\_ per ADS, the U.S. dollar equivalent of the last reported sale price of our ordinary shares on the ASX on \_\_\_\_\_, 2023, after giving effect to the Australian dollar/U.S. dollar exchange rate of \_\_\_\_\_ as of \_\_\_\_\_, 2023, and an ADS-to-ordinary share ratio of \_\_\_\_\_-to-1 after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	As of December 31,	
	Actual	As adjusted (1)
	US\$ 2022	US\$ 2022
<b>Consolidated Balance Sheet Data:</b>		
Cash and cash equivalents	1,682	
Total current assets	7,936	
Total assets	9,539	
Total current liabilities	6,068	
Total liabilities	6,535	
Total equity	3,004	

- (1) The unaudited as adjusted consolidated balance sheet data has been adjusted to reflect the issuance and sale of \_\_\_\_\_ ADSs by us in this offering and our receipt of the estimated net proceeds from such issuance and sale in this offering, each based on an assumed initial public offering price of US\$ \_\_\_\_\_ per ADS, the U.S. dollar equivalent of the last reported sale price of our ordinary shares on the ASX on \_\_\_\_\_, 2023, after giving effect to the Australian dollar/U.S. dollar exchange rate of \_\_\_\_\_ as of \_\_\_\_\_, 2023, and an ADS-to-ordinary share ratio of \_\_\_\_\_-to-1, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

#### Preliminary Financial Information (Unaudited)

As of March 31, 2023, we had US\$852 thousand in cash and cash equivalents. For the three months ended March 31, 2023 we had:

- net cash used in operating activities of US\$3.24 million, with cash receipts from customers of US\$0.53 million, less payments for research and development of US\$0.52 million, product manufacturing and operating costs of US\$0.50 million, advertising and marketing of US\$0.20 million, leased assets of US\$42 thousand, staff costs of US\$1.75 million and administration and corporate costs of US\$0.76 million;
- net cash used in investing activities of US\$11 thousand; and
- net cash from financing activities of US\$2.47 million, with proceeds from issues of equity securities of US\$2.65 million offset by transaction costs related to issues of equity securities of US\$0.18 million.

This preliminary information has not been reviewed or audited. These results could change as a result of further review or audit.

## RISK FACTORS

*You should carefully consider the risks described below and all other information contained in this prospectus before making an investment decision. If any of the following risks actually occur, our business, financial condition and results of operations could be materially and adversely affected. In that event, the trading price of our ADSs could decline, and you may lose part or all of your investment. This prospectus also contains forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of many factors, including the risks described below and elsewhere in this prospectus. The risks described below are not the only risks that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business.*

### **Risks Related to Our Business and Industry**

***We have incurred operating losses in the past, may incur operating losses in the future, and may not achieve or maintain profitability in the future.***

We have incurred operating losses each year since our inception in 1994, including net losses of US\$8.6 million and US\$3.9 million for FY2022 and FY2021, respectively, and net losses of US\$5.9 million and US\$4.8 million for the six months ended December 31, 2022 and December 31, 2021, respectively, and may continue to incur net losses in the future. We expect our operating expenses to increase in the future as we grow our business, including by continuing our sales and marketing efforts for our products and the beginning of our sales and marketing efforts of our CONNEQT Products, continuing to invest in research and development, expanding our operating and retail infrastructure, adding content and software features to our CONNEQT App and “Arty,” our digital ecosystem and remote monitoring platform, expanding into new geographies, developing new products, and in connection with legal, accounting, and other expenses related to operating as a public company listed on a U.S. exchange. These efforts and additional expenses may be more costly than we expect, and we cannot guarantee that we will be able to increase our revenue to offset our operating expenses. Our revenue growth may slow or our revenue may decline for a number of other reasons, including reduced demand for our products and services, increased competition, a decrease in the growth or reduction in size of our overall market, the impacts to our business from the COVID-19 pandemic, or if we cannot capitalize on growth opportunities. If our revenue does not grow at a greater rate than our operating expenses, we will not be able to achieve and maintain profitability, which may have a material adverse effect on the trading price of our ADSs.

***We have disclosed that there is substantial doubt about our ability to continue as a going concern. We may require additional capital in order to execute our business plan and continue the operations of our business. Any capital-raising transaction we are able to complete may result in substantial dilution to our existing shareholders.***

As a result of our loss after tax, net cash outflows from operating activities and net current liability position, our independent registered public accounting included an explanatory paragraph in its report on our financial statements as of, and for the year ended June 30, 2022 that raises substantial doubt about our ability to continue as a going concern. The conditions giving rise to this uncertainty and our plan with respect to this uncertainty are disclosed in Note 1 to our consolidated financial statements appearing at the end of this prospectus. If we are unable to obtain sufficient funding, we could be forced to delay, reduce or eliminate all of our research and development programs, future research and development efforts and ongoing preclinical studies and clinical trials, and our financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. After the completion of this offering, future financial statements may continue to disclose substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. Any capital-raising transaction we are able to complete may result in substantial dilution to our existing shareholders, require us to relinquish significant rights, or restrict our operations.

***We currently derive the majority of our revenue from our SphygmoCor technology enabled products. If these products do not continue to achieve market acceptance, our business, financial condition and results of operations would be adversely affected.***

We are highly dependent upon the continued success, intellectual property protection, and market acceptance of our proprietary SphygmoCor technology enabled products which are the only products currently generating revenue for us. Continued market education of the SphygmoCor technology is required to grow the awareness and adoption of our products. The growth in the patient monitoring market, in particular will depend upon us continuing to provide evidence demonstrating that the arterial health parameters provided by the SphygmoCor technology will achieve better health outcomes and is more cost-effective than simply using conventional blood pressure measurements. Healthcare providers that currently have significant investments in competitive blood pressure monitor products may be reluctant to purchase our products. If hospitals and other healthcare providers do not believe our SphygmoCor products are cost-effective, safe, clinically superior, or more accurate or reliable than competitive blood pressure monitors, they may not buy our product in sufficient quantities to enable us to generate revenue growth from the sale of products. In addition, allegations regarding the safety and effectiveness of our SphygmoCor products and digital solutions, whether or not substantiated, may impair or impede the acceptance of our products, which may have a material adverse effect on the trading price of our ADSs.

Our products are sold in highly competitive markets with limited barriers to entry. Changes to our price structure, including with respect to the introduction by competitors of comparable products at lower price points, a maturing product lifecycle, a decline in consumer spending, or other factors (including factors disclosed herein) could result in a decline in our revenue derived from our products, which may have an adverse effect on our business, financial condition, and operating results. Because we currently derive a significant majority of our revenue from the sales or leasing of our SphygmoCor XCEL device, any material decline in sales or leasing revenue from our SphygmoCor XCEL device would have a pronounced impact on our future revenue and operating results.

***Some of our products are in development and may not achieve market acceptance, which could limit our growth and adversely affect our business, financial condition, and results of operations.***

We plan to begin marketing and commercializing the first of our CONNEQT Products, the CONNEQT Pulse, in the second half of calendar 2023. Because we do not have proven marketing or sales strategies with our CONNEQT Products, nor do we know if customers will accept our CONNEQT Products, we do not know how the introduction of the CONNEQT Products will affect our business. Our product portfolio continues to expand, and we are investing significant resources to enter into, and in some cases create new markets for our products. We are continuing to invest in sales and marketing resources to achieve market acceptance of the CONNEQT Products but are unable to guarantee that they will achieve general market acceptance.

The degree of market acceptance of our CONNEQT Products will depend on a number of factors, including but not limited to:

- perceived benefits from our CONNEQT Products;
- perceived cost effectiveness of our CONNEQT Products;
- perceived safety and effectiveness of our CONNEQT Products;
- in certain instances, reimbursement available through government and private healthcare programs for using some of our CONNEQT Products; and
- introduction and acceptance of competing products or technologies.

If our CONNEQT Products do not gain market acceptance or if our customers prefer our competitors' products, our potential revenue growth would be limited, which would adversely affect our business, financial condition, and results of operations.

***We operate in a highly competitive market and we may be unable to compete successfully against existing and future competitors.***

Our products and services are offered in a highly competitive market. We operate in a large and fragmented industry, subject to change and affected by new product introductions, results of clinical research, corporate combinations and other factors. For our ATCOR business, we view as competitors those companies whose primary business is developing and marketing cBP and arterial stiffness measurement devices and services for research and clinical trials. We principally compete with 80 Beats Medical, Uscom Limited and IEM GmbH. For our CONNEQT business, we view as competitors those companies whose primary business is developing and marketing blood pressure monitoring devices and services targeting in-office, home, and remote patient monitoring applications. We principally compete with GE Healthcare, Philips Healthcare, Hill-Rom Holdings, Inc (which was acquired by Baxter International), A&D Medical, OMRON Corporation, Withings, and iHealth Labs. In addition to the foregoing, we are also aware of some small start-up companies continuing to develop wearable “cuff-less” blood pressure monitoring devices such as Biobeat and Aktiia.

We face significant competition in every aspect of our business. Moreover, we expect the competition in our market to intensify in the future as new and existing competitors introduce new or enhanced products and services that may compete with ours. Large medical device companies may continue to acquire or form alliances with these smaller companies in order to diversify their product offering and participate in the digital health space. Many of our competitors have substantially greater financial, manufacturing, marketing and technical resources than we do. Furthermore, many of our competitors have well-established brands, widespread distribution channels, broader product offerings and an established customer base. Competition may also emerge from large technology companies, such as Apple, Amazon, Facebook, Google, or Microsoft, who may wish to develop their own blood pressure monitoring and/or wearable solutions.

Our competitors may develop, or have already developed, products, features, services, or technologies that are similar to ours or that achieve greater acceptance, may undertake more successful product development efforts, be more efficient at meeting consumer demand, create more compelling employment opportunities, or marketing campaigns, or may adopt more aggressive pricing policies. Our competitors may develop or acquire, or may have already developed or acquired, intellectual property rights that significantly limit or prevent our ability to compete effectively in the public marketplace. In addition, our competitors may have significantly greater resources than us, allowing them to identify and capitalize more efficiently upon opportunities in new markets and consumer preferences and trends, quickly transition and adapt their products and services, devote greater resources to marketing and advertising or licensing rights, or be better positioned to withstand substantial price competition. Due to the highly volatile and competitive nature of the industry in which we compete, we may face pressure to continually introduce new products, services and technologies, enhance existing products and services, effectively stimulate customer demand for new and upgraded products and services, and successfully manage the transition to these new and upgraded products and services. If we are not able to compete effectively against our competitors, they may acquire, engage and retain customers or generate revenue at the expense of our efforts, which could have an adverse effect on our business, financial condition, and operating results.

***We may be unable to attract and retain users, which could have an adverse effect on our business and rate of growth.***

Our business and revenue growth is dependent on our ability to attract and retain users, and we cannot be sure that we will be successful in these efforts, or that if we attract users that their retention levels will not materially decline. There are a number of factors that could lead to a decline in user levels or that could prevent us from increasing our user levels, including:

- our failure to introduce new features, products, or services that users find engaging or our introduction of new products or services, or changes to existing products and services that are not favorably received;
- harm to our brand and reputation;
- pricing and perceived value of our offerings;
- our inability to deliver quality products and functionality, content, and services;
- actual or perceived safety concerns regarding our products;
- unsatisfactory experiences with our products;

- our users engaging with competitive products and services;
- technical or other problems preventing users from accessing our CONNEQT App, CONNEQT Portal or Arty platform in a rapid and reliable manner or otherwise affecting the user experience;
- a decline in the public's interest in wearable health technology;
- deteriorating general economic conditions or a change in consumer spending preferences or buying trends;
- changes in consumer preferences regarding home fitness and wearable health technology whether as a result of the COVID-19 pandemic or otherwise;
- interruptions in our ability to sell or deliver our products as a result of the COVID-19 pandemic or otherwise; and
- supply chain disruptions.

Additionally, with our expansion into international markets such as Europe, Asia, and the Middle East, we may face new challenges in attracting and retaining users that we may not successfully address. As a result of these factors, we cannot be sure that our user levels will be adequate to maintain or permit the expansion of our operations. A decline in user levels could have an adverse effect on our business, financial condition, and operating results.

***If we are unable to anticipate consumer preferences and successfully develop and introduce new, innovative, and updated products and services in a timely manner, or effectively manage the introduction of new or enhanced products and services, our business may be adversely affected.***

Our success in maintaining and increasing our user base depends on our ability to identify and originate trends as well as to anticipate and react to changing consumer demands in a timely manner. Our products and services are subject to changing consumer preferences that cannot be predicted with certainty. If we are unable to introduce new or enhanced offerings in a timely manner, or our new or enhanced offerings are not accepted by our users, our competitors may introduce similar offerings faster than us, which could negatively affect our rate of growth. Moreover, our new offerings may not receive consumer acceptance as preferences could shift rapidly to different types of wearable or other product offerings or away from these types of offerings altogether, and our future success depends in part on our ability to anticipate and respond to these changes. Failure to anticipate and respond in a timely manner to changing consumer preferences could lead to, among other things, lower subscription rates, lower sales, pricing pressure, lower gross margins, discounting of our health wearable or other products, and potential excess inventory levels. Even if we are successful in anticipating consumer preferences, our ability to adequately react to and address them will partially depend upon our continued ability to develop and introduce innovative, high-quality product offerings. Development of new or enhanced products and services may require significant time and financial investment, which could result in increased costs and a reduction in our profit margins. In addition, we may continue to experience delays in the development and introduction of new or enhanced products and services due to the ongoing supply chain effects of the COVID-19 pandemic and other market constraints.

Moreover, we must successfully manage introductions of new or enhanced products and services, which could adversely impact the sales of our existing products and services. For instance, customers may choose to forgo purchasing existing products or services in advance of new product and service launches, and we may experience higher returns from users of existing products. As we introduce new or enhanced products and services, we may face additional challenges managing a more complex supply chain and manufacturing process, including the time and cost associated with onboarding and overseeing additional suppliers, contract manufacturers, and logistics providers. We may also face challenges managing the inventory of new or existing products, which could lead to excess inventory and discounting of such products. In addition, new or enhanced products or services may have varying selling prices and costs compared to legacy products and services, which could negatively impact our brand, gross margins and operating results.



***Our operating results could be adversely affected if we are unable to accurately forecast consumer demand for our products and adequately manage our inventory.***

To ensure adequate inventory supply, we must forecast inventory needs and expenses and place orders sufficiently in advance with our suppliers and contract manufacturers, based on our estimates of future demand for our products. Failure to accurately forecast our needs may result in manufacturing delays or increased costs. Our ability to accurately forecast demand could be affected by many factors, including changes in consumer demand for our products and services, changes in demand for the products and services of our competitors, unanticipated changes in general market conditions, and the weakening of economic conditions or consumer confidence in future economic conditions, such as those caused by the COVID-19 pandemic. This risk could be exacerbated by the fact that we may not carry a significant amount of inventory and may not be able to satisfy short-term demand increases, or at times will have an excess in inventory that we are unable to effectively utilize. If we fail to accurately forecast consumer demand, we may experience excess inventory levels or a shortage of products available for sale.

If we experience inventory levels in excess of consumer demand then that may result in inventory write-downs or write-offs and the sale of excess inventory at discounted prices, which would cause our gross margins to suffer and could impair the strength and premium nature of our brand. Furthermore, lower than forecasted demand could also result in excess manufacturing capacity or reduced manufacturing efficiencies, which could result in lower margins. In periods when we experience a decrease in demand for our products and an increase in inventory, we may be unable to renegotiate our agreements with existing suppliers or partners on mutually acceptable terms. In addition, our loss contingencies may include liabilities for contracts that we cannot cancel, reschedule or adjust with suppliers or partners. Further, we are required to evaluate goodwill impairment on an annual basis and between annual evaluations in certain circumstances, and future goodwill impairment evaluations may result in a charge to earnings. Conversely, if we underestimate consumer demand, our suppliers and manufacturers may not be able to deliver products to meet our requirements or we may be subject to higher costs in order to secure the necessary production capacity. See “*-Increases in component costs, long lead times, supply shortages, and supply changes could disrupt our supply chain and have an adverse effect on our business, financial condition, and operating results.*” An inability to meet consumer demand and delays in the delivery of our products to our customers could result in reputational harm and damaged customer relationships and have an adverse effect on our business, financial condition, and operating results.

***The health wearable market is relatively new and, if the general market and specific demand for our products and services does not continue to grow, grows more slowly than we expect, or fails to grow as much as we expect, our business, financial condition, and operating results may be adversely affected.***

The general health wearable market is relatively new but rapidly growing, and it is uncertain whether it will sustain high levels of demand and achieve wider market acceptance. Our success depends substantially on the willingness of consumers to widely adopt our products and services, and the demand for wearable and other products focused on arterial health monitoring. We will need to educate consumers about our products and services through significant investment and provide quality products and services that are superior to those provided by our competitors. Additionally, the health wearable market at large is reasonably saturated, and the demand for and market acceptance of new products and services in the market is uncertain. It is difficult to predict the future growth rates, if any, and size of our market. We cannot assure you that our market will develop or be sustained at current levels, that the public’s interest in health wearables or other arterial health monitoring products will continue, or that our products and services will be widely adopted. If our market does not develop, develops more slowly than expected, or becomes saturated with competitors, or if our products and services do not achieve or sustain market acceptance, our business, financial condition, and operating results could be adversely affected.

***We have a limited operating history with certain of our products from which to predict our long-term performance, and our past financial results may not be indicative of our future performance.***

We began operations in 1994 with the original SphygmoCor product marketed and sold by our ATCOR subsidiary. Our CONNEQT Band is targeted for FDA clearance in the first quarter of calendar year 2024, and our new CONNEQT Pulse device received 510(k) clearance in April 2023. We have no history of generating revenue with our CONNEQT Products. As with any new product introduced to the market after obtaining FDA marketing authorization, we can provide no assurance of its performance, as our historical revenue growth based on other products may not be indicative of our future performance with respect to a new product. It remains uncertain how the COVID-19 pandemic and other market constraints will impact consumer demand for our products and services over the long term. Estimates of future revenue growth are subject to many risks and uncertainties, and our future revenue may differ materially from our projections. We have encountered, and will continue to encounter, risks and difficulties frequently experienced by growing companies in rapidly changing industries, including market acceptance of our products and services, attracting and retaining users, and increasing competition and expenses as we expand our business. We cannot be sure that we will be successful in addressing these and other challenges we may face in the future, and our business may be adversely affected if we do not manage these risks successfully. In addition, we may not achieve sufficient revenue to attain or maintain positive cash flows from operations or profitability in any given period, or at all.

***If we fail to maintain or develop relationships with physicians, sales of our products would decline.***

The success of our remote patient and in-clinic monitoring businesses are dependent upon physicians prescribing and utilizing our solution. The utilization of our solution by physicians for both remote patient and in-clinic monitoring is directly influenced by a number of factors, including:

- the ongoing support for the efficacy of our products and services by peer reviewed publications and industry associations;
- our ability to educate physicians regarding the benefits of our biometric monitoring solutions over alternative monitoring solutions;
- the availability of insurance coverage and the adequacy of reimbursement for our commercial products or procedures involving our products, and continued reimbursement to physicians for remote patient monitoring at an economically attractive level;
- our demonstrating that our proposed products and services are reliable and supported by us in the field; and
- the pricing of our products and services in a medical device industry that is becoming increasingly price sensitive and competitive.

In addition, if the FDA disagrees with our interpretation of the regulation or how we market our products and services, or if the FDA changes its policies and regulations in the future, we may be required to obtain additional FDA clearance or approval before we can continue to market our products and services, including our general consumer or at-home products and services.

If we are unable to drive physician utilization, our revenues may never materialize or may not meet our projections. Our failure to develop or maintain our relationships with physicians may cause us to lose market share and could have a material adverse effect on our business, financial condition and results of operations. In addition, if we are unable to develop new relationships with physicians, our competitive position would likely suffer and our opportunities to grow our revenues and business would be harmed.

***We rely on a limited number of suppliers, contract manufacturers, and logistics partners for our products. A loss of any of these partners could negatively affect our business.***

We rely on a limited number of contract manufacturers and suppliers to manufacture our products. In the event of interruption from any of our contract manufacturers or suppliers, we may not be able to increase capacity from other sources or develop alternate or secondary sources without incurring material additional costs and substantial delays. Furthermore, a large portion of our contract manufacturers' primary facilities are located in China. Thus, our business could be adversely affected if one or more of our suppliers is impacted by a natural disaster, an epidemic such as the current COVID-19 pandemic, or other interruption at a particular location. Certain interruptions may be due to, among other things, temporary closures of our facilities or those of our contract manufacturers, and other vendors in our supply chain; restrictions on or delays surrounding travel or the import/export of goods and services from certain ports that we use; and local quarantines or other public safety measures. Additionally, we may increase our reliance on third-party suppliers, manufacturers and other logistics partners. If any of our independent contractors do not perform their obligations or meet the expectations of us or our users, our brand, reputation and business could suffer. See *"We have limited control over our suppliers and contract manufacturers, which may subject us to significant risks, including the potential inability to produce or obtain quality products and services on a timely basis or in sufficient quantity."*

If we experience a significant increase in demand for our products that cannot be satisfied adequately through our existing supply channels, or if we need to replace an existing supplier, manufacturer or partner, or if we find we need to engage additional suppliers, manufacturers and partners to support our operations, we may be unable to supplement or replace them under our required timing, at a quality standard to our satisfaction, or on market terms that are acceptable to us, which may undermine our ability to deliver our products to users in a timely manner and otherwise impact our users' experience. Further, materials changes made to our FDA-regulated medical devices due to supply changes can require the need to obtain further FDA premarket review and authorization before we can implement the change and commercialize our products, which could have a material adverse effect on our business. If we require additional manufacturing support, it may take a significant amount of time to identify a manufacturer that has the capability and resources to build our products to our specifications in sufficient volume. See *"Our operating results have been, and could in the future be, adversely affected if we are unable to accurately forecast consumer demand for our products and adequately manage our inventory."* Identifying suitable suppliers, manufacturers, and logistics partners is an extensive process that requires us to become satisfied with their quality control, technical capabilities, responsiveness and service, financial stability, regulatory compliance, and labor and other ethical practices. Accordingly, a loss of any of our significant suppliers or contract manufacturers, could have an adverse effect on our business, financial condition and operating results.

***Our reliance on manufacturers in China and other foreign countries could make us vulnerable to supply interruptions related to the political, legal and cultural environment in such countries.***

The CONNEQT Pulse devices are currently manufactured by a third-party manufacturer in China. In the future, we may increase the number of third-party manufacturers we use in foreign countries and we may have third-party manufacturers produce other products for us.

In addition to the risks related to reliance on third-party manufactures generally, reliance on international manufacturing is subject to significant, additional risks, including, among other things:

- Labor unrest;
- Social, political and economic instability;
- Restrictions on transfer of funds;
- Domestic and international customs and tariffs;
- Unexpected changes in regulatory environments; and
- Potentially adverse tax consequences.

Labor in China has historically been readily available at relatively low cost as compared to labor costs in North America. However, because China is experiencing rapid social, political and economic changes, labor costs have risen in some regions and labor may not continue to be available to us in China at costs consistent with historical levels or changes in labor or other laws may not be enacted, either of which would harm our operations in China. Any future increase in labor cost in China is likely to be higher than historical amounts.

As a result of experiencing such rapid social, political and economic change, China is also likely to enact new, and/or revise its existing, labor laws and regulations on employee compensation and benefits. Any such changes in Chinese labor laws and regulations would likely have an adverse effect on product manufacturing costs in China. Furthermore, if China laborers go on strike to demand higher wages, our operations could be disrupted. We cannot assure you that our business will not be affected by the aforementioned risk or similar risks in other countries we may seek third-party manufacturers in, each of which could harm our business, results of operations and financial condition.

***Our business can be impacted by political events, trade and other international disputes, war, terrorism, natural disasters, public health issues, industrial accidents and other business interruptions.***

Political events, trade and other international disputes, war, terrorism, natural disasters, public health issues, industrial accidents and other business interruptions can harm or disrupt international commerce and the global economy, and could have a material adverse effect on us and our customers, suppliers, contract manufacturers, logistics providers, distributors, and other channel partners.

We have a global business, and we believe that it generally benefits from growth in international trade. Trade and other international disputes can result in tariffs, sanctions, and other measures that restrict international trade and can adversely affect the Company's business. For example, tensions between the U.S. and China have led to a series of tariffs being imposed by the U.S. on imports from China mainland, as well as other business restrictions. Tariffs may increase the cost of our products and the components and raw materials that go into making them. These increased costs adversely impact the gross margin that we earn on our products. Tariffs can also make our products more expensive for customers, which could make our products less competitive and reduce consumer demand. Countries may also adopt other measures, such as controls on imports or exports of goods, technology or data, that could adversely impact our operations and supply chain and limit our ability to offer our products as designed. These measures can require us to take various actions, including changing suppliers, and restructuring business relationships. Changing our operations in accordance with new or changed trade restrictions can be expensive, time-consuming, disruptive to our operations and distracting to management. Such restrictions can be announced with little or no advance notice and we may not be able to effectively mitigate all adverse impacts from such measures. Political uncertainty surrounding trade and other international disputes could also have a negative effect on consumer confidence and spending, which could adversely affect our business.

Some of our operations and facilities, as well as critical business operations of our suppliers and contract manufacturers, may be in locations that are prone to earthquakes and other natural disasters. In addition, such operations and facilities are subject to the risk of interruption by fire, power shortages, nuclear power plant accidents and other industrial accidents, terrorist attacks and other hostile acts, ransomware and other cybersecurity attacks, labor disputes, public health issues, including pandemics such as the COVID-19 pandemic, and other events beyond our control. Global climate change is resulting in certain types of natural disasters occurring more frequently or with more intense effects. Such events can make it difficult or impossible for us to manufacture and deliver products to our customers, and create delays and inefficiencies in our supply and manufacturing chain. Following an interruption to our business, we may experience substantial recovery time, or experience significant expenditures to resume operations, and lose significant sales. Because we rely on single or limited sources for the supply and manufacture of many critical components, a business interruption affecting such sources would exacerbate any negative consequences to us.

Our operations are also subject to the risks of industrial accidents at our suppliers and contract manufacturers. While our suppliers are required to maintain safe working environments and operations, an industrial accident could occur and could result in disruption to our business and harm to our reputation. Major public health issues, including pandemics such as the COVID-19 pandemic, have adversely affected, and could in the future adversely affect, us due to their impact on the global economy and demand for consumer products; the imposition of protective public safety measures, such as stringent employee travel restrictions and limitations on freight services and the movement of products between regions; and disruptions in our supply chain and sales and distribution channels, resulting in interruptions of the supply of current products and delays in production ramps of new products.

While we maintain insurance coverage for certain types of losses, such insurance coverage may be insufficient to cover all losses that may arise.

***We have limited control over our suppliers and contract manufacturers, which may subject us to significant risks, including the potential inability to produce or obtain quality products and services on a timely basis or in sufficient quantity.***

We currently rely on a limited number of suppliers of components for our devices and we have limited control over our suppliers, contract manufacturers, and logistics partners, which subjects us to the following risks:

- inability to satisfy demand for our current and future products and services;
- reduced control over delivery timing and related customer experience and product reliability;

- reduced ability to monitor the manufacturing process and components used in our products;
- limited ability to develop comprehensive manufacturing specifications that take into account any materials shortages or substitutions;
- variance in the manufacturing capability of our third-party manufacturers;
- price increases;
- failure of a significant supplier or manufacturer partner to perform its obligations to us for technical, market, or other reasons;
- variance in the quality of services provided by our third-party partners;
- inability of suppliers to comply with applicable provisions of the FDA's Quality System Regulation or other applicable laws or regulations enforced by the FDA or other state regulatory authorities and foreign regulatory authorities;
- inability to ensure the quality of products and components manufactured by third parties;
- production delays related to the evaluation and testing of products and components from alternative suppliers and corresponding regulatory qualifications;
- difficulties in establishing additional supplier or manufacturer partner relationships if we experience difficulties with our existing suppliers, manufacturers or logistics partners;
- shortages of materials or components;
- production shortages resulting from any events affecting raw material supply;
- misappropriation of our intellectual property;
- exposure to natural catastrophes, epidemics such as the COVID-19 pandemic, political unrest, terrorism, labor disputes, and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured or the components thereof are sourced;
- changes in local economic conditions in the jurisdictions where our suppliers, manufacturers, and logistics partners are located;
- the imposition of new laws and regulations, including those relating to labor conditions, quality and safety standards, imports, duties, tariffs, taxes, and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds; and
- insufficient warranties and indemnities on components supplied to our manufacturers or performance by our partners.

If our suppliers became unable to provide components in the volumes needed or at an acceptable price, we would have to identify and qualify acceptable replacements from alternative sources of supply. The process of qualifying suppliers is lengthy. Delays or interruptions in the supply of our requirements could limit or stop our ability to provide sufficient quantities of devices on a timely basis or meet demand for our devices or services, which could have a material adverse effect on our business, financial condition and results of operations.

Furthermore, our failure or the failure of our manufacturing partners and suppliers to maintain compliance with either the QSR or MDD/MDR requirements could result in the shutdown of our manufacturing operations or the recall of our products, which would harm our business. In the event that one of our suppliers fails to maintain compliance with our or governmental quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result.

The occurrence of any of these risks, especially during seasons of peak demand, could cause us to experience a significant disruption in our ability to produce and deliver our products to our customers and could harm our brand and reputation.

***Our success depends on our ability to maintain the value and reputation of the CardieX, ATCOR, SphygmoCor, and CONNEQT brands.***

We believe that our brands are important to attracting and retaining users. Maintaining, protecting, and enhancing our brands depends on the success of a variety of factors, such as: our marketing efforts; our ability to provide consistent, high-quality products, services, and support, and our ability to successfully secure, maintain, and defend our rights to use the “ATCOR” and “CONNEQT” marks and logos, and other trademarks important to our brands. We believe that the importance of our brands will increase as competition further intensifies and brand promotion activities may require substantial expenditures. Our brands could be harmed if we fail to achieve these objectives or if our public image were to be tarnished by negative publicity. Unfavorable publicity about us, our strategic initiatives, our products, services, technology, customer service, personnel, and suppliers could diminish confidence in, and the use of, our products and services. Negative publicity also could have an adverse effect on the size, engagement and loyalty of our customers and result in decreased revenue, which could have an adverse effect on our business, financial condition, and operating results.

***Our business is heavily dependent on the brand recognition and market reputation of our vascular health products and technologies, which may not be as successful as we expect.***

We believe that our success is heavily dependent on the market recognition of the brand and reputation of our vascular health products and technologies, which may not be as successful as we expect. A variety of factors can potentially impact the reputation of our vascular health products and technologies, such as customer satisfaction, technology defects of our products, negative press and/or approvals that will enable us to operate our business in the manner we anticipate.

We promote our brands by conducting certain marketing activities. However, we cannot assure you that we will be successful in promoting our vascular health brand or our efforts will be sufficient in helping us to remain competitive. If we are unable to further enhance our reputation and increase market awareness of our vascular health products and technologies, or if we have to incur excessive marketing and promotional expenses in order to remain competitive, our business, financial condition and results of operations may be materially and adversely affected. We cannot assure you that we are able to monitor our promotion and marketing activities effectively and the promotion of our products and brand may not be successful as we expect.

***We may pursue strategic investments or acquisitions in the future. If we fail to successfully select, execute, or integrate our acquisitions, then our business, results of operations, and financial condition could be materially and adversely affected, and the stock price could decline.***

From time to time, we may pursue investments or acquisitions to add new products and technologies, acquire talent, gain new sales channels, or enter into new markets or sales territories. In addition to possible shareholder approval, we may need approvals and licenses from relevant government authorities for the acquisitions and to comply with any applicable laws and regulations, which could result in increased delay and costs. Furthermore, acquisitions and the subsequent integration of new assets, businesses, key talent, customers, vendors, and suppliers require significant attention from our management and could result in a diversion of resources from our existing business, which in turn could have an adverse effect on our operations. Acquired assets or businesses may not generate the financial results we expect. Acquisitions could result in the use of substantial amounts of cash, potentially dilutive issuances of equity securities, the occurrence of significant goodwill impairment charges, amortization expenses for other intangible assets, and exposure to potential unknown liabilities of the acquired business. Moreover, the costs of identifying and consummating acquisitions may be significant. Failure to successfully identify, complete, manage, and integrate acquisitions could materially and adversely affect our business, financial condition, and results of operations and could cause our stock price to decline.

***Increases in component costs, long lead times, supply shortages, and supply changes could disrupt our supply chain and have an adverse effect on our business, financial condition, and operating results.***

Accurately forecasting and meeting customer demand partially depends on our ability to obtain timely and adequate delivery of components for our products. All of the components that go into the manufacturing of our products are sourced from a limited number of third-party suppliers, and some of these components are provided by a single supplier. We could be subject to the risk of shortages and long lead times in the supply of these components and the risk that our suppliers discontinue or modify components used in our products. In addition, the lead times associated with certain components are lengthy and preclude rapid changes in design, quantities, and delivery schedules. Our ability to meet temporary unforeseen increases or decreases in demand has been, and may in the future be, impacted by our reliance on the availability of components from these sub-suppliers. We may in the future experience component shortages, and the predictability of the availability of these components may be limited. In the event of a component shortage or supply interruption from suppliers of these components, we may not be able to develop alternate sources in a timely manner. Developing alternate sources of supply for these components may be time-consuming, difficult, and costly and we may not be able to source these components on terms that are acceptable to us, or at all, which may undermine our ability to fill our orders in a timely manner. Any interruption or delay in the supply of any of these parts or components, or the inability to obtain these parts or components from alternate sources at acceptable prices and within a reasonable amount of time, would harm our ability to meet our scheduled product sales to our customers. Conversely, in periods when we experience a decrease in demand for our products and an increase in inventory, we may be unable to renegotiate our agreements or purchase commitments with existing suppliers or partners on mutually acceptable terms. See “-Our operating results have been, and could in the future be, adversely affected if we are unable to accurately forecast consumer demand for our products and adequately manage our inventory.”

Moreover, volatile economic conditions may make it more likely that our suppliers may be unable to timely deliver supplies, or at all, and there is no guarantee that we will be able to timely locate alternative suppliers of comparable quality at an acceptable price. In addition, international supply chains may be impacted by events outside of our control and limit our ability to procure timely delivery of supplies or finished goods and services. Since the beginning of 2018, importing and exporting has involved more risk, as there has been increasing rhetoric, in some cases coupled with legislative or executive action, from several U.S. and foreign leaders regarding tariffs against foreign imports of certain materials. Several of the components that go into the manufacturing of our products are sourced internationally, including from China, from where imports on specified products are subject to tariffs by the United States following the U.S. Trade Representative Section 301 Investigation. These issues appear to have been and could be further exacerbated by the continuation of the COVID-19 pandemic. We have seen, and may continue to see, increased congestion and/or new import/export restrictions implemented at ports that we rely on for our business. We may have to secure alternative transportation, such as air freight, or use alternative routes, at increased costs to run our supply chain. These tariffs and other supply chain issues may also have an impact on our component costs and have the potential to have an even greater impact depending on the outcome of the current trade negotiations, which have been protracted and recently resulted in increases in U.S. tariff rates on specified products from China. Increases in our component costs could have a material effect on our gross margins. The loss of a significant supplier, an increase in component costs, or delays or disruptions in the delivery of components, could adversely impact our ability to generate future revenue and earnings and have an adverse effect on our business, financial condition, and operating results.

***Our business could be adversely affected from an accident, safety incident, or workforce disruption.***

Health pandemics increase our exposure to significant personal injury claims that could subject us to substantial liability. For example, in connection with the COVID-19 pandemic, we have had to secure personal protective equipment, institute vaccination and testing policies and otherwise implement new methods of monitoring employee health, such as temperature checks. Our inability to timely adapt to changing norms and requirements around maintaining a safe workplace could cause employee illness, accidents, may not successfully prevent outbreaks, or may result in team discontent if we fail or if it is perceived that we are failing to protect the health and safety of our employees. Our liability insurance may not be adequate to cover fully all claims, and we may be forced to bear substantial losses from an accident or safety incident resulting from our manufacturing activities. Additionally, if our employees decide to join or form a labor union, we may become party to a collective bargaining agreement, which could result in higher employee costs and increased risk of work stoppages. It is also possible that a union seeking to organize one subset of our employee population, such as the employees in our manufacturing facility, could also mount a corporate campaign, resulting in negative publicity and reputational harm or other impacts that require attention by our management team and our employees. Negative publicity, work stoppages, or strikes by unions could have an adverse effect on our business, prospects, financial condition, and operating results.

***Parts of our business may be affected by seasonality.***

The sale of both our CONNEQT and ATCOR products may be influenced by seasonal trends common to university and research grant funding timetables and traditional retail selling periods, and we may generate a disproportionate amount of sales activity related to our CONNEQT products during the period from November through February due in large part to seasonal holiday demand and New Year's resolutions. As a result of quarterly fluctuations caused by these and other factors, comparisons of our operating results across different fiscal quarters may not be accurate indicators of our future performance. Furthermore, our performance in recent years may obscure the extent to which seasonality trends have affected our business and may continue to affect our business. Accordingly, yearly or quarterly comparisons of our operating results may not be useful and our results in any particular period will not necessarily be indicative of the results to be expected for any future period. Seasonality in all our products and its effect on our business can also be affected by introductions of new or enhanced products and services, including the costs associated with such introductions, as well as external factors beyond our control, such as the duration and trajectory of the COVID-19 pandemic.

***We plan to continue our expansion into international markets, which will expose us to significant risks.***

We currently operate in the United States and Australia and are continuing to expand our operations to other countries, which requires significant resources and management attention and subjects us to regulatory, economic, and political risks in addition to those we already face in the United States and Australia. There are significant risks and costs inherent in doing business in international markets, including:

- difficulty establishing and managing international operations and the increased operations, travel, infrastructure, including establishment of local customer service operations, and legal compliance costs associated with locations in different countries or regions;
- obtaining necessary regulatory authorizations to commercialize our products in the applicable foreign jurisdictions;
- the need to vary pricing and margins to effectively compete in international markets;
- the need to adapt and localize products for specific countries, including obtaining rights to third-party intellectual property used in each country;
- increased competition from local providers of similar products and services;
- the ability to protect and enforce intellectual property rights abroad;
- difficulties in understanding and complying with local laws, regulations, and customs in other jurisdictions;
- compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act (the "FCPA"), the Anti-Money Laundering and Counter-Terrorism Financing Act 2006, the U.K. Bribery Act 2010 (the "U.K. Bribery Act"), by us, our employees, and our business partners;
- complexity and other risks associated with current and future legal requirements in other countries, including legal requirements related to consumer protection, consumer product safety, and data privacy frameworks, such as the General Data Protection Regulation 2016/679 ("GDPR");
- varying levels of internet technology adoption and infrastructure, and increased or varying network and hosting service provider costs;
- tariffs and other non-tariff barriers, such as quotas and local content rules, as well as tax consequences;
- fluctuations in currency exchange rates and the requirements of currency control regulations, which might restrict or prohibit conversion of other currencies into U.S. dollars; and
- political or social unrest or economic instability in a specific country or region in which we operate, which could have an adverse impact on our operations in that location.



In addition to expanding our operations into international markets through the sale of our products, we have, and may in the future, expand our international operations through acquisitions of, or investments in, foreign entities, which may result in additional operational costs and risks. We have limited experience with international regulatory environments and market practices and may not be able to penetrate or successfully operate in the markets we choose to enter. In addition, we may incur significant expenses as a result of our international expansion, and we may not be successful. We may face limited brand recognition in certain parts of the world that could lead to non-acceptance or delayed acceptance of our products and services by consumers in new markets. We may also face challenges to acceptance of our products in new markets. Our failure to successfully manage these risks could harm our international operations and our plans for expansion into international markets, and have an adverse effect on our business, financial condition, and operating results.

***Cybersecurity risks could adversely affect our business and disrupt our operations.***

Threats to network and data security are increasingly diverse and sophisticated. Despite our efforts and processes to prevent security breaches and incidents, our products and services, as well as our servers, computer systems, and those of third parties that we use in our operations are vulnerable to cybersecurity risks, including cyber-attacks such as viruses, worms, ransomware, and other malicious code, phishing attacks, denial-of-service attacks, physical or electronic break-ins, third-party or employee theft or misuse, and similar disruptions from unauthorized tampering with our servers and computer systems or those of third parties that we use in our operations, which could lead to interruptions, delays, loss, corruption, unavailability, and unauthorized processing of critical data, unauthorized access to or other processing of user health data, a negative impact on our users' experience, and loss of consumer confidence. In addition, we may be the target of email scams and other means of social engineering that attempt to acquire personal data, company assets, or access to such data or assets. Despite our efforts to create security barriers to such threats, we may not be able to entirely mitigate these risks. Additionally, there is an increased risk that we may experience cybersecurity related incidents as a result of increased numbers of our employees, service providers, and third parties working remotely on less secure systems. Any cyber-attack that attempts to obtain our or our users' health data, disrupt our service, or otherwise access our systems, or those of third parties we use, if successful or any other type of security breach or incident suffered by ourselves or any third parties we use in our operations, could adversely affect our business, financial condition, operating results and be expensive to remedy. We and the third parties we use in our operations may face difficulties or delays in identifying or responding to any cyberattack or any other security breach or incident. In addition, any such attacks, breaches or incidents, or the perception they have occurred, may result in negative publicity and adversely affect our brand and reputation, impacting demand for our products and services, and could have an adverse effect on our business, financial condition, and operating results. We incur significant costs in our efforts to detect and prevent security breaches and other security-related incidents and we expect to incur additional costs in connection with improvements to our systems and processes in ongoing efforts to prevent such breaches and incidents. In the event of a breach or incident, we could be required to expend additional significant capital and other resources in an effort to prevent further breaches or incidents, which may require us to divert substantial resources. Moreover, we could be required or otherwise find it appropriate to expend significant capital and other resources to respond to, notify third parties of, and otherwise address the incident or breach and its root cause.

In addition, our insurance applicable to these matters may not be adequate to cover a potential claim and may be subject to exclusions, including the possibility that the insurer will deny coverage as to any future claim or exclude from our coverage such claims in policy renewals. The denial of our claims by our insurers or the successful assertion of claims by others against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, financial condition, results of operations and reputation. Further, there are no assurances that adequate product liability insurance will continue to be available to us in the future on commercially reasonable terms or at all.

***Interruptions or delays in telecommunications systems or in the data services provided to us by cellular communication providers or the loss of our wireless or data services could impair the delivery, and/or usability of our products and services.***

The success of our products and services will be dependent upon the ability to transmit, store, retrieve, process and manage data and to maintain and upgrade our data processing and communication capabilities. Our monitoring solutions rely on third-party wireless carriers to transmit data over their data networks. We are therefore dependent upon third-party wireless carriers to provide data transmission services to us and our customers.

As we expand our commercial activities, an increased burden is expected to be placed upon our data processing systems and the equipment upon which they rely. Interruptions of our data networks, or the data networks of wireless carriers, for any extended length of time, loss of stored data or other computer problems could have a material adverse effect on our business and operating results. Frequent or persistent interruptions in our monitoring services could cause permanent harm to our reputation and could cause current or potential users or prescribing physicians to believe that our systems are unreliable, leading them to switch to our competitors. Such interruptions could result in liability, claims and litigation against us for damages or injuries resulting from the disruption in service.

Our systems are also expected to be vulnerable to damage to or interruption of telecommunication services from earthquakes, floods, fires, power loss, telecommunication failures, terrorist attacks, computer viruses, break-ins, sabotage, and acts of vandalism. Despite any precautions that we may take, the occurrence of a natural disaster or other unanticipated problems could result in lengthy interruptions in these services. We do not carry business interruption insurance to protect against losses that may result from interruptions in service as a result of system failures. Moreover, the communications and information technology industries are subject to rapid and significant changes, and our ability to operate and compete is dependent on our ability to update and enhance the communication technologies used in our systems and services.

The success of our monitoring services will also be dependent upon our ability to perform computing functions associated with our signal processing algorithms and data management. The diagnostic and monitoring functions rely partly on the uninterrupted availability of third-party cloud based computational and data management services. Availability of the cloud-based infrastructure is a critical link in our ability to deliver our services and could have a material adverse effect on our business and operating results. Furthermore, loss of data due to catastrophic events at the sites for these cloud-based computer systems could cause permanent harm to our customers. These adverse events associated with unavailability of our cloud based computational infrastructure could result in liability, claims and litigation against us for damages or injuries resulting from the disruption in service.

Our systems are also expected to be vulnerable to damage or interruption in cloud computational services from earthquakes, floods, fires, power loss, technical failures, terrorist attacks, computer viruses, break-ins, sabotage, and acts of vandalism. Despite any precautions that we may take, the occurrence of a natural disaster or other unanticipated problems could result in lengthy interruptions in these services.

***We could be exposed to significant liability claims if we are unable to obtain insurance at acceptable costs and adequate levels or otherwise protect ourselves against potential product liability claims.***

The design, manufacture and marketing of our hardware and software products involve certain inherent risks. Manufacturing or design defects, unanticipated use of our products, or inadequate disclosure of risks relating to the use of our products can lead to negative publicity, government investigation, litigation, or other adverse events. These events could lead to recalls or safety alerts relating to our products (either voluntary or required by the FDA, or similar governmental authorities in other countries), and could result, in certain cases, in the removal of a product from the market. A recall could result in significant costs, as well as negative publicity and damage to our reputation that could reduce demand for our products. In some circumstances, such adverse events could also cause delays in new product clearance and commercialization plans.

The testing, manufacture, marketing and sale of medical devices entail the inherent risk of liability claims or product recalls. Product liability insurance is expensive and, if available, may not be available on acceptable terms at all periods of time. A successful product liability claim or product recall could inhibit or prevent the successful commercialization of our products, cause a significant financial burden on us, or both, which in either case could have a material adverse effect on our business and financial condition.

***If we are unable to anticipate appropriate pricing levels for our products, our business could be adversely affected.***

If we are unable to anticipate appropriate pricing levels for our products, whether due to consumer sentiment and spending power, brand perception, competitive pressure, or otherwise, our revenues and/or gross margins could be significantly reduced. Further, our decisions around the development of new products and services are in part based upon assumptions around pricing levels. If there is price compression in the market after these decisions are made, it could have a negative effect on our business.

***An economic downturn or economic uncertainty may adversely affect consumer discretionary spending and demand for our products and services.***

Our CONNEQT Pulse and CONNEQT Band may be considered a discretionary item for consumers. Factors affecting the level of consumer spending for such discretionary items include general economic conditions, and other factors, such as consumer confidence in future economic conditions, fears of recession, the availability and cost of consumer credit and spending power, levels of unemployment, and tax rates. In recent years, the United States and other significant economic markets have experienced cyclical downturns and worldwide economic conditions remain uncertain. As global economic conditions continue to be volatile or economic uncertainty remains, including due to the COVID-19 pandemic, trends in consumer discretionary spending also remain unpredictable and subject to reductions and fluctuations. To date, our business has operated mostly in a relatively strong economic environment and, therefore, we cannot be sure the extent to which we may be affected by recessionary conditions. Unfavorable economic conditions may lead consumers to delay or reduce purchases of our products and services and consumer demand for our products may not grow as we expect. Our sensitivity to economic cycles and any related fluctuation in consumer demand for our products and services could have an adverse effect on our business, financial condition, and operating results.

***If we fail to establish and maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.***

Section 404(a) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires that, beginning with our annual report for the year ending June 30, 2024, our management assess and report annually on the effectiveness of our internal controls over financial reporting and identify any material weaknesses in our internal controls over financial reporting. Although Section 404(b) of the Sarbanes-Oxley Act requires our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal controls over financial reporting, we have opted to rely on the exemptions provided to us by virtue of being a foreign private issuer and emerging growth company, and consequently will not be required to comply with SEC rules that implement Section 404(b) of the Sarbanes-Oxley Act until we lose our emerging growth company status.

In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting, we will need to expend significant resources and provide significant management oversight. We have commenced the process of reviewing and improving our internal controls over financial reporting for compliance with Section 404(a) of the Sarbanes-Oxley Act. We have made efforts to improve our internal controls and accounting policies and procedures, including hiring a new CFO and new accounting personnel and engaging external temporary resources. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in maintaining the adequacy of our internal control.

As of the date of this filing we have identified deficiencies in our internal controls that are deemed to be a material weakness. The matters involving internal controls and procedures that our management considered to be a material weakness under the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB") were: (1) no formally implemented system of internal control over financial reporting and limited/no associated written documentation of our internal control policies and procedures and (2) lack of sufficient resources and key accounting personnel with sufficient knowledge and experience in the reporting and compliance with SEC and PCAOB. Consequently, we have determined there is a material weakness in the internal control over financial reporting.

Although this material weakness did not result in material adjustments to the financial statements there is a reasonable possibility that a material misstatement of the annual financial statements would not have been prevented or detected on a timely basis due to the failure to design and implement appropriate segregation of duty controls. We are developing a plan to remediate this material weakness as follows:

- Our board of directors has approved, and the Company has implemented a revised Delegation of Authority, documenting stringent controls throughout the business. This will be reviewed by the board of directors on an annual basis, or more frequently if there are significant changes in the business.
- The Company has also implemented a monthly financial reporting close process, starting from the quarter-ended March 31, 2023. This process includes a review process performed by both the CFO and CEO, and formal reporting to the board of directors.
- The Company is in the process of documenting its internal control policies and procedures and designing an education process for the entire Company to ensure policies and procedures are understood and adhered to by all. The Company believes that it has documented all internal control policies and procedures by June 30, 2023, and believes that it will have the education program completed by August 31, 2023.

If either we are unable to conclude that we have effective internal controls over financial reporting or, at the appropriate time, our independent auditors are unwilling or unable to provide us with an unqualified report on the effectiveness of our internal controls over financial reporting as required by Section 404(b) of the Sarbanes-Oxley Act, investors may lose confidence in our operating results, the price of the ADSs could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404 of the Sarbanes-Oxley Act, we may not be able to remain listed on the Nasdaq Capital Market.

***Consolidation in the healthcare industry could lead to demands for price concessions or to the exclusion of existing market participants from certain markets, which could have an adverse effect on our business, results of operations or financial condition.***

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry to aggregate purchasing power. As the healthcare industry consolidates, competition to provide products and services to industry participants has become, and will continue to become, more intense. This has resulted in, and will likely continue to result in, greater pricing pressures and the exclusion of certain existing market participants from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions for hospitals.

We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to impact the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers, which may reduce competition, exert further downward pressure on the prices of our products and adversely impact our business, financial condition and results of operations

***Our business could be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic, which could cause significant disruptions in our operations.***

Health pandemics or epidemics, including the ongoing COVID-19 pandemic, have in the past and could again in the future result in quarantines, stay-at-home orders, remote work policies or other similar events that may disrupt businesses, delay our research and development programs and timelines, negatively impact productivity and increase risks associated with cybersecurity, the future magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations. More specifically, these types of events may negatively impact personnel at third-party manufacturing facilities or the availability or cost of materials, which could disrupt our supply chain. In addition, impact on the operations of the FDA or other regulatory authorities could negatively affect our planned approval processes. Finally, economic conditions and business activity may be negatively impacted and may not recover as quickly as anticipated. To date, the COVID-19 pandemic has had a limited impact on our research and development activities, other than, in certain cases, prices and access to raw materials; however, the effects of the COVID-19 pandemic continue to evolve and as a result, the ultimate impact of the COVID-19 pandemic (or a similar health pandemic or epidemic) is highly uncertain and subject to change. The COVID-19 pandemic continues to evolve and it remains difficult to predict the full impact of the pandemic on the broader economy and how consumer behavior may change, and whether such change is temporary or permanent. The duration and extent of the impact from the COVID-19 pandemic on our business will continue to depend on future developments that cannot be accurately forecasted at this time, such as the transmission rate and geographic spread of the disease, the extent and effectiveness of current or future containment actions, the widespread use of effective vaccines, the severity of breakthrough cases and emergence of new COVID-19 variants, and the impact of these and other factors on our employees, customers, partners, contract manufacturers, suppliers and other third-party providers. If we are not able to respond to and manage the impact of such events effectively and if the macroeconomic conditions of the general economy or the industry in which we operate do not improve, or worsen from present levels, our business, operating results, financial condition and cash flows could be adversely affected.

The Company continues to monitor the situation and take appropriate actions in accordance with the recommendations and requirements of relevant authorities. The extent to which the COVID-19 pandemic may impact the Company's operational and financial performance remains uncertain and will depend on many factors outside the Company's control, including the timing, extent, trajectory and duration of the pandemic, the emergence of new variants, the development, availability, distribution and effectiveness of vaccines and treatments, the imposition of protective public safety measures, and the impact of the pandemic on the global economy and demand for consumer products and services. Additional future impacts on the Company may include material adverse effects on demand for the Company's products and services, the Company's supply chain and sales and distribution channels, the Company's ability to execute its strategic plans, and the Company's profitability.

#### **Risks Related to Our Business and Products**

*Our products and services may be affected from time to time by design and manufacturing defects, real or perceived, that could adversely affect our business and result in harm to our reputation.*

We offer and will offer complex hardware and software products and services that can be affected by design and manufacturing defects. Sophisticated applications, such as our CONNEQT Portal, CONNEQT App and our other products, often have issues that can unexpectedly interfere with the intended operation of hardware or software products. Defects may also exist in components and products that we source from third parties, or may arise from upgrades or changes to hardware that we or our third party manufacturing partners may make in the ordinary course of a product's lifecycle. Actual or perceived defects may not be identified until after a product is in market. Any defects could impact our customer experience, tarnish our brand reputation or make our products and services unsafe and create a risk of environmental or property damage and/or personal injury. We may also become subject to the hazards and uncertainties of product liability claims and related litigation. Given that such proceedings are subject to uncertainty, there can be no assurance that such legal and regulatory proceedings, either individually or in the aggregate, will not have a material adverse effect on our stock price, business, results of operations, financial condition or cash flows. Furthermore, the occurrence of real or perceived defects in any of our products, now or in the future, could result in additional negative publicity, regulatory investigations, recalls, or lawsuits filed against us. We may also incur expenses to defend or settle any claims or government inquiries and our brand and reputation may be harmed.

In addition, from time to time we may experience hardware issues, or software errors that affect our users' ability to use our CONNEQT Portal or CONNEQT App. As a result, our products and services may not perform as anticipated and may not meet our expectations, or legal or regulatory requirements, or the expectations of our users. There can be no assurance that we will be able to timely detect and fix all issues and defects in the hardware and software we offer. Failure to do so could result in widespread technical and performance issues affecting our products and services and could lead to claims or investigations against us.

Design and manufacturing defects, real or perceived, and claims related thereto, may subject us to judgments or settlements that result in damages materially in excess of the limits of our insurance coverage. In addition, we may be exposed to recalls, product replacements or modifications, write-offs of inventory, property and equipment, or intangible assets, and significant warranty and other expenses such as litigation costs and regulatory fines. If we cannot successfully defend any large claim, maintain our general liability insurance on acceptable terms, or maintain adequate coverage against potential claims, our financial results could be adversely impacted. Further, quality problems could adversely affect the experience for users of our products and services, and result in harm to our reputation, loss of competitive advantage, poor market acceptance, reduced demand for our products, delay in new product introductions, and lost revenue.

***Our users will use their CONNEQT Products and companion digital solutions to track and record health data. If our products fail to provide accurate metrics and data to our users, our brand and reputation could be harmed and we may be unable to retain our users.***

Our users will use their CONNEQT Products and companion digital solutions (CONNEQT App and Portal) to track and record certain health metrics. Examples of metrics tracked on our platform include central blood pressure, arterial stiffness, and heart rate. These metrics assist our users in tracking their health data. If the software used in our CONNEQT Products or on our platform malfunctions and fails to accurately track, display, or record user's health data, it could negatively impact our users health and experience, and we could face claims alleging that our products do not operate as advertised. Such reports and claims could result in negative publicity, product liability and/or product safety claims, and, in some cases, may require us to expend time and resources to refute such claims and defend against potential litigation. If our products and services fail to provide accurate metrics and data to our users, or if there are reports or claims of inaccurate metrics and data or claims of inaccuracy regarding the overall health benefits of our products and services in the future, our users' experience may be negatively impacted, we may become the subject of negative publicity, litigation, regulatory proceedings, and warranty claims, and our brand, operating results, and business could be harmed.

***We may be subject to warranty claims that could result in significant direct or indirect costs, or we could experience greater product returns than expected, either of which could have an adverse effect on our business, financial condition, and operating results.***

We generally provide a 12-month limited warranty on our XCEL device, and a 120 day warranty on the companion tonometer. Our CONNEQT Pulse device comes with a 12-month limited warranty. The occurrence of any defects, real or perceived, in our products could result in an increase in returns or make us liable for damages and warranty claims in excess of our current reserves, which could result in an adverse effect on our business prospects, liquidity, financial condition, and cash flows if returns or warranty claims were to materially exceed anticipated levels. In addition, in the future we could be subject to costs related to product recalls, and we could incur significant costs to correct any defects, warranty claims, or other problems. Any negative publicity related to the perceived quality and safety of our products could affect our brand image, decrease consumer and user confidence and demand, and adversely affect our financial condition and operating results. Also, while our warranty is limited to repairs and returns, warranty claims may result in litigation, the occurrence of which could have an adverse effect on our business, financial condition, and operating results.

***If we are unable to manage our growth or expansion of operations, including in a cost-efficient manner, our business, operations, and financial condition, as well as our ability to scale our operations, could be materially and adversely affected.***

Our ability to effectively manage our anticipated growth and expansion of operations, and to manage our transition to operating as an Australian public company that is dual listed in Australia and the United States will also require us to enhance our operational, financial, and management controls and infrastructure, human resources policies, and reporting systems. These enhancements and improvements will require significant capital expenditures, investments in additional headcount and other operating expenditures, and allocation of valuable management and employee resources. Our future financial performance and ability to execute on our business plan will depend, in part, on our ability to effectively manage any future growth and expansion. We may be unable to effectively manage any future growth or expansion in an efficient or timely manner. Further, we may not be able to implement improvements in an efficient or timely manner and may discover deficiencies in existing controls, programs, systems, and procedures, which could have an adverse effect on our business, reputation, and financial results.

***Unsuccessful clinical trials relating to products under development could have a material adverse effect on our prospects.***

Seeking regulatory authorization for certain new products or new indications for existing products may require us to conduct clinical trials to support our regulatory submission. Unfavorable or inconsistent clinical data from current or future clinical trials or procedures conducted by us, our competitors, or third parties, or perceptions regarding this clinical data, could adversely affect our ability to obtain necessary clearance or approval and the market's view of our future prospects. Such clinical trials are inherently uncertain and there can be no assurance that any clinical trial we conduct or sponsor will be completed in a timely or cost-effective manner or result in a commercially viable product. Failure to successfully complete the requisite clinical trials in a timely and cost-effective manner could have a material adverse effect on our prospects. Clinical trials may experience significant setbacks even after earlier trials have shown promising results. Further, preliminary results from clinical trials may be contradicted by subsequent clinical analysis. In addition, results from already completed clinical trials or research may not be supported by actual long-term studies, research, or clinical experience. If preliminary clinical results are later contradicted, or if initial results cannot be supported by actual long-term studies or clinical experience, our business could be adversely affected. Clinical trials may be suspended or terminated by us, the FDA or other regulatory authorities at any time if it is believed that the trial participants face unacceptable health risks.

***Market opportunity estimates and growth forecasts included in this prospectus are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate.***

The forecasts and estimates in this prospectus relating to the expected size and growth of the markets for consumer wearables and medical devices may prove to be inaccurate. Even if these markets experience the forecasted growth described in this prospectus, we may not grow our business at similar rates, or at all. Our future growth is subject to many factors, including market adoption of our products, which is subject to many risks and uncertainties. Accordingly, the forecasts and estimates of market size and growth described in this prospectus should not be taken as indicative of our future growth. In addition, these forecasts may also be materially and adversely affected as a result of the COVID-19 pandemic.

#### **Risks Related to the Regulatory Environment**

***Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.***

The medical technologies we create, study, manufacture and market globally are subject to rigorous regulation and scrutiny by the U.S. Food and Drug Administration (FDA) and various other federal, state, and foreign governmental authorities. Government regulation applies to nearly all aspects of our products' lifecycles, including testing, clinical study, manufacturing, transporting, sourcing, safety, labeling, storing, packaging, recordkeeping, reporting, advertising, promoting, distributing, marketing, and importing or exporting of medical devices and products. In general, unless an exemption applies, a medical device or product must receive regulatory clearance or approval or clearance before it can be marketed or sold. Modifications to existing products or the marketing of new uses for existing products also may require regulatory clearance or approvals, or supplemental approvals. If we are unable to obtain these required marketing authorizations, our ability to commercialize new products will be delayed or adversely impacted.

Regulatory agencies may refuse to grant approval or clearance, or disagree with our interpretation of the data, or disagree with our interpretation of the regulatory requirements, such as products that are subject to enforcement discretion or consumer products that do not meet the definition of an FDA-regulated medical device. Further, the FDA and other regulatory agencies may change their policies, adopt additional regulations, or revise existing regulations, each of which could impact how our products are regulated, prevent or delay approval or clearance of devices, or could impact our ability to market a previously cleared, approved, or unregulated device. Our failure to comply with these regulatory requirements of the FDA or other applicable regulatory requirements in the United States or elsewhere might subject us to administratively or judicially imposed sanctions. These sanctions include, among others, warning letters, fines, civil penalties, criminal penalties, injunctions, debarment, product seizure or detention, product recalls and total or partial suspension of production, sale and/or promotion. Any of the foregoing actions could result in decreased sales including as a result of negative publicity and product liability claims, and could have a material adverse effect on our financial condition, results of operations, and prospects. In addition to the sanctions for noncompliance described above, commencement of an enforcement proceeding, inspection, or investigation could divert substantial management attention from the operation of our business and have an adverse effect on our business, results of operations, and financial condition.

***We are subject to significant regulation by numerous government agencies, including the FDA. We cannot market or commercially distribute our products without obtaining and maintaining necessary regulatory clearances or approvals and such authorizations may be revoked or revised if an agency like the FDA believes it necessary.***

Our products are anticipated to be marketed as medical devices, and as such, will be subject to extensive regulation in the United States and in the foreign markets where we distribute our products. The FDA and other U.S. and foreign governmental agencies regulate, among other things, with respect to medical devices:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;

- product safety;
- marketing, sales and distribution;
- pre-market clearance and approval;
- record keeping;
- advertising and promotion;
- recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market approval studies; and
- product import and export.

Before we can market or sell a medical device in the United States, we must first submit and receive 510(k) clearance pursuant to Section 510(k) of the Food, Drug and Cosmetic Act (FD&C Act), approval of a PMA by the FDA, or grant of a de novo classification request from the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing.

Our existing commercial products, the SphygmoCor XCEL and SunTech Oscar 2™ Ambulatory Blood Pressure Monitor with “SphygmoCor Inside”, have previously received 510(k) clearance by the FDA. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which, depending on the specific action, could cause the majority of our sales to decline or cease altogether. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain pre-market approval process. Although we do not currently market any devices subject to pre-market approval, the FDA may demand that we obtain a pre-market approval prior to marketing certain future products. In addition, if the FDA disagrees with our determination that a product we currently market is subject to an exemption from pre-market review, the FDA may require us to submit a 510(k), de novo application or pre-market approval application in order to continue marketing the product. Further, even with respect to those future products where a pre-market approval is not required, we cannot assure you that we will be able to obtain the 510(k) clearances with respect to those products or do so in a timely fashion.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA’s satisfaction that our products are safe and effective for their intended uses;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities, including those of our suppliers or contract manufacturing partners, for any of our products may not meet the FDA’s applicable Quality System Regulations.

Medical devices may only be promoted and sold for the indications for which they are approved or cleared. In addition, even if the FDA has approved or cleared a product, it can take action affecting such product approvals or clearances if serious safety or other problems develop in the marketplace. Delays in obtaining clearances or approvals could adversely affect our ability to introduce new products or modifications to our existing products in a timely manner, which would delay or prevent commercial sales of our products. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could affect the perceived safety and performance of our products and dissuade our customers from using our products.



In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products in foreign countries. Obtaining regulatory authorization in one jurisdiction does not mean we will be successful in obtaining the requisite authorization to commence a clinical trial or to market our products in a foreign jurisdiction, as the regulatory process and requirements for marketing authorization vary from jurisdiction to jurisdiction, and the time may be longer or shorter than that required for FDA clearance or approval. The requirements governing the conduct of clinical trials, product registration and listing, pricing and reimbursement also vary greatly from country to country.

The policies of the FDA and foreign regulatory authorities may change and additional government regulations may be enacted which could prevent or delay regulatory authorization of our products and could also increase the cost of regulatory compliance. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

The FDA and non-U.S. regulatory authorities require that our products be manufactured according to rigorous standards. These regulatory requirements may significantly increase our production costs and may even prevent us from making our products in quantities sufficient to meet market demand. If we make material changes our approved manufacturing process, the FDA may need to review the process before the change may be implemented. Failure to comply with applicable regulatory requirements discussed could subject us to enforcement actions, including warning letters, fines, injunctions and civil penalties, recall or seizure of our products, operating restrictions, partial suspension or total shutdown of our production, and even criminal prosecution.

Federal, state and non-U.S. regulations regarding the manufacture and sale of medical devices are subject to future changes. The complexity, timeframes and costs associated with obtaining marketing clearances are unknown. Although we cannot predict the impact, if any, these changes might have on our business, the impact could be material.

Following the introduction of a product, these agencies will also periodically review our design and manufacturing processes and product performance. The process of complying with the applicable good manufacturing practices, adverse event reporting, clinical trial and other requirements can be costly and time consuming, and could delay or prevent the production, manufacturing or sale of our products. In addition, if we fail to comply with applicable regulatory requirements, it could result in fines, delays or suspensions of regulatory clearances, closure of manufacturing sites, seizures or recalls of products and damage to our reputation. Recent changes in enforcement practice by the FDA and other agencies have resulted in increased enforcement activity, which increases the compliance risk for us and other companies in our industry. In addition, governmental agencies may impose new requirements regarding registration, labeling or prohibited materials that may require us to modify or re-register products already on the market or otherwise impact our ability to market our products in those countries. Once clearance or approval has been obtained for a product, there is an obligation to ensure that all applicable FDA, and other regulatory requirements continue to be met.

Additionally, injuries caused by the malfunction or misuse of medical devices, even where such malfunction or misuse occurs with respect to one of our competitor's products, could cause regulatory agencies to implement more conservative regulations on the medical monitoring industry, which could significantly increase our operating costs.

***If we fail to obtain and maintain necessary regulatory clearances, approvals, or certifications for our products, or if clearances, approvals or certifications for future products and indications are delayed or not issued, our commercial operations would be harmed.***

Our products are subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries outside of the United States. Government regulations specific to medical devices are wide ranging and govern, among other things:

- product design, development, and manufacture;
- laboratory, preclinical and clinical testing, labeling, packaging, storage, and distribution;
- premarketing clearance, approval, or certification;
- record keeping;
- product marketing, promotion and advertising, sales, and distribution; and
- post marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals.

Before we can market or sell a medical device in the United States, we must first submit and receive 510(k) clearance pursuant to Section 510(k) of the Food, Drug and Cosmetic Act (FD&C Act), approval of a PMA by the FDA, or grant of a de novo classification request from the FDA, unless an exemption applies.

In many cases, the process of obtaining pre-market approval (PMA) is much more rigorous, costly, lengthy, and uncertain than the 510(k) clearance process. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, in order to clear the proposed device for marketing. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence. In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based on extensive data, including technical, pre-clinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices for which the 510(k) process cannot be used and that are deemed to pose the greatest risk, such as life sustaining, life supporting, or implantable devices. In the de novo classification process, a manufacturer whose novel device under the FD&C Act would otherwise be automatically classified as Class III and require the submission and approval of a PMA prior to marketing is able to request down-classification of the device to Class I or Class II on the basis that the device presents a low or moderate risk. If the FDA grants the de novo classification request, the applicant will receive authorization to market the device. This device type may be used subsequently as a predicate device for future 510(k) submissions. Modifications to products that are approved through a PMA application generally need prior FDA approval of a PMA supplement. Similarly, some modifications made to products cleared through a 510(k) submission may require a new 510(k) clearance, or such modification may put the device into Class III and require PMA or the grant of a de novo classification request.

The PMA, 510(k) clearance, and de novo classification processes can be expensive, lengthy, and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. Any delay or failure to obtain necessary regulatory approvals, clearances or certifications would have a material adverse effect on our business, financial condition, and results of operations.

The FDA and foreign bodies can delay, limit, or deny clearance, approval, or certification of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses or substantially equivalent to a predicate device;
- the disagreement of the FDA or the applicable foreign body with the design, conduct or implementation of our clinical trials or investigations or the analyses or interpretation of data from pre-clinical studies or clinical trials or investigations;
- serious and unexpected adverse device effects experienced by participants in our clinical trials or investigations;
- the data from our pre-clinical studies and clinical trials or investigations may be insufficient to support clearance, de novo classification, approval, or certification, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- an advisory committee, if convened by the applicable regulatory authority, may recommend against approval of our application or may recommend that the applicable regulatory authority require, as a condition of approval, additional preclinical studies, clinical trials or investigations, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee, if convened, makes a favorable recommendation, the respective regulatory authority or notified body may still not approve or certify the product;
- the applicable regulatory authority or notified body may identify significant deficiencies in our manufacturing processes, facilities, or analytical methods or those of our third-party contract manufacturers;
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory submissions insufficient for clearance, de novo classification, approval, or certification; and
- the FDA or foreign regulatory authorities or bodies may audit our clinical trial or investigation data and conclude that the data is not sufficiently reliable to support approval, clearance, or certification.

Similarly, regulators may determine that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial or investigation site, or the utility of the clinical trial or investigation itself. Even if we are granted regulatory clearances, approvals, or certifications, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Moreover, the FDA, the Federal Trade Commission (FTC), and other foreign counterparts strictly regulate the labeling, promotion, and advertising of our products, including comparative and superiority claims vis-a-vis competitors' products.

As a condition of approving a PMA application or granting a de novo request, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

In addition, we are required to investigate all product complaints we receive, and timely file reports with the FDA, including medical device reports that require that we report to regulatory authorities if our products may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not submitted in a timely manner, regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, including warning letters, untitled letters, fines, civil penalties, recalls, seizures, operating restrictions, denial of requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products, withdrawal of current 510(k) clearances or premarket approvals, and narrowing of approved or cleared product labeling, all of which could harm our business. In addition, the FDA may provide notice of and conduct additional inspections, such as "for cause" inspections, of our business, sites, and facilities as part of its review process. Similar requirements may apply in foreign countries.

If we initiate a correction or removal action for our products to reduce a significant risk to health posed by our products, we would be required to submit a publicly available correction and removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny from the FDA, other international regulatory agencies, and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports could be used by competitors against us and cause physicians to delay or cancel orders, which could harm our reputation.

The FDA and the FTC also regulate the advertising, promotion, and labeling of our products to ensure that the claims we make are consistent with our regulatory authorizations, that there is adequate and reasonable scientific data to substantiate the claims, and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated, or not permissible, we may be subject to enforcement actions, including adverse publicity and/or warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

The FDA, state authorities, and foreign counterparts have broad investigation and enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state agencies, or foreign counterparts, which may include any of the following sanctions: adverse publicity, warning letters, fines, injunctions, consent decrees, and civil penalties; repair, replacement, refunds, recalls, termination of distribution, administrative detention, or seizure of our products; operating restrictions, partial suspension, or total shutdown of production; denial of our requests for marketing authorizations or certifications for new products, new intended uses, or modifications to existing products; withdrawal of marketing authorizations or certifications that have already been granted; and criminal prosecution. If any of these events were to occur, our business and financial condition could be harmed. In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval or certification that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, financial condition, and results of operations.

Our products must be manufactured in accordance with federal, state, and foreign regulations, and we could be forced to recall our devices or terminate production if we fail to comply with these regulations. If we, or our suppliers, fail to comply with the FDA's QSR or similar foreign regulatory requirements, our manufacturing or distribution operations could be delayed or shut down and our revenue could suffer.

Even after we have obtained regulatory clearance or approval to market a product, we have ongoing responsibilities under FDA regulations. Our manufacturing and design processes, and those of our third-party component suppliers, are required to comply with the FDA's QSR and similar foreign requirements. These rules cover procedures and documentation of the design, testing, production, process, controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing, and shipping of our products. We are also subject to similar state requirements and licenses, and to ongoing ISO 13485 compliance in our operations, including design, manufacturing, and service.

In addition, we must engage in extensive recordkeeping and reporting and must make available our records and facilities, and of the facilities certain of our contract manufacturers, for periodic unannounced or planned inspections or audits by governmental agencies or bodies, including the FDA, state authorities, and comparable agencies in other countries. If we fail a regulatory inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take timely and adequate corrective action in response to an adverse regulatory inspection could result in, among other things, a shutdown of our manufacturing or product distribution operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions, and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our third-party manufacturers and key component suppliers may not currently be, or may not continue to be, in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenue to decline.

We are registered with the FDA as a medical device specifications developer and manufacturer. The FDA has broad post-market and regulatory enforcement powers. We and our third-party manufacturers and suppliers, including subcontractors, are subject to unannounced or planned inspections or audits by the FDA and similar state and foreign bodies to determine our compliance with the QSR and other regulations at both our design and manufacturing facilities, and these inspections may include the manufacturing facilities of our suppliers. These inspections may be initiated as a result of concerns regarding the safety of our products or the components thereof.

Furthermore, we are required to verify that our suppliers maintain facilities, procedures, and operations that comply with our quality standards and applicable regulatory requirements. We can provide no assurance that we or our third-party manufacturers or suppliers will continue to remain in material compliance with the QSR or similar foreign requirements. If the FDA or other state and foreign bodies inspect any of our facilities and discover compliance problems, we may have to cease manufacturing and product distribution until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming, and a distraction for management, and if we experience a delay at our manufacturing facility, we may be unable to produce our products, which would harm our business.

In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals or certifications; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products and similar decisions from a notified body; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us, our suppliers, or our employees. Any of these actions could significantly and negatively affect supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims, and we could lose customers and experience reduced sales and increased costs.

***If we fail to comply with healthcare and other governmental regulations, we could face substantial fines and penalties and our business, results of operations and financial condition could be adversely affected.***

We are subject to certain federal, state, and foreign fraud and abuse laws, health information privacy and security laws, and transparency laws regarding payments and other transfers of value made to physicians and other healthcare professionals that could subject us to substantial penalties. Additionally, any challenge to, or investigation into, our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

The products we offer are highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely in the future. Our arrangements with physicians, hospitals and medical centers will expose us to broadly applicable fraud and abuse laws and other laws and regulations that may restrict the financial arrangements and relationships through which we market, sell, and distribute our products. Our employees, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements. Federal and state healthcare laws and regulations that may affect our ability to conduct business, include, without limitation:

- federal and state laws and regulations regarding billing and claims payment applicable to relevant procedures involving our commercial products and regulatory agencies enforcing those laws and regulations;
- FDA, Department of Justice, and other government authority prohibitions against the advertisement, promotion, and labeling of our products for off-label uses, or uses outside the specific indications approved by the FDA;
- the federal Anti-Kickback Statute, which broadly prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order, or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government. These laws have been interpreted to apply to arrangements between medical device manufacturers, on the one hand, and prescribers, purchasers, and other healthcare-related professionals on the other. They can apply to manufacturers who provide inaccurate information on coverage, coding, and reimbursement of their products to persons who bill third-party payors. In addition, medical device companies have been prosecuted or faced civil and criminal liability under these laws for a variety of alleged promotional and marketing activities, including violations of the federal Anti-Kickback Statute and engaging in off-label promotion that caused claims to be submitted for non-covered off-label uses. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the FCPA, the U.K. Bribery Act of 2010, and other local anti-corruption laws that apply to our international activities;
- the federal Physician Payment Sunshine Act (Open Payments), created under the ACA, and its implementing regulations, which requires applicable group purchasing organizations and manufacturers of covered drugs, medical devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to certain payments or other transfers of value made to covered recipients, including licensed physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require medical device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers, foreign and state laws, including the GDPR, governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

The scope and enforcement of each of the laws applicable to our business and products are uncertain and subject to rapid change in the current environment of healthcare reform. The U.S. Department of Justice has increased its scrutiny of interactions between manufacturers and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. Responding to a government investigation is time and resource intensive, and may cause harm to our business and reputation even if we are able to successfully defend against it. Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions or safe harbors, it is possible that some of our activities could be subject to challenge under one or more of such laws. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments.

If we were to grow our business and expand our sales organization or rely on distributors outside of the United States, we would be at increased risk of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment for individuals, exclusion from participation in government programs, such as Medicare and Medicaid, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

***Our employees, consultants, and other commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, consultants, and other commercial partners and business associates may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless, or negligent conduct or other unauthorized activities that violate the regulations of the FDA and other regulators (both domestic and foreign), including those laws requiring the reporting of true, complete, and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws, and regulations in the United States and internationally or laws that require the true, complete, and accurate reporting of financial information or data. In particular, sales, marketing, and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. It is not always possible to identify and deter misconduct by our employees, consultants, and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal, and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, any of which could adversely affect our business, financial condition and results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees and reputational harm, and divert the attention of management in defending ourselves against any of these claims or investigations.

***Healthcare policy changes may have a material adverse effect on us.***

In the United States, there have been, and continue to be, a number of legislative initiatives to contain healthcare costs. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (ACA) was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Since its enactment, there have been judicial, executive, and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, with the exception of a temporary suspension implemented under various COVID-19 relief legislation. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future. Any of these could make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market, or distribute our products after clearance or approval is obtained. Any such reforms could have a material adverse effect on our industry generally and on our customers. In addition, any healthcare reforms that expand the government's role in the U.S. healthcare industry may result in decreased sale of our products and lower reimbursement by payors for procedures using our products, any of which could affect demand for our products and/or result in additional pricing pressure, which in turn could impact our ability to successfully commercialize our products and could have an adverse material effect on our business, financial condition, and results of operations. Changes and reforms in the EU and other countries where we may decide to commercialize could have similar effects.

***If coverage and reimbursement from third-party payors for procedures using our products significantly decline, physicians, hospitals, and other healthcare providers may be reluctant to use our products and our sales may decline.***

Healthcare providers and related facilities are generally reimbursed for their services through payment systems managed by various governmental agencies worldwide, private insurance companies, and managed care organizations. The manner and level of reimbursement in any given case may depend on the site of care, the procedure(s) performed, the final patient diagnosis, the device(s) utilized, available budget, the efficacy, safety, performance and cost-effectiveness of our planned products and services, or a combination of these or other factors, and coverage and payment levels are determined at each payor's discretion. The coverage policies and reimbursement levels of these third-party payors may impact the decisions of healthcare providers and facilities regarding which medical products they purchase and the prices they are willing to pay for those products. Thus, changes in reimbursement levels or methods may impact sales of our products.

We have no direct control over payor decision-making with respect to coverage and payment levels for our medical device products and services. Additionally, we expect many payors to continue to explore cost-containment strategies that may potentially impact coverage and/or payment levels for our products and services.

The ability of physicians to be reimbursed by payors for utilizing our remote patient and in-clinic monitoring solutions is critical to our business because physicians will select solutions other than ours in the event that payors refuse such reimbursement.

The sales of our proposed products and services could depend, in part, on the extent to which healthcare providers and facilities or individual users are reimbursed by government authorities, private insurers and other third-party payors for the costs of our products or the services performed with our products. The coverage policies and reimbursement levels of third-party payors, which can vary among public and private sources and by country, may affect which products customers purchase and the prices they are willing to pay for those products and services in a particular jurisdiction. Reimbursement rates can also affect the acceptance rate of new technologies. Legislative or administrative reforms to reimbursement systems in the United States or abroad, or changes in reimbursement rates by private payors, could significantly reduce reimbursement for medical actions using our products or result in denial of reimbursement for those products, which would adversely affect customer demand or the price customers may be willing to pay for such products and services.

Many commercial payors refuse to enter into contracts to reimburse the fees associated with medical devices or services that such payors determine to be "experimental and investigational." Commercial payors typically label medical devices or services as "experimental and investigational" until such devices or services have demonstrated product superiority evidenced by a randomized clinical trial.

Reimbursement by Medicare is highly regulated and subject to change; our failure to comply with applicable regulations could decrease our expected revenue and may subject us to penalties or have an adverse impact on our business. The Medicare program is administered by CMS, which imposes extensive and detailed requirements on medical services providers, including, but not limited to, rules that impact how we structure our relationships with physicians, and how and where we provide our solutions. Our failure to comply with applicable Medicare rules could result in the inability of physicians to receive reimbursement as they will likely utilize our biometric monitoring solutions under the Medicare payment program.

When payors combine their operations, the combined company may elect to reimburse physicians for monitoring services at the lowest rate paid by any of the participants in the consolidation. If one of the payors participating in the consolidation does not reimburse for these services at all, the combined company may elect not to reimburse at any rate. Reimbursement rates tend to be lower for larger payors. As a result, as payors consolidate, the expected average reimbursement rate for procedures involving our products may decline.

Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets have government-managed healthcare systems that govern reimbursement for surgical procedures. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods. If adequate levels of reimbursement from third-party payors outside of the United States are not obtained, international sales of our products may decline. The marketability of our products may suffer if government and commercial third-party payors fail to provide adequate coverage and reimbursement. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

***We collect, store, process, and use personal data, which subjects us to legal obligations and laws and regulations related to security and privacy, and any actual or perceived failure to meet those obligations could harm our business.***

We collect, process, store, and use a wide variety of data from our customers, including personal information. We are subject to federal, state and international laws relating to the collection, use, retention, security and transfer of various types of personal information. U.S. federal, state, and international laws and regulations governing privacy and data protection impose restrictions on what we can do with our customers' personal data and provide for related obligations. These obligations include heightened transparency about data collection, use and sharing practices, new data privacy rights, and rules in respect to cross-border data transfers, which carry significant enforcement penalties for non-compliance. These laws and regulations also require us to safeguard our customers' personal data. Although we have established security procedures to protect customer information, our or our third-party service providers' security and testing measures may not prevent security breaches. Any compromise of our security or breach of our customers' privacy could harm our reputation or financial condition and, therefore, our business.

In addition to the risks generally relating to the collection, use, retention, security and transfer of personal information, we are also subject to specific obligations relating to information considered sensitive under applicable laws, such as health data and biometric data. Health data is subject to additional privacy, security and breach notification requirements, and we are subject to audit by governmental authorities regarding our compliance with these obligations. The collection, handling, and other processing of biometric data also are subject to particular scrutiny and obligations under applicable laws and regulations, including consumer protection legislation (such as the Federal Trade Commission Act and similar state legislation), general privacy legislation (such as the California Consumer Privacy Act, or CCPA), and state statutes addressing biometric information specifically (including Illinois' Biometric Information Privacy Act, or BIPA), and by consumer protection regulators. If we fail to adequately comply with applicable rules and requirements, or if health data is handled in a manner not permitted by law or under our agreements with healthcare institutions, we can be subject to litigation or government investigations or other proceedings, and can be liable for associated investigatory expenses, and can also incur significant fees or fines. Some of those laws, including BIPA, provide consumers with a private right of action for certain violations and large potential statutory damages awards. Recent litigation around these laws has encouraged plaintiffs' attorneys to bring additional actions against other targets. Further, the FTC issued a policy statement regarding biometric information on May 18, 2023, that identifies numerous risks the FTC considers key, outlines relevant practices the FTC plans to scrutinize, and affirms the FTC's commitment to addressing deceptive and unfair practices involving the collection and use of biometric information, as well as deceptive marketing of biometric information technologies. These developments underscore the legal and regulatory risks applicable to our collection, use, disclosure, and other processing of health and biometric information.

In addition, a party who circumvents our security measures or exploits inadequacies in our security measures, could, among other effects, misappropriate customer data or other proprietary information or cause interruptions in our operations. Actual or perceived vulnerabilities may lead to claims against us. To the extent that the measures we or our third-party business partners have taken are, or are perceived to be, insufficient or inadequate, we may become subject to litigation, breach notification obligations, or regulatory or administrative sanctions, which could result in significant fines, penalties, or damages and harm to our reputation. Depending on the nature of the information compromised, in the event of a data breach or other unauthorized processing of our customer data, we may also have obligations to notify customers about the incident and we may need to provide some form of remedy for the individuals affected by the incident. A growing number of legislative and regulatory bodies have adopted consumer notification requirements in the event of unauthorized access to or acquisition of certain types of personal data. Such breach notification laws continue to evolve and may be inconsistent from one jurisdiction to another. Complying with these obligations could cause us to incur substantial costs and could increase negative publicity surrounding any incident that compromises customer data.

Violations of applicable laws relating to privacy, data protection, or cybersecurity, or cybersecurity breaches or incidents, as well as the perception that any of the foregoing have occurred, could impact our business in a number of ways, such as a temporary suspension of some or all of our operating and/or information systems, damage to our reputation and brand and our relationships with customers, suppliers, vendors, and service providers and could result in lost, unavailable, or corrupted data, lost sales, increased insurance premiums, substantial breach-notification and other remediation costs and claims, demands, and litigation, as well as adversely affect results of operations. In addition, we may also face regulatory investigations and other proceedings with corresponding fines, penalties, and other liabilities, civil claims including representative actions, and other class action type litigation (where individuals have suffered harm), potentially amounting to significant compensation or damages liabilities, as well as associated costs, diversion of internal resources, and reputational harm. We may also incur additional costs in the future related to the implementation of additional security measures to protect against new or enhanced data security and privacy threats, to comply with state, federal, and international laws that may be enacted to address personal data processing risks and data security threats, or to investigate or address potential or actual data security breaches or incidents or violations of our actual or alleged obligations relating to privacy, data protection, or cybersecurity.

***Data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.***

As we conduct our clinical trials and continue to enroll patients in our current and future clinical trials, we may be subject to additional restrictions relating to privacy, data protection and data security. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, or EU, including personal health data, is subject to the GDPR. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. Certain aspects of cross-border data transfers under the GDPR are subject to uncertainty, including as the result of legal proceedings in the EU. For example, a July 2020 decision by the Court of Justice for the European Union invalidated the EU-U.S. Privacy Shield and imposed additional obligations in connection with the use of standard contractual clauses approved by the EU Commission. The EU Commission subsequently issued new standard contractual clauses that are required to be implemented by companies relying on such standard contractual clauses. These and other developments with respect to cross-border data transfers may increase the complexity of transferring personal data across borders and may require us to review and amend our mechanisms relating to cross-border data transfer.

Further, the exit of the United Kingdom, or UK, from the EU, referred to as Brexit, has created uncertainty with regard to data protection regulation in the UK. The UK has implemented legislation similar to the GDPR, referred to as the UK GDPR, which provides for fines of up to the greater of up to the greater of £17.5 million or 4% of global turnover. The GDPR and UK GDPR can increase our responsibility and liability in relation to personal data that we process where subject to these regimes, and we may be required to put in place or modify policies and measures to ensure compliance with the GDPR, including as implemented by individual countries, and the UK GDPR, each of which may require us to modify our policies and procedures and engage in additional contractual negotiations, and which may cause us to incur liabilities, expenses, costs, and operational losses. Compliance with the GDPR and UK GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and may expose us to greater liabilities under these regulations.

In addition, California has enacted the CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA went into effect on January 1, 2020, and the California Attorney General commenced enforcement actions for violations on July 1, 2020. In November 2020, California passed the California Privacy Rights Act, or CPRA, which amended and expanded the CCPA as of January 1, 2023. While the CCPA includes exemptions for certain clinical trial data, the CCPA, as modified by the CPRA, may increase our compliance costs and potential liability with respect to other personal information we may collect about California consumers. Additionally, numerous other states have proposed or enacted laws addressing privacy and security that impose obligations similar to those of the CCPA. The U.S. federal government also is contemplating federal privacy legislation. These and other evolving laws and regulations may impact our business activities and exemplify the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Any actual or alleged failure to comply with U.S. or international laws and regulations relating to privacy, data protection, and data security could result in governmental investigations, proceedings and enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity, harm to our reputation, and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information or impose other obligations or restrictions in connection with our use, retention and other processing of information, and we may otherwise face contractual restrictions applicable to our use, retention, and other processing of information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.



***The failure to comply with anti-corruption and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act (FCPA) and similar laws associated with our activities outside of the United States, could materially adversely affect our business and result in civil and/or criminal sanctions.***

We operate a global business and may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. We are subject to the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the U.K. Bribery Act, and possibly other anti-bribery and anti-money laundering laws in countries in which we conduct activities. These laws prohibit companies and their employees and third-party intermediaries from corruptly promising, authorizing, offering, or providing, directly or indirectly, improper payments or anything of value to foreign government officials, political parties, and private-sector recipients for the purpose of obtaining or retaining business, directing business to any person, or securing any advantage. Because of the predominance of government-administered healthcare systems in many jurisdictions around the world, many of our customer relationships outside of the U.S. are with governmental entities and are therefore potentially subject to such laws. We also participate in public-private partnerships and other commercial and policy arrangements with governments around the globe.

In addition, U.S. public companies are required to maintain records that accurately and fairly represent their transactions and have an adequate system of internal accounting controls. In many foreign countries, including countries in which we may conduct business, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. We face significant risks if we or any of our directors, officers, employees, agents or other partners or representatives fail to comply with these laws and governmental authorities in the United States and elsewhere could seek to impose substantial civil and/or criminal fines and penalties which could have a material adverse effect on our business, reputation, operating results and financial condition.

Global enforcement of anti-corruption laws has increased in recent years, including investigations and enforcement proceedings leading to assessment of significant fines and penalties against companies and individuals. Our international operations create a risk of unauthorized payments or offers of payments by one of our employees, consultants, sales agents, or distributors. We maintain policies and programs to implement safeguards to educate our employees and agents on these legal requirements, and to prevent and prohibit improper practices. However, existing safeguards and any future improvements may not always be effective, and our employees, consultants, sales agents or distributors may engage in conduct for which we could be held responsible. In addition, regulators could seek to hold us liable for conduct committed by companies in which we invest or that we acquire. Any alleged or actual violations of these regulations may subject us to government scrutiny, criminal or civil sanctions, adverse media coverage, investigations, and other liabilities, including suspension or debarment from government contracting, and could disrupt our business, adversely affect our reputation and result in a material adverse effect on our business, results of operations, financial condition and cash flows.

***The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines, or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.***

If the FDA or any foreign regulatory body determines that any of our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal, state, or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil, and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations.

In addition, physicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

***Failure to comply with HIPAA, the Health Information Technology for Economic and Clinical Health Act (HITECH Act) and implementing regulations could result in significant penalties.***

Numerous federal and state laws and regulations, including HIPAA and the HITECH Act, govern the collection, dissemination, security, use and confidentiality of patient-identifiable health information. HIPAA and the HITECH Act require us to comply with standards for the use and disclosure of protected health information within our company and with third parties. The Privacy Standards and Security Standards under HIPAA establish a set of basic national privacy and security standards for the protection of individually identifiable health information by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services. Notably, whereas HIPAA previously directly regulated only these covered entities, the HITECH Act, which was signed into law as part of the stimulus package in February 2009, makes certain of HIPAA's privacy and security standards also directly applicable to covered entities' business associates. As a result, both covered entities and business associates are now subject to significant civil and criminal penalties for failure to comply with Privacy Standards and Security Standards.

In certain situations, a medical device company can be considered a "health care provider" under the HIPAA Privacy Rule if it furnishes, bills, or is paid for health care in the normal course of business. When we access PHI as a business associate or as a "health care provider", as applicable, HIPAA requires us to develop and maintain policies and procedures with respect to protected health information that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information from unauthorized disclosure. The HITECH Act expands the notification requirement for breaches of patient-identifiable health information, restricts certain disclosures and sales of patient-identifiable health information and provides a tiered system for civil monetary penalties for HIPAA violations. The HITECH Act also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney fees and costs associated with pursuing federal civil actions. Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA.

If we are determined to be out of compliance with existing or new laws and regulations related to patient health information, we could be subject to criminal or civil sanctions. New health information standards, whether implemented pursuant to HIPAA, the HITECH Act, congressional action or otherwise, could have a significant effect on the manner in which we handle healthcare related data and communicate with payors, and the cost of complying with these standards could be significant.

***Regulations requiring the use of "standard transactions" for healthcare services issued under HIPAA may negatively affect our profitability and cash flows.***

Pursuant to HIPAA, final regulations have been implemented to improve the efficiency and effectiveness of the healthcare system by facilitating the electronic exchange of information in certain financial and administrative transactions while protecting the privacy and security of the information exchanged.

The HIPAA transaction standards are complex, and subject to differences in interpretation by third-party payors. For instance, some third-party payors may interpret the standards to require us to provide certain types of information, including demographic information not usually provided to us by physicians. As a result of inconsistent application of transaction standards by third-party payors or our inability to obtain certain billing information not usually provided to us by physicians, we could face increased costs and complexity, a temporary disruption in accounts receivable and ongoing reductions in reimbursements and net revenue. Changes and updates to HIPAA transaction standards could prove technically difficult, time-consuming or expensive to implement, all of which could harm our business.

***Enforcement of federal and state laws regarding privacy and security of patient information may adversely affect our business, financial condition or operations.***

The use and disclosure of certain health care information by health care providers and their business associates have come under increasing public scrutiny. Recent federal standards under HIPAA establish rules concerning how individually-identifiable health information may be used, disclosed and protected. Historically, state law has governed confidentiality issues, and HIPAA preserves these laws to the extent they are more protective of a patient's privacy or provide the patient with more access to his or her health information. As a result of the implementation of the HIPAA regulations, many states are considering revisions to their existing laws and regulations that may or may not be more stringent or burdensome than the federal HIPAA provisions. We must operate our business in a manner that complies with all applicable laws, both federal and state, and that does not jeopardize the ability of our customers to comply with all applicable laws. We believe that our operations are consistent with these legal standards. Nevertheless, these laws and regulations present risks for healthcare providers and their business associates that provide services to patients in multiple states. Because these laws and regulations are recent, and few have been interpreted by government regulators or courts, our interpretations of these laws and regulations may be incorrect. If a challenge to our activities is successful, it could have an adverse effect on our operations, may require us to forego relationships with customers in certain states and may restrict the territory available to us to expand our business. In addition, even if our interpretations of HIPAA and other federal and state laws and regulations are correct, we could be held liable for unauthorized uses or disclosures of patient information as a result of inadequate systems and controls to protect this information or as a result of the theft of information by unauthorized computer programmers who penetrate our network security. Enforcement of these laws against us could have a material adverse effect on our business, financial condition and results of operations.

**Risks Related to Our Intellectual Property**

***We are significantly dependent on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to our rights or the rights of others may result in our payment of significant monetary damages and/or royalty payments, negatively impacting our ability to sell current or future products.***

We are significantly dependent on patent and other proprietary rights and rely on a combination of patents, trademarks, tradenames, copyrights, trade secrets, and agreements (such as employee confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements) to protect our business and proprietary intellectual property. We also operate in an industry characterized by extensive patent litigation. Patent litigation can result in significant damage awards and injunctions that could prevent our manufacture and sale of affected products or require us to pay significant royalties in order to continue to manufacture or sell affected products. At any given time, we may become involved in patent infringement actions, the outcomes of which may not be known for prolonged periods of time. While it is not possible to predict the outcome of patent litigation, it is possible that the results of such litigation could require us to pay significant monetary damages and/or royalty payments, negatively impact our ability to sell current or future products, or that enforcement actions to protect our patent and proprietary rights against others could be unsuccessful, any of which could have a material adverse impact on our business, results of operations, financial condition, and cash flows.

While we intend to defend against any threats to our intellectual property, our patents, trademarks, tradenames, copyrights, trade secrets or agreements (such as employee confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements) may not adequately protect our intellectual property. Further, pending patent applications may not result in patents being issued to us, patents issued to or licensed by us may be challenged or circumvented by competitors and such patents may be found invalid, unenforceable or too limited in scope to protect our technology or provide us with any competitive advantage. Third parties could obtain patents that may require us to negotiate licenses to conduct our business, and such licenses may not be available on reasonable terms or at all. We also rely on non-disclosure and non-competition agreements with certain employees, consultants and other parties to protect, in part, trade secrets and other proprietary rights. We cannot be certain that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information, or that third parties will not otherwise gain access to our trade secrets or proprietary knowledge.

In addition, the laws of certain countries in which we market or manufacture some of our products do not protect our intellectual property rights to the same extent as the laws of the U.S., which could make it easier for competitors to capture market position. Competitors also may harm our sales by designing products that substantially mirror the capabilities of our products or technology without infringing our intellectual property rights. If we are unable to protect our intellectual property in these countries, it could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

***Our intellectual property rights are valuable, and any inability to protect them could reduce the value of our products and brand.***

Our success depends in large part on our proprietary technology and our patents, trade secrets, trademarks, and other intellectual property rights. We rely on, and expect to continue to rely on, a combination of trademark, copyright, trade secret and patent laws, as well as confidentiality and license agreements with our employees, contractors, consultants, and third parties with whom we have relationships, to establish and protect our technology brand and other intellectual property. However, our efforts to protect our intellectual property rights may not be sufficient or effective and any of our intellectual property rights may be challenged, which could result in them being narrowed in scope or declared invalid or unenforceable. There can be no assurance that our intellectual property rights will be sufficient to protect against others offering products, services, or technologies that infringe on our rights or are substantially similar to ours and that compete with our business.

Effective protection of patents, trademarks, and domain names is expensive and difficult to maintain, both in terms of application and registration costs as well as the costs of defending and enforcing those rights. As we have grown, we have sought to obtain and protect our intellectual property rights in an increasing number of countries, a process that can be expensive and may not always be successful. For example, the U.S. Patent and Trademark Office (USPTO) and various foreign governmental patent agencies require compliance with a number of procedural requirements to complete the patent application process and to maintain issued patents, and noncompliance or non-payment could result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in a relevant jurisdiction. Further, intellectual property protection may not be available to us in every country in which our products are available. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against certain third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

In order to protect our brand and intellectual property rights, we spend significant resources to monitor and protect these rights. Litigation brought to protect and enforce our intellectual property rights can be costly, time-consuming, and distracting to management and could result in the impairment or loss of portions of our intellectual property. Furthermore, our efforts to enforce our intellectual property rights may be met with defenses, counterclaims, and countersuits attacking the validity and enforceability of our intellectual property rights. Accordingly, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Our failure to secure, protect, and enforce our intellectual property rights could seriously damage our brand and our business.

***Our products could infringe or appear to infringe the intellectual property rights of others, which may lead to patent and other intellectual property litigation that could itself be costly, could result in the payment of substantial damages or royalties, prevent us from using technology that is essential to our products, and/or force us to discontinue selling our products.***

The medical device industry in general has been characterized by extensive litigation and administrative proceedings regarding patents and other intellectual property rights. Our competitors hold a significant number of patents relating to cardiovascular health devices and products. Third parties may in the future assert that we are employing their proprietary technology without authorization. If we fail in defending against lawsuits or claims brought against us in the future, we could be subject to substantial monetary damages, injunctive relief, and loss of valuable intellectual property rights, and we cannot predict the outcome of any lawsuit. An adverse determination or protracted defense costs of such lawsuits could have a material effect on our business and operating results.

Monitoring unauthorized use of our intellectual property is difficult and costly. Unauthorized use of our intellectual property may have occurred or may occur in the future. Although we have taken steps to minimize the risk of this occurring, any such failure to identify unauthorized use and otherwise adequately protect our intellectual property would adversely affect our business. Moreover, if we are required to commence litigation, whether as a plaintiff or defendant, not only will this be time-consuming, but we will also be forced to incur significant costs and divert our attention and efforts of our employees, which could, in turn, result in lower revenue and higher expenses.

We cannot provide assurance that our products or methods do not infringe or appear to not infringe the patents or other intellectual property rights of third parties and if our business is successful, the possibility may increase that others will assert infringement claims against us whether valid or frivolous.

Determining whether a product infringes a patent involves complex legal and factual issues, defense costs and the outcome of a patent litigation action are often uncertain. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims covering or appearing to cover our products, parts of our products, technology or methods do not exist, have not been filed or could not be filed or issued. Because of the number of patents issued and patent applications filed in our technical areas, our competitors or other parties may assert that our products and the methods we employ in the use of our products are covered by U.S. or foreign patents held by them. In addition, because patent applications can take many years to issue and because publication schedules for pending applications may vary by jurisdiction and some patent applications may not be published in the U.S., there may be applications now pending of which we are unaware and which may result in issued patents that our current or future products infringe or appear to infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. There could also be existing patents that one or more of our products or parts may infringe and of which we are unaware. As the number of competitors in the market for vascular health products and the number of patents issued in this area grows, the possibility of patent infringement claims against us increases. In certain situations, we may determine that it is in our best interests to voluntarily challenge a party's patents in litigation or other proceedings, including declaratory judgment actions, patent reexaminations, post grant reviews, or inter partes reviews. As a result, we may become involved in unwanted protracted litigation that could be costly, result in diversion of management's attention, require us to pay damages and/or licensing royalties and force us to discontinue selling our products.

Infringement and other intellectual property claims and proceedings brought against us, whether successful or not, could result in substantial costs and harm to our reputation. Such claims and proceedings can also distract and divert management and key personnel from other tasks important to the success of the business. We cannot be certain that we will successfully defend against allegations of infringement of patents or other intellectual property rights. In the event that we become subject to a patent infringement or other intellectual property related lawsuit and if the asserted patents or other intellectual property were upheld as valid and enforceable and we were found to infringe the asserted patents or other intellectual property, or violate the terms of a license to which we are a party, we could be required to do one or more of the following:

- cease selling or using any of our products that incorporate the asserted intellectual property, which would adversely affect our revenue;
- pay damages for past use of the asserted intellectual property, which may be substantial;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable royalty terms, if at all, and which could reduce profitability; and
- redesign or rename, in the case of trademark claims, our products to avoid infringing the intellectual property rights of third parties, which may not be possible and could be costly and time-consuming if it is possible to do so.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on our products and technology, including, but not limited to, our SphymoCor central blood pressure technology, CONNEQT Band and CONNEQT Pulse, in all countries throughout the world could be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we and any future licensor may encounter difficulties in protecting and defending such rights in foreign jurisdictions. Consequently, we and any future licensor may not be able to prevent third parties from practicing our inventions in some or all countries outside the United States, or from selling or importing products made using our or any future licensor's inventions in and into the United States or other jurisdictions. Competitors and other third parties may be able to use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and technologies and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products. We and any future licensor's patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. Furthermore, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of any patents.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the misappropriation or other violations of our intellectual property rights including infringement of our patents in such countries. The legal systems in certain countries may also favor state-sponsored companies or companies headquartered in particular jurisdictions over our patents and other intellectual property protection. The absence of harmonized intellectual property protection laws and effective enforcement makes it difficult to ensure consistent respect for patent, trade secret, and other intellectual property rights on a worldwide basis. As a result, it is possible that we will not be able to enforce our rights against third parties that misappropriate our proprietary technology in those countries.

Proceedings to enforce our or any future licensor's patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our and any future licensor's patents at risk of being invalidated or interpreted narrowly and our and any future licensor's patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We and any future licensor may not prevail in any lawsuits that we and any future licensor initiates, or that are initiated against us or any future licensor, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our products, services and other technologies and the enforcement of intellectual property. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Issued patents covering our products and technologies could be found invalid or unenforceable if challenged.***

Our owned and any future licensed patents and patent applications may be subject to validity, enforceability and priority disputes. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Some of our patents or patent applications may be challenged at a future point in time in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference or other similar proceedings. Any successful third-party challenge to our patents in this or any other proceeding could result in the unenforceability or invalidity of such patents, which may lead to increased competition to our business, which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, if we or any future licensor initiates legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that such patent covering our products, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. There are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including, but not limited to, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the relevant patent office, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include *ex parte* re-examination, *inter partes* review, post-grant review, derivation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover and protect our products. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which us, any future licensor, our patent counsel and the patent examiner were unaware during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. If a defendant or other third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection for our products and technologies, which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license intellectual property or develop or commercialize current or future products.

We may not be aware of all third-party intellectual property rights potentially relating to our products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until approximately 18 months after filing or, in some cases, not until such patent applications issue as patents. We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings or other post-grant proceedings declared by the USPTO, or other similar proceedings in non-U.S. jurisdictions, that could result in substantial cost to us and the loss of valuable patent protection. The outcome of such proceedings is uncertain. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, changes to the patent laws of the United States in the last decade allow for various post-grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Furthermore, if third parties bring these proceedings against our patents, regardless of the merit of such proceedings and regardless of whether we are successful, we could experience significant costs and our management may be distracted. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations and prospects.

***If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, and our business could be harmed.***

We rely heavily on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information, and to maintain our competitive position. However, trade secrets and know-how can be difficult to protect. In particular, we anticipate that with respect to our technologies, these trade secrets and know how may, over time, be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel between industry scientific positions.

In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, corporate partners and, when needed, our advisers. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors or other third parties will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure, which could adversely impact our ability to establish or maintain a competitive advantage in the market, business, financial condition, results of operations and prospects.

We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor or other third party, absent patent protection, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Competitors or third parties could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, design around our protected technology, develop their own competitive technologies that fall outside the scope of our intellectual property rights or independently develop our technologies without reference to our trade secrets. If any of our trade secrets were to be disclosed to or independently discovered by a competitor or other third party, it could materially and adversely affect our business, financial condition, results of operations and prospects.

***Obtaining and maintaining our patent protection depends on compliance with various required procedures, document submissions, fee payments and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States at several stages over the lifetime of the patents and/or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we may rely on any future licensor to pay these fees due to the U.S. and non-U.S. patent agencies and to take the necessary action to comply with these requirements with respect to any future licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors may be able to enter the market without infringing our patents and this circumstance would have a material adverse effect on our business, financial condition, results of operations and prospects.

***Our use of open-source software and failure to comply with the terms of the underlying open-source software licenses could impose limitations on our ability to commercialize our products and provide third parties access to our proprietary software.***

Our products utilize open-source software that contain modules licensed for use from third-party authors under open-source licenses. In particular, some of the software may be provided under license arrangements that allow use of the software for research or other noncommercial purposes. Use and distribution of open-source software may entail greater risks than use of third-party commercial software, as open-source software licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the code. Some open-source software licenses contain requirements that the licensee make its source code publicly available if the licensee creates modifications or derivative works using the open-source software, depending on the type of open-source software the licensee uses and how the licensee uses it. If we combine our proprietary software with open-source software in a certain manner, we could, under certain open-source software licenses, be required to release the source code of our proprietary software to the public for free. This would allow our competitors and other third parties to create similar products with less development effort and time and ultimately could result in a loss of our product sales and revenue, which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, some companies that use third-party open-source software have faced claims challenging their use of such open-source software and their compliance with the terms of the applicable open-source license. We may be subject to suits by third parties claiming ownership of what we believe to be open-source software or claiming non-compliance with the applicable open-source licensing terms. Use of open-source software may also present additional security risks because the public availability of such software may make it easier for hackers and other third parties to compromise or attempt to compromise our technology platform and systems.



Although we review and monitor our use of open-source software to avoid subjecting our proprietary software to conditions we do not intend, the terms of many open-source software licenses have not been interpreted by United States courts, and there is a risk that these licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to commercialize our products and proprietary software. Moreover, we cannot assure investors that our processes for monitoring and controlling our use of open-source software in our products will be effective. If we are held to have breached the terms of an open-source software license, we could be subject to damages, required to seek licenses from third parties to continue offering our products on terms that are not economically feasible, to re-engineer our products, to discontinue the sale of our products if re-engineering could not be accomplished on a timely basis, or to make generally available, in source code form, our proprietary code, any of which could adversely affect our business, financial condition, results of operations and prospects.

#### **Risks Related to Ownership of Our ADSs, Our Trading Market and This Offering**

*The market price and trading volume of our ordinary shares, and that of the ADSs, may be volatile and may be affected by economic conditions beyond our control.*

The market price of our ordinary shares on the ASX, and the market price of the ADSs following this offering, may be highly volatile and subject to wide fluctuations. In addition, the trading volume of our ordinary shares and the ADSs may fluctuate and cause significant price variations to occur. If the market price of the ADSs declines significantly, you may be unable to resell your ADSs at or above the public offering price, if at all. We cannot assure you that the market price of our ordinary shares or the ADSs will not fluctuate or significantly decline in the future.

Some specific factors that could negatively affect the price of the ADSs or result in fluctuations in their price and trading volume include:

- results of clinical trials of our product candidates;
- results of clinical trials of our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated fluctuations in our quarterly operating results or those of our competitors;
- publication of research reports by securities analysts about us or our competitors in the industry;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations of exchange rates between the U.S. dollar and the Australian dollar;
- additions to or departures of our key management personnel;
- issuances by us of debt or equity securities;
- litigation involving our company, including: shareholder litigation; investigations or audits by regulators into the operations of our company; or proceedings initiated by our competitors or clients;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- the passage of legislation or other regulatory developments affecting us or our industry;

- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- trading prices of our ordinary shares on the ASX;
- changes in trading volume of ADSs on the Nasdaq Capital Market and of our ordinary shares on the ASX;
- sales or perceived potential sales of the ADSs or ordinary shares by us, our directors, senior management or our shareholders in the future;
- short selling or other market manipulation activities;
- announcement or expectation of additional financing efforts;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities;
- changes in market conditions for biopharmaceutical stocks; and
- conditions in the U.S. or Australian financial markets or changes in general economic conditions.

***An active trading market for the ADSs may not develop in the United States and the trading price for our ordinary shares may fluctuate significantly.***

If an active public market in the United States for the ADSs does not develop after this offering, the market price and liquidity of the ADSs may be materially and adversely affected. While we have applied for the listing of the ADSs on the Nasdaq Capital Market, a liquid public market in the United States for the ADSs may not develop or be sustained after this offering. The initial public offering price for the ADSs will be determined by negotiation among us and the underwriters, and the price at which the ADSs are traded after this offering may decline below the initial public offering price, which means you may experience a decrease in the value of your ADSs regardless of our operating performance or prospects. In the past, following periods of volatility in the market price of a company's securities, shareholders often instituted securities class action litigation against that company. If we were involved in a class action suit, it could divert the attention of senior management and, if adversely determined, could have a material adverse effect on our results of operations and financial condition. Investors in this offering will suffer immediate and substantial dilution.

***Investors in this offering will experience immediate and substantial dilution.***

The portion of the public offering price attributable to an ordinary share will be substantially higher than the net tangible book value per share of our outstanding ordinary shares immediately after this offering. If you purchase ADSs in this offering, you will incur substantial and immediate dilution in the net tangible book value of your investment. Net tangible book value per ordinary share represents the amount of total tangible assets less total liabilities, divided by the number of ordinary shares, respectively, then outstanding. To the extent that performance rights and options that are currently outstanding are exercised or converted there will be further dilution in your investment. We may also issue additional ordinary shares, performance rights, options and other securities in the future that may result in further dilution of your ordinary shares. See "Dilution" for a calculation of the extent to which your investment will be diluted.

***An investment in our ADSs is speculative and there can be no assurance of any return on any such investment.***

An investment in our ADSs is speculative and there is no assurance that investors will obtain any return on their investment. Investors will be subject to substantial risks involved in an investment in our company, including the risk of losing their entire investment.

***The dual listing of our ordinary shares and the ADSs following this offering may adversely affect the liquidity and value of the ADSs.***

Following this offering and after the ADSs are listed on the Nasdaq Capital Market, our ordinary shares will continue to be listed on the ASX. We cannot predict the effect of this dual listing on the value of our ordinary shares and ADSs. However, the dual listing of our ordinary shares and ADSs may dilute the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for the ADSs in the United States. The price of the ADSs could also be adversely affected by trading in our ordinary shares on the ASX.

***Our issuance of additional ordinary shares in connection with financings, acquisitions, investments, or otherwise will dilute all other ADS holders.***

We expect to issue additional ordinary shares in the future that will result in dilution to all other ADS holders. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity securities to pay for any such acquisition or investment. While we will be subject to the constraints of the ASX Listing Rules regarding the percentage of our capital that we are able to issue within a 12-month period (subject to applicable exceptions), any such issuances of additional ordinary shares may cause ADS holders to experience significant dilution of their ownership interests and the per ADS value of our ADSs to decline.

***As long as we remain subject to the rules of the ASX and the Nasdaq Capital Market, we will be unable to access equity capital without shareholder approval if such equity capital sales would result in an equity issuance above regulatory thresholds and, consequently, we could be unable to obtain financing sufficient to sustain our business if we are unsuccessful in soliciting requisite shareholder approvals.***

Our ability to access equity capital is currently limited by the ASX Listing Rules. Under the ASX Listing Rules, a company must not, subject to specified exceptions, without the approval of its shareholders, issue or agree to issue, during any 12 month period, any equity securities, or other securities with rights to convert into equity, if the number of those securities exceeds 15% of the number of shares on issue at the commencement of that 12 month period (“Placement Capacity”), plus an additional 10% of such shares in certain circumstances. Further, all issues of equity securities to related parties will require prior shareholder approval. Our equity issuances will be limited by the ASX Listing Rules as long as we continue to be listed on the ASX and this constraint may prevent us from raising the full amount of equity capital needed for operations without prior shareholder approval. See “Description of share capital” for further details.

***We are subject to risks associated with currency fluctuations, and changes in foreign currency exchange rates could impact our results of operations.***

Historically, a substantial portion of our operating expenses has been denominated in U.S. dollars and our main currency requirements are Australian dollars. Approximately 38% of our cash and cash equivalents as of June 30, 2022 were denominated in U.S. dollars, 35% were denominated in Australian dollars, and 27% were denominated in Euros. Because we have multiple functional currencies across different jurisdictions, changes in the exchange rate between these currencies and the foreign currencies of the transactions recorded in our accounts could materially impact our reported results of operations and distort period-to-period comparisons. For example, a portion of our research and clinical trials are undertaken in Australia. As such, payment will be made in Australian dollar currency, and may exceed the budgeted expenditure if there are adverse currency fluctuations against the U.S. dollar. In addition, our capital raises have historically been in Australian dollars.

Further, any significant change in the value of the Australian dollar may have a material adverse effect on the value of our ADSs in U.S. dollars. More specifically, if we decide to convert our Australian dollars into U.S. dollars for any business purpose, appreciation of the U.S. dollar against the Australian dollar would have a negative effect on the U.S. dollar amount available to us. To the extent that we need to convert U.S. dollars we receive from our initial public offering into Australian dollars for our operations, appreciation of the Australian dollar against the U.S. dollar would have an adverse effect on the Australian dollar amount we would receive from the conversion. Consequently, appreciation or depreciation in the value of the Australian dollar relative to the U.S. dollar would affect our financial results reported in U.S. dollar terms without giving effect to any underlying change in our business or results of operations. As a result of such foreign currency fluctuations, it could be more difficult to detect underlying trends in our business and results of operations.

***Future sales of our ordinary shares or ADSs, or the perception that such sales may occur, could depress the price of our ADSs.***

After the completion of this offering, we expect to have \_\_\_\_\_ ordinary shares outstanding, including the shares underlying the ADSs we are selling in this offering, almost all of which may be resold in the public market immediately after this offering. We, all of our directors, our chief executive officer, our chief financial officer and \_\_\_\_\_ have signed lock-up agreements for a period of \_\_\_\_\_ days following the date of this prospectus, subject to extension in the case of an earnings release, material news, or a material event relating to us. See “Underwriting.”

The underwriters may, in their sole discretion and without notice, release all or any portion of the ordinary shares subject to lock-up agreements. As restrictions on resale end, the market price of our ADSs could drop significantly if the holders of these securities sell them or are perceived by the market as intending to sell them. These factors could also make it more difficult for us to raise additional funds through future offerings of our ordinary shares, ADSs or other securities.

***The public offering price will be determined by negotiations between us and the representatives of the underwriters and set by our board of directors and does not necessarily indicate the actual or market value of our ADSs.***

Prior to this offering, there has been no public market for our ADSs. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters and our board of directors will approve the public offering price and other terms of this offering. In determining the initial public offering price, we and the representatives of the underwriters expect to consider, among other things: the information set forth in this prospectus and otherwise available to the representative, including the current market price of our ordinary shares, trading prices of our ordinary shares over time, the volatility of our ordinary shares, and the availability of and likely cost of capital of other potential sources of capital; our prospects and the history and prospects for the industry in which we compete; an assessment of our management; our prospects for future earnings; the general condition of the securities markets at the time of this offering; the recent market prices of, and demand for, publicly traded securities of generally comparable companies; and other factors deemed relevant by the underwriters and us. The offering price is not intended to bear any relationship to the book value of our assets or our past operations, cash flows, losses, financial condition, net worth or any other established criteria used to value securities. The public offering price may not be indicative of the fair value of the ADSs or the underlying ordinary shares.

***We currently report our financial results under IFRS, which differs in certain significant respects from U.S. GAAP.***

Currently we report our financial statements under IFRS. There have been and there may in the future be certain significant differences between IFRS and U.S. GAAP, including differences related to revenue recognition, intangible assets, share-based compensation expense, income tax and earnings per share. As a result, our financial information and reported earnings for historical or future periods could be significantly different if they were prepared in accordance with U.S. GAAP. In addition, we do not intend to provide a reconciliation between IFRS and U.S. GAAP unless it is required under applicable law. As a result, you may not be able to meaningfully compare our financial statements under IFRS with those companies that prepare financial statements under U.S. GAAP.

***As a foreign private issuer, we are permitted and expect to follow certain home country corporate governance practices in lieu of certain Nasdaq Capital Market requirements applicable to domestic issuers and we are permitted to file less information with the Securities and Exchange Commission than a company that is not a foreign private issuer. This may afford less protection to holders of our ADSs.***

As a “foreign private issuer,” as defined in Rule 405 under the Securities Exchange Act of 1933, as amended, or the Securities Act, whose ADSs will be listed on the Nasdaq Capital Market, we will be permitted to, and plan to, follow certain home country corporate governance practices in lieu of certain Nasdaq Capital Market requirements. For example, we may follow home country practice with regard to certain corporate governance requirements, such as the composition of the board of directors and quorum requirements applicable to shareholders’ meetings. This difference may result in a board that is more difficult to remove and less shareholder approvals required generally. In addition, we may follow home country practice instead of the Nasdaq Capital Market requirement to hold executive sessions and to obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions or private placements of securities. The above differences may result in less shareholder oversight and requisite approvals for certain acquisition or financing related decisions. Further, we may follow home country practice instead of the Nasdaq Capital Market requirement to obtain shareholder approval prior to the establishment or amendment of certain share option, purchase or other compensation plans. This difference may result in less shareholder oversight and requisite approvals for certain company compensation related decisions. A foreign private issuer must disclose in its annual reports filed with the SEC, and the Nasdaq Capital Market, the requirements with which it does not comply followed by a description of its applicable home country practice. The Australian home country practices described above may afford less protection to holders of the ADSs than that provided under the Nasdaq Capital Market rules.

Further, as a foreign private issuer, we are exempt from certain rules under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that impose disclosure requirements as well as procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and “short-swing” profit recovery provisions of Section 16 of the Exchange Act. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as a company that files as a domestic issuer whose securities are registered under the Exchange Act, nor are we generally required to comply with the SEC’s Regulation FD, which restricts the selective disclosure of material non-public information. Accordingly, the information may not be disseminated in as timely a manner, or there may be less information publicly available concerning us generally than there is for a company that files as a domestic issuer.

*We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur additional legal, accounting and other expenses.*

In order to maintain our current status as a foreign private issuer, either (1) a majority of our ordinary shares must be either directly or indirectly owned of record by non-residents of the United States or (2) (a) a majority of our executive officers or directors must not be U.S. citizens or residents, (b) more than 50 percent of our assets cannot be located in the United States and (c) our business must be administered principally outside the United States. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC rules and Nasdaq Capital Market listing standards. Further, we would be required to comply with United States generally accepted accounting principles, as opposed to IFRS, in the preparation and issuance of our financial statements for historical and current periods. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs.

***Our securities will be traded on more than one market and this may result in price variations.***

Our ordinary shares have been traded on the ASX since 2005, and we have applied to list our ADSs on the Nasdaq Capital Market. Trading in our securities on these markets will take place in different currencies (U.S. dollars on the Nasdaq Capital Market and Australian dollars on the ASX), and at different times (resulting from different time zones, trading days and public holidays in the United States and Australia). The trading prices of our securities on these two markets may differ due to these and other factors, including the fact that ASX and Nasdaq have different criteria for trading halts as well as different listing rules and disclosure requirements. Any decrease in the price of our ordinary shares on the ASX could cause a decrease in the trading price of our ADSs on the Nasdaq Capital Market.

***We will incur significant increased costs as a result of operating as a company whose ADSs are publicly traded in the United States, and our management will be required to devote substantial time to new compliance initiatives.***

As a company whose ADSs will be publicly traded in the United States, we will incur significant legal, accounting, insurance and other expenses that we did not previously incur. In addition, the Sarbanes-Oxley Act, Dodd-Frank Wall Street Reform and Consumer Protection Act and related rules implemented by the SEC and Nasdaq Capital Market, have imposed various requirements on public companies including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives, and we will need to add additional personnel and build our internal compliance infrastructure. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. These laws and regulations could also make it more difficult and expensive for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our senior management. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of the ADSs, fines, sanctions and other regulatory action and potentially civil litigation.

***ADS holders may be subject to additional risks related to holding ADSs rather than ordinary shares.***

ADS holders do not hold ordinary shares directly and, as such, are subject to, among others, the following additional risks:

- As an ADS holder, we will not treat you as one of our shareholders and you will not be able to exercise shareholder rights, except through the American depositary receipt, or ADR, depositary as permitted by the deposit agreement.
- Distributions on the ordinary shares represented by your ADSs will be paid to the ADR depositary, and before the ADR depositary makes a distribution to you on behalf of your ADSs, any withholding taxes that must be paid will be deducted. Additionally, if the exchange rate fluctuates during a time when the ADR depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution.
- We and the ADR depositary may amend or terminate the deposit agreement without the ADS holders' consent in a manner that could prejudice ADS holders.

***You must act through the ADR depositary to exercise your voting rights and, as a result, you may be unable to exercise your voting rights on a timely basis.***

As a holder of ADSs (and not the ordinary shares underlying your ADSs), we will not directly treat you as one of our shareholders, and you will not be able to directly exercise your shareholder rights. The ADR depositary will be the holder of the ordinary shares underlying your ADSs, and ADS holders will be able to exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the deposit agreement relating to the ADSs. There are practical limitations on the ability of ADS holders to exercise their voting rights due to the additional procedural steps involved in communicating with these holders. For example, holders of our ordinary shares will receive notice of shareholders' meetings by mail or email and will be able to exercise their voting rights by either attending the shareholders meeting in person or voting by proxy. ADS holders, by comparison, will not receive notice directly from us. Instead, in accordance with the deposit agreement, we will provide notice to the ADR depositary of any such shareholders meeting and details concerning the matters to be voted upon. As soon as practicable after receiving notice from us of any such meeting, the ADR depositary will mail to holders of ADSs the notice of the meeting and a statement as to the manner in which voting instructions may be given by ADS holders. To exercise their voting rights, ADS holders must then instruct the ADR depositary as to voting the ordinary shares represented by their ADSs. Due to these procedural steps involving the ADR depositary, the process for exercising voting rights may take longer for ADS holders than for holders of ordinary shares. The ordinary shares represented by ADSs for which the ADR depositary fails to receive timely voting instructions will not be voted. Under Australian law and our Constitution, any resolution to be considered at a meeting of the shareholders shall be decided on a show of hands unless a poll is demanded by the Chair of the meeting or by a sufficient number of shareholders at or before the declaration of the result of the show of hands. Under voting by a show of hands, multiple "yes" votes by ADS holders will only count as one "yes" vote and will be negated by a single "no" vote, unless a poll is demanded.

***We may be or become classified as a passive foreign investment company, which could result in adverse U.S. federal income tax consequences to U.S. holders of our ADSs or ordinary shares.***

Based on our business projections and the anticipated composition of our income and assets for the current and future years, we do not expect that we will be a “passive foreign investment company,” or PFIC, for the taxable year ending June 30, 2023. However, if there is a change in the type or composition of our gross income, or our actual business results do not match our projections, it is possible that we may become a PFIC in future taxable years. We will be a PFIC for any taxable year if either: (i) 75% or more of our gross income for the taxable year is passive income (such as certain dividends, interest, rents or royalties and certain gains from the sale of shares and securities or commodities transactions, including amounts derived by reason of the temporary investment of funds raised in offerings of our ordinary shares or ADSs), or (ii) the average percentage value of our gross assets during the taxable year that produce passive income or are held for the production of passive income is at least 50% of the value of our total assets. For purposes of the PFIC asset test, passive assets generally include any cash, cash equivalents and cash invested in short-term, interest bearing, debt instruments or bank deposits that is readily convertible into cash. If we own at least 25% (by value) of the stock of another corporation, we will be treated, for purposes of the PFIC income and asset tests, as owning our proportionate share of the other corporation’s assets and receiving our proportionate share of the other corporation’s income. Investors should be aware that our gross income for purposes of the PFIC income test depends on the receipt of Australian research and development tax incentive credits and other revenue, and there can be no assurances that such tax incentive credit programs will not be revoked or modified, that we will continue to conduct our operations in the manner necessary to be eligible for such incentives or that we will receive other gross income that is not considered passive for purposes of the PFIC income test. The value of our assets for purposes of the PFIC asset test will generally be determined by reference to our market capitalization, which may fluctuate. The composition of our income and assets will also be affected by how, and how quickly, we spend the cash raised in this offering. Under circumstances where our gross income from activities that produce passive income significantly increases relative to our gross income from activities that produce non-passive income or where we decide not to deploy significant amounts of cash for active purposes, our risk of becoming classified as a PFIC may substantially increase. Since a separate factual determination as to whether we are or have become a PFIC must be made each year (after the close of such year), we cannot assure you that we will not be or become a PFIC in the current or any future taxable year. If we are treated as a PFIC for any taxable year, then U.S. holders generally would be subject to adverse U.S. federal income tax consequences (regardless of whether we continued to be a PFIC) unless a U.S. holder makes a “mark-to-market” election or a “Qualified Electing Fund” election. We intend to provide U.S. holders with the information necessary to make and maintain a “Qualified Electing Fund” election if we are treated as a PFIC for any taxable year. See “Taxation—Default PFIC Rules.”

***We have never declared or paid dividends on our ordinary shares, and we do not anticipate paying dividends in the foreseeable future. Therefore, you must rely on price appreciation of our ADSs for a return on your investment.***

We have never declared or paid cash dividends on our ordinary shares. For the foreseeable future, we currently intend to retain all available funds and any future earnings to support our operations and to finance the growth and development of our business. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to compliance with applicable laws and covenants under current or future credit facilities, which may restrict or limit our ability to pay dividends, and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. We do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. As a result, a return on your investment in our ADSs will likely only occur if our ADS price appreciates. There is no guarantee that our ADSs will appreciate in value after this offering or even maintain the price at which you purchase the ADSs. You may not realize a return on your investment in our ADSs and you may even lose your entire investment in our ADSs.

***Changes in foreign currency exchange rates could impact amounts you receive as a result of any dividend or distribution we declare on our ordinary shares.***

Any significant change in the value of the Australian dollar may impact amounts you receive in U.S. dollars as a result of any dividend or distribution we declare on our ordinary shares as a holder of our ADSs. More specifically, any dividends that we pay on our ordinary shares will be in Australian dollars. The depository for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses, including any such fees or expenses incurred to convert any such Australian dollars into U.S. dollars. You will receive these distributions in U.S. dollars in proportion to the number of our ordinary shares your ADSs represent. Depreciation of the U.S. dollar against the Australian dollar would have a negative effect on any such distribution payable to you.

***You may not receive distributions on our ordinary shares represented by the ADSs or any value for such distribution if it is illegal or impractical to make them available to holders of ADSs.***

While we do not anticipate paying any dividends on our ordinary shares in the foreseeable future, if such a dividend is declared, the depository for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of our ordinary shares your ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to take any other action to permit the distribution of the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that you may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have a material adverse effect on the value of your ADSs.

***Our management has discretion as to the use of the net proceeds from this offering, and such use may not produce income or increase the market price of our ADSs.***

We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents for: (i) marketing, branding, lead-generation, and sales activities relating to our existing and new products; (ii) supporting our commercial expansion, including hiring additional commercial, marketing and sales personnel; (iii) research, clinical trial, and product development expenses; (iv) inventory, fulfillment, customer care operations and facilities, (v) regulatory and market access expenses, (vi) development of digital, web, and social assets and communities; and (vii) funding working capital and other general operations and other corporate purposes. However, our management will have considerable discretion in the application of the net proceeds received by us. For more information, see “Use of Proceeds.” You will not have the opportunity, as part of your investment decision, to assess whether proceeds are being used appropriately. You must rely on the judgment of our management regarding the application of the net proceeds from this offering. The net proceeds may be used for corporate purposes that do not improve our efforts to maintain profitability or increase our ADS price. Moreover, the net proceeds from this offering may be placed in investments that do not produce income or that lose value.

***If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, the market price and trading volume of our ordinary shares and/or ADSs could decline.***

The trading market for our ordinary shares and ADSs may be influenced by the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts may discontinue research on our company, to the extent such coverage currently exists, or in other cases, may never publish research on our company. If no or too few securities or industry analysts commence coverage of our company, the trading price for our ordinary shares and ADSs would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our ordinary shares or ADSs or publish inaccurate or unfavorable research about our business, the market price of our ADSs would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our ordinary shares and/or ADSs could decrease, which might cause our price and trading volume to decline.



***You may be subject to limitations on transfers of your ADSs.***

Your ADSs are transferable on the books of the depository. However, the depository may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depository may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depository are closed, or at any time if we or the depository deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason.

***U.S. investors may have difficulty enforcing civil liabilities against our company, our directors or members of senior management and the experts named in this prospectus.***

Several of our officers, directors and the experts named in this prospectus are non-residents of the United States, and a substantial portion of the assets of such persons are located outside the United States. As a result, it may be impossible to serve process on such persons in the United States or to enforce judgments obtained in U.S. courts against them based on civil liability provisions of the securities laws of the United States. Even if you are successful in bringing such an action, there is doubt as to whether Australian courts would enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in Australia or elsewhere outside the U.S. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered and is intended to punish the defendant. The enforceability of any judgment in Australia will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and Australia do not currently have a treaty or statute providing for recognition and enforcement of the judgments of the other country (other than arbitration awards) in civil and commercial matters.

As a result, our public shareholders may have more difficulty in protecting their interests through actions against us, our management, our directors than would shareholders of a corporation incorporated in a jurisdiction in the United States.

In addition, as a company incorporated in Australia, the provisions of the Corporations Act regulate the circumstances in which shareholder derivative actions may be commenced, which may be different to the circumstances for companies incorporated in the United States.

***Australian takeover laws may discourage takeover offers being made for us or may discourage the acquisition of a significant position in our ordinary shares or ADSs.***

We are incorporated in Australia and are subject to the takeover laws of Australia. Among other things, we are subject to the Corporations Act 2001 (Cth), or the Corporations Act. Subject to a range of exceptions, the Corporations Act prohibits the acquisition of a direct or indirect interest in our issued voting shares if the acquisition of that interest will lead to a person's voting power in us increasing from 20% or below to more than 20%, or increasing from a starting point that is above 20% and below 90%. Australian takeover laws may discourage takeover offers being made for us or may discourage the acquisition of a significant position in our ordinary shares. This may have the ancillary effect of entrenching our board of directors and may deprive or limit our shareholders' opportunity to sell their ordinary shares and may further restrict the ability of our shareholders to obtain a premium from such transactions. See "Description of Share Capital—Change of Control."

***Our Constitution and Australian laws and regulations applicable to us may adversely affect our ability to take actions that could be beneficial to our shareholders and holders of our ADSs.***

As an Australian company we are subject to different corporate requirements than a corporation organized under the laws of the United States. Our Constitution, as well as the Corporations Act and ASX Listing Rules, sets forth various rights and obligations that apply to us as an Australian company listed on the ASX and which may not apply to a U.S. corporation. These requirements may operate differently than those of many U.S. companies. You should carefully review the summary of these matters set forth under the section entitled, "Description of Share Capital" as well as our Constitution, which is included as an exhibit to this registration statement to which this prospectus forms a part, prior to investing in our securities.

***The deposit agreement for our ADSs provides that the United States District Court for the Southern District of New York will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act and our Constitution provides that certain actions may only be instituted in the courts of New South Wales, Australia, which could limit our securityholders' ability to choose the judicial forum for disputes with us or our directors, shareholders, officers, or others.***

Section 22 of the Securities Act creates concurrent jurisdiction for U.S. federal and state courts over all causes of action arising under the Securities Act. Accordingly, both U.S. state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our Constitution provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. The deposit agreement similarly provides that any legal suit, action or proceeding against or involving the depository and/or us brought by ADR holders or beneficial owners, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated thereby, including without limitation, claims under the Securities Act and Exchange Act, may only be instituted in the United States District Court for the Southern District of New York (or, except for claims under the Exchange Act, in the state courts of New York County in New York if either (i) the United States District Court for the Southern District of New York lacks subject matter jurisdiction over a particular dispute or (ii) the designation of the United States District Court for the Southern District of New York as the exclusive forum for any particular dispute is, or becomes, invalid, illegal or unenforceable). Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to the foregoing provisions.

Further, our Constitution provides that, unless we consent in writing to the selection of an alternative forum, the Courts of New South Wales, Australia, will, to the fullest extent permitted by law, be the sole and exclusive form for (i) any derivative action or proceeding brought on our behalf, (ii) any action, including any action commenced by a shareholder in its own name or on our behalf, asserting a claim of breach of any fiduciary or other duty owed by any of our directors, officers or other employees (including duties arising under the Corporations Act), or (iii) any action arising out of or in connection with the Constitution or otherwise in any way relating to the constitution or our conduct.

Although we believe these exclusive forum provisions benefit us by providing increased consistency in the application of U.S. federal securities laws and the laws of Australia in the types of lawsuits to which they apply, these provisions may limit a shareholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or any of our directors, shareholders, officers, or others, or may increase the cost of doing so, both of which may discourage lawsuits with respect to such claims. Our shareholders will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder as a result of our exclusive forum provision. Further, in the event a court finds the exclusive forum provisions contained in our Constitution or the deposit agreement to be unenforceable or inapplicable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our results of operations.

***Anti-takeover provisions in our Constitution and our right to issue preference shares could make a third-party acquisition of us difficult.***

Some provisions of our Constitution may discourage, delay or prevent a change in control of our company or management that shareholders may consider favorable, including provisions that only require certain of our board of directors to be elected annually and, subject to the Corporations Act and the ASX Listing Rules, authorize our board of directors to issue an unlimited number of ordinary shares and preference shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preference shares as set out in the Constitution or as approved by special resolution of shareholders. See "Our Constitution."

***We are subject to the laws of Australia, which differ in certain material respects from the laws of the United States.***

As an Australia-incorporated company, we are required to comply with the laws of Australia, certain of which are capable of extra-territorial application, as well as our Constitution. In addition, as a company listed on the ASX, we are required to comply with the requirements of ASX and the ASX Listing Rules. The application of Australian laws and regulations, and the actions and regulatory policies of ASIC as our primary corporate regulator, may in certain circumstances impose more stringent requirements on us, our shareholders, directors or officers than would otherwise be applicable to a U.S.-incorporated company listed on the Nasdaq Capital Market, and this may hinder our ability to raise capital or undertake certain other corporate actions compared with a U.S.-incorporated company.

Additionally, the corporate laws of Australia and of the United States differ in certain significant respects. As a result, the rights of our shareholders and the obligations of our directors and officers under Australian law are different from those applicable to a U.S.-incorporated company in several material respects, and our shareholders may have more difficulty and less clarity in protecting their interests in connection with actions taken by our management, members of our board of directors or our significant shareholders than would otherwise apply to a U.S.-incorporated company.

See also “*Our Constitution and Australian laws and regulations applicable to us may adversely affect our ability to take actions that could be beneficial to our shareholders and holders of our ADSs.*” “*Australian takeover laws may discourage takeover offers being made for us or may discourage the acquisition of a significant position in our ordinary shares or ADSs*” and “*As a foreign private issuer, we are permitted and expect to follow certain home country corporate governance practices in lieu of certain Nasdaq Capital Market requirements applicable to domestic issuers and we are permitted to file less information with the Securities and Exchange Commission than a company that is not a foreign private issuer. This may afford less protection to holders of our ADSs.*”

***ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable results to the plaintiff(s) in any such action.***

The deposit agreement governing our ADSs provides that owners and holders of ADSs irrevocably waive the right to a trial by jury in any legal proceeding arising out of, based on or relating in any way to the ordinary shares or other deposited securities, the ADSs or the ADRs, the deposit agreement or any transaction contemplated therein, including claims under U.S. federal securities laws, against us or the depository to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. Although we are not aware of a specific federal decision that addresses the enforceability of a jury trial waiver in the context of U.S. federal securities laws, it is our understanding that jury trial waivers are generally enforceable. Moreover, insofar as the deposit agreement is governed by the laws of the State of New York, New York laws similarly recognize the validity of jury trial waivers in appropriate circumstances. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this is the case with respect to the deposit agreement and the ADSs.

In addition, New York courts will not enforce a jury trial waiver provision in order to bar a viable setoff or counterclaim of fraud or one which is based upon a creditor’s negligence in failing to liquidate collateral upon a guarantor’s demand, or in the case of an intentional tort claim (as opposed to a contract dispute). No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depository of compliance with any provision of U.S. federal securities laws and the rules and regulations promulgated thereunder.

If any owner or holder of our ADSs brings a claim against us or the depository in connection with matters arising under the deposit agreement or the ADSs, including claims under U.S. federal securities laws, such owner or holder may not be entitled to a jury trial with respect to such claims, which may have the effect of discouraging claims or limiting shareholders’ ability to bring a claim against us or the depository in a judicial forum that they find favorable. If a lawsuit is brought against us or the depository under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different results than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing. Such a waiver also may result in risks to shareholders such as increased costs to bring a claim, limited access to information, and other imbalances of resources between the Company and shareholders.

#### ***Potential for laws and regulations to change***

We are required to comply with a range of laws and regulations in Australia, the United States and in other foreign jurisdictions in which we operate and from which we source our products. These laws and regulations include product safety standards, fair trading and consumer protection, public health, employment, customs and tariff and tax laws. Compliance with these laws and regulations, and our ability to comply with any changes to these laws and regulations, is critical to the success of our business. Any failure to comply with existing or new laws and regulations may result in a fine or penalty, loss of accreditation and brand damage, any of which could have a material and adverse effect on our operations, performance and reputation.

Additionally, any material adverse changes in government policies or legislation of Australia, the United States or any other country that we have an economic interest in may affect the viability and profitability of CardieX.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Words such as, but not limited to, “believe,” “expect,” “anticipate,” “estimate,” “intend,” “plan,” “targets,” “likely,” “will,” “would,” “could,” and similar expressions or phrases identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and future events and financial trends that we believe may affect our financial condition, results of operation, business strategy and financial needs. Forward-looking statements include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and future clinical trials;
- our expectations about the timing or likelihood of achieving regulatory authorization of our product candidates, including the 510(k) clearance of the CONNEQT Band;
- our reliance on the success of our SphygmoCor and other technology;
- preliminary financial information relating to completed fiscal year ended June 30, 2023;
- our belief that our clinical trial pipeline is strong, which, combined with the upcoming launch of the CONNEQT Pulse, gives us confidence that strong revenue growth will be achieved through FY24 and FY25;
- our expectation that the global clinical trials, academic clinical research, and patient care global business segments will be a significant revenue generator for us going forward;
- our expectation that the CONNEQT Band and CONNEQT Pulse will comply with CPT codes and be reimbursable;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our products;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- the market opportunity and competitive landscape for our product candidates, including our estimates of the number of patients who suffer from the conditions we are targeting;
- our ability to maintain, expand, protect and enforce our intellectual property portfolio;
- our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of third parties;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- business disruptions affecting the initiation, patient enrollment, development and operation of our clinical trials, including as a result of a public health emergency, such as the global outbreak of the COVID-19 pandemic;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our expectation of anticipated sales of our products and product candidates;
- the rate and degree of market acceptance of our products;
- regulatory developments in the United States, Australia and other jurisdictions;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the success of competing products that are or may become available;

- our anticipated growth and expansion of operations;
- our ability to attract and retain key scientific or management personnel;
- our financial performance;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- our expectations regarding the period during which we will qualify as a foreign private issuer and be exempt from a number of rules under the U.S. securities laws and Nasdaq Capital Market corporate governance rules and permitted to file less information with the SEC than U.S. companies;
- our use of the proceeds from this offering;
- cyber security risks and any failure to maintain the confidentiality, integrity and availability of our computer hardware, software and internet applications and related tools and functions;
- the future trading price of the ADSs and impact of securities analysts' reports on these prices; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

You should read thoroughly this prospectus and the documents that we refer to herein with the understanding that our actual future results may be materially different from and/or worse than what we expect. We qualify all of our forward-looking statements by these cautionary statements. Other sections of this prospectus include additional factors which could adversely impact our business and financial performance. Moreover, we operate in an evolving environment. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. The forward-looking statements made in this prospectus relate only to events or information as of the date on which the statements are made in this prospectus. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

## USE OF PROCEEDS

Assuming we sell all ADSs offered pursuant to this prospectus, we anticipate that the net proceeds from this offering will be approximately US\$ [redacted], or approximately US\$ [redacted] if the underwriters exercise their option to purchase additional ADSs in full, at an assumed initial public offering price of US\$ [redacted] per ADS, the U.S. dollar equivalent of the last reported sale price of our ordinary shares on the ASX on [redacted], 2023, after giving effect to the Australian dollar/U.S. dollar exchange rate of [redacted] as of [redacted], 2023, and an ADS-to-ordinary share ratio of [redacted]-to-1, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. A US\$1.00 increase (decrease) in the assumed initial public offering price of US\$ [redacted] per ADS would increase (decrease) the net proceeds of this offering by US\$ [redacted] million, after deducting underwriting discounts and commissions.

The principal purposes of this offering are to increase our financial flexibility, create a U.S. public market for our ADSs in addition to our existing Australian public market thereby enhancing our access to public equity markets. We anticipate that the proceeds received from the offering will fund eighteen months of business operation, enabling us to scale our current business operations in the U.S. to support the launch of our CONNEQT Products into target markets. We currently intend to use the net proceeds from this offering, together with our existing cash resources, toward the following activities in their order of importance:

- approximately US\$ [redacted] million for device manufacturing, marketing, and sales activities necessary to commercialize the CONNEQT Pulse in patient monitoring and clinical trials markets;
- approximately US\$ [redacted] million for device manufacturing, marketing, and sales activities necessary to commercialize the CONNEQT Band in the health wearable market;
- approximately US\$ [redacted] million to support our commercial expansion, including scaling of our supply chain, order-fulfilment, and customer care operations in support of our business growth;
- approximately US\$ [redacted] million for market access initiatives (regulatory clearance and outcomes research) in support of our commercialization efforts into domestic and international geographies;
- approximately US\$ [redacted] million to research and product development expenses to iterate CONNEQT Pulse and CONNEQT Band features and capabilities to further strengthen capabilities of our solutions; and
- the remainder to fund working capital and other general operations and other corporate purposes.

In the event that the net proceeds from this offering are inadequate to fully fund the aforementioned activities as described above, we will prioritize the use of available funds towards sales and marketing, inventory, and general operations of the CONNEQT business in a manner that will enable us to reach profitability in a capital efficient manner.

This expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions. We have not determined the exact amounts we may spend on any of the items listed above or the timing of these expenditures.

The amounts and timing of our actual use of net proceeds will vary depending on numerous factors, including:

- our capacity to attract and hire qualified personnel;
- our ability to scale the collection of clinical and scientific evidence necessary to support our product development timetable;
- changes in regulatory requirements that may lengthen the timing on the regulatory clearance of our products;
- ongoing inventory requirements based on the success of our product sales efforts;
- available cash flow from existing and new revenue sources due to our success in winning new, or expanding existing service contracts;
- changes in costs relating to product components and manufacturing;
- cost changes related to social media, advertising, lead generation, digital, and traditional marketing & distribution pricing; and
- manufacturing and supply chain delays impacting the commercial launch of our products.

As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering. We may find it necessary or advisable to use the net proceeds from this offering for other purposes, and we will have broad discretion in the application of net proceeds. Although we may use a portion of the net proceeds of this offering for the acquisition or licensing, as the case may be, of additional technologies, other assets or businesses, we have no current understandings, agreements or commitments to do so.

## PRICE RANGE OF OUR ORDINARY SHARES

The following tables present, for the periods indicated, the high and low market prices for our ordinary shares reported on the ASX under the symbol “CDX” for the periods indicated in Australian dollars and U.S. dollars. U.S. dollar per ordinary share amounts have been translated into U.S. dollars at a rate of A\$1.00 to US\$0.6905 based on the certified foreign exchange rates published by Federal Reserve Bank of New York on June 30, 2022.

Period	Price per ordinary share (A\$)		Price per ordinary share (US\$)	
	High	Low	High	Low
<b>Annual:</b>				
Fiscal Year Ended June 30, 2019	0.6700	0.2300	0.4626	0.1588
Fiscal Year Ended June 30, 2020	0.3700	0.1400	0.2555	0.0967
Fiscal Year Ended June 30, 2021	1.1500	0.2100	0.7941	0.1450
Fiscal Year Ended June 30, 2022	0.8000	0.2500	0.5524	0.1726
Fiscal Year Ended June 30, 2023	0.4450	0.1550	0.3073	0.1070
<b>Quarterly</b>				
<b>Fiscal Year ended June 30, 2019:</b>				
First quarter ended September 30, 2018	0.4700	0.2400	0.3245	0.1657
Second quarter ended December 31, 2018	0.4300	0.2800	0.2969	0.1933
Third quarter ended March 31, 2019	0.6700	0.2900	0.4626	0.2002
Fourth quarter ended June 30, 2019	0.4300	0.2300	0.2969	0.1588
<b>Fiscal Year ended June 30, 2020:</b>				
First quarter ended September 30, 2019	0.3700	0.2200	0.2555	0.1519
Second quarter ended December 31, 2019	0.3400	0.2400	0.2348	0.1657
Third quarter ended March 31, 2020	0.3100	0.1400	0.2141	0.0967
Fourth quarter ended June 30, 2020	0.2900	0.1500	0.2002	0.1036
<b>Fiscal Year ended June 30, 2021:</b>				
First quarter ended September 30, 2020	0.6800	0.2100	0.4695	0.1450
Second quarter ended December 31, 2020	0.6400	0.4100	0.4419	0.2831
Third quarter ended March 31, 2021	1.1500	0.5800	0.7941	0.4005
Fourth quarter ended June 30, 2021	1.0000	0.5500	0.6905	0.3798
<b>Fiscal Year ended June 30, 2022:</b>				
First quarter ended September 30, 2021	0.8000	0.5800	0.5524	0.4005
Second quarter ended December 31, 2021	0.7700	0.4800	0.5317	0.3314
Third quarter ended March 31, 2022	0.7200	0.3450	0.4972	0.2382
Fourth quarter ended June 30, 2022	0.6000	0.2500	0.4143	0.1726
<b>Fiscal Year ended June 30, 2023:</b>				
First quarter ended September 30, 2022	0.4450	0.2650	0.3073	0.1830
Second quarter ended December 31, 2022	0.4400	0.2700	0.3038	0.1864
Third quarter ended March 31, 2023	0.7200	0.3450	0.4972	0.2382
Fourth quarter ended June 30, 2023	0.4200	0.1550	0.2900	0.1070
<b>Most Recent Six Months:</b>				
Month ended January 31, 2023	0.4100	0.3500	0.2800	0.2400
Month ended February 28, 2023	0.3650	0.2500	0.2500	0.1700
Month ended March 31, 2023	0.2650	0.2350	0.1800	0.1600
Month ended April 30, 2023	0.4200	0.2450	0.2800	0.1600
Month ended May 31, 2023	0.3350	0.1800	0.2313	0.1243
Month ended June 30, 2023	0.2050	0.1550	0.1416	0.1070

## EXCHANGE RATE INFORMATION

The Australian dollar is convertible into U.S. dollars at freely floating rates. There are no legal restrictions on the flow of Australian dollars between Australia and the United States. Any remittances of dividends or other payments by us to persons in the United States are not and will not be subject to any exchange controls.

The table below sets forth for the periods identified the number of U.S. dollars per Australian dollar as quoted by the Federal Reserve Bank of New York. These rates are provided solely for your convenience and are not necessarily the exchange rates that we used in this prospectus or will use in the preparation of our periodic reports or any other information to be provided to you. We make no representation that any Australian dollar or U.S. dollar amounts could have been, or could be, converted into U.S. dollars or Australian dollars, as the case may be, at any particular rate, the rates stated below, or at all. For information on the effect of currency fluctuations on our results, see "Management's Discussion and Analysis of Financial Condition and Results of Operations."

<b>Period</b>	<b>Period end</b>	<b>Average (1)</b>	<b>High</b>	<b>Low</b>
<b>Year Ended:</b>				
June 30, 2020	0.6893	0.6711	0.7043	0.5755
June 30, 2021	0.7496	0.7472	0.7953	0.6917
June 30, 2022	0.6905	0.7256	0.7598	0.6852
June 30, 2023	0.6663	0.6731	0.7119	0.6219
<b>Month Ended:</b>				
Month ended January 31, 2023	0.7050	0.6955	0.7102	0.6730
Month ended February 28, 2023	0.6744	0.6893	0.7084	0.6730
Month ended March 31, 2023	0.6704	0.6676	0.6768	0.6600
Month ended April 30, 2023	0.6617	0.6688	0.6784	0.6614
Month ended May 31, 2023	0.6473	0.6643	0.6792	0.6473
Month ended June 30, 2023	0.6663	0.6713	0.6871	0.6577
<b>Fiscal Year Ended June 30, 2023:</b>				
First quarter ended September 30, 2022	0.6437	0.6833	0.7119	0.6437
Second quarter ended December 31, 2022	0.6805	0.6574	0.6869	0.6219
Third quarter ended March 31, 2023	0.6704	0.6833	0.7102	0.6600
Fourth quarter ended June 30, 2023	0.6663	0.6681	0.6871	0.6473

- (1) For the fiscal years, determined by averaging daily closing exchange rate. Monthly and interim period averages are calculated using the average of the daily rates during the relevant period.



## DIVIDENDS AND DIVIDEND POLICY

Since our inception, we have not declared or paid any dividends on our shares. We intend to retain any earnings for use in our business and do not currently intend to pay cash dividends on our ordinary shares. Dividends, if any, on our outstanding ordinary shares will be declared by and subject to the discretion of our board of directors, and subject to Australian law.

Any dividend we declare on our ordinary shares will be paid in Australian dollars. Any dividend we declare will also be paid to the holders of ADSs, subject to the terms of the deposit agreement, to the same extent as holders of our ordinary shares, to the extent permitted by applicable law and regulations, less the fees and expenses payable under the deposit agreement, including any fees or expenses incurred to convert any such Australian dollars into U.S. dollars. Any dividend we declare will be distributed by the depositary bank to the holders of our ADSs. Cash dividends on our ordinary shares, if any, will be paid in Australian dollars. See "Description of American Depositary Shares."

## CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2022:

- on an actual basis; and
- on an as adjusted basis, giving effect to the sale by us of \_\_\_\_\_ ADSs in this offering at an assumed initial public offering price of US\$ \_\_\_\_\_ per ADS, the U.S. dollar equivalent of the last reported sale price of our ordinary shares on the ASX on \_\_\_\_\_, 2023, after giving effect to the Australian dollar/U.S. dollar exchange rate of \_\_\_\_\_ as of \_\_\_\_\_, 2023 and an ADS-to-ordinary share ratio of \_\_\_\_\_-to-1, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, and, after deducting the estimated underwriting discounts and commissions and estimated offering expenses.

You should read this table in conjunction with our consolidated financial statements and the related notes thereto included elsewhere in this prospectus and the information under "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of December 31, 2022	
	Actual	As adjusted (1)
	US\$	US\$
	(in thousands)	
	(unaudited)	
Cash and cash equivalents	1,682	
Borrowings - current	1,475	
Shareholder's Equity:		
Ordinary shares, no par value, no authorization limit, and 129,984,144 shares issued and outstanding as of December 31, 2022	49,463	
Reserves	6,974	
Accumulated losses	(53,433)	
Total Shareholder's Equity	3,004	
Total Capitalization	4,479	

- (1) A US\$1.00 increase (decrease) in the assumed initial public offering price of US\$ \_\_\_\_\_ per ADS would increase (decrease) total cash and cash equivalents, equity and total capitalization by US\$ \_\_\_\_\_ million, assuming the number of ADSs offered by us as set forth on the cover page of this prospectus remains the same, and after deducting the estimated underwriting discounts and commissions payable by us and assuming no exercise of the underwriters' option to purchase additional ADSs. The pro forma as adjusted information discussed above is illustrative only. Our capitalization following the completion of this offering is subject to adjustment based on the actual initial public offering price and other terms of this offering determined at pricing.

The table above excludes the following:

- the exercise of outstanding employee options under our Performance Rights and Option Plan outstanding at December 31, 2022 to purchase 7,280,000 ordinary shares issuable upon at a weighted average exercise price of A\$0.68 per ordinary share.
- the exercise of outstanding options outstanding at December 31, 2022 to purchase 7,605,492 ordinary shares issuable upon at a weighted average exercise price of A\$0.48 per ordinary share.
- the vesting of outstanding performance rights under our Performance Rights and Option Plan outstanding at December 31, 2022 that will convert into 22,800,000 ordinary shares subject to the satisfaction of certain vesting conditions.

Except as otherwise noted, all information in this prospectus reflects and assumes (i) no exercise of outstanding options issued under our Performance Rights and Option Plan and (ii) no exercise of the underwriters' option to purchase additional ADSs.

## DILUTION

If you invest in the ADSs in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per ADS and the as-adjusted net tangible book value per ADS after this offering. Dilution results from the fact that the initial public offering price per ADS is substantially in excess of the net tangible book value per ordinary shares underlying the ADSs.

As of December 31, 2022, our net tangible book value was US\$0.02 per ordinary share equivalent to US\$ per ADS. Net tangible book value per ordinary share represents total tangible assets minus total liabilities divided by the total number of ordinary shares outstanding. Dilution is determined by subtracting net tangible book value per ordinary share from the assumed public offering price per ordinary share.

Without taking into account any other changes in net tangible book value after December 31, 2022, other than giving effect to our sale of ADSs in the offering at an assumed initial public offering price of US\$ per ADS, the U.S. dollar equivalent of the closing price of our ordinary shares on the ASX of A\$ on 2023 (based on an assumed exchange rate of A\$1.00 to US\$ ) and after deducting underwriting discounts and commissions and estimated expenses of the offering payable by us, but without taking into account any other changes in such net tangible book value after December 31, 2022, the net tangible book value per ordinary share would increase to US\$ per ordinary share (or US\$ per ADS), or US\$ per ordinary share (or US\$ per ADS) if the underwriters' over-allotment option is exercised in full. This represents an immediate increase in net tangible book value of US\$ per ordinary share (or US\$ per ADS) to our existing shareholders (or US\$ per ordinary share (or US\$ per ADS) if the underwriters' over-allotment option is exercised in full), and an immediate dilution of US\$ per ordinary share (or US\$ per ADS) to purchasers of ADS in the offering (or US\$ per ordinary share (or US\$ per ADS), if the underwriters' over-allotment option is exercised in full).

The following table illustrates this dilution on a per ordinary share basis and a per ADS basis assuming that all ADSs are exchanged for ordinary shares:

	Per ordinary share	Per ADS
Assumed initial public offering price per ADS		
Historical net tangible book value per ADS as of December 31, 2022		
Increase in as-adjusted net tangible value per ADS attributable to this offering		
Pro forma net tangible book value per ADS after this offering		
Dilution per ADS to investors in this offering		

A US\$1.00 increase (decrease) in the assumed initial public offering price of US\$ per ADS would increase (decrease) our pro forma net tangible book value after giving effect to the offering by US\$ per ordinary share and US\$ per ADS, respectively, and the dilution in pro forma net tangible book value per ordinary share and per ADS to new investors in this offering by US\$ per ordinary share and US\$ per ADS, respectively, assuming no change to the number of ADSs offered by us as set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions.

The following table summarizes, on a pro forma basis as of December 31, 2022, the differences between our existing shareholders as of such date and the new investors with respect to the number of ordinary shares purchased from us, the total consideration paid and the average price per ordinary shares paid at an assumed initial public offering price of US\$ per ADS (the U.S. dollar equivalent of the closing price of our ordinary shares on the ASX on , 2023) before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The information discussed above is illustrative only. Our net tangible book value following the completion of this offering is subject to adjustment based on the actual initial public offering price of the ADSs and other terms of this offering determined at pricing.

	Ordinary shares purchased		Total consideration		Average price per share	Average price per ADS
	Number	Percent	Amount	Percent		
(in millions, except percent and per share data)						
Existing shareholders		%	US\$		%	
Purchasers of ordinary shares						
Total		100.0%			100.0%	

A US\$1.00 increase (decrease) in the assumed initial public offering price of US\$      per ADS would increase (decrease) total consideration paid by new investors, total consideration paid by all shareholders and the average price per ADS paid by all shareholders by US\$      million, and US\$      , respectively, assuming no change in the number of ADSs sold by us as set forth on the cover page of this prospectus and without deducting underwriting discounts and commissions.

The number of ordinary shares to be outstanding following the offering is based on 129,984,144 ordinary shares outstanding at December 31, 2022, and excludes:

- the exercise of outstanding employee options under our Performance Rights and Option Plan outstanding at December 31, 2022 to purchase 7,280,000 ordinary shares issuable upon at a weighted average exercise price of A\$0.68 per ordinary share.
- the exercise of outstanding options outstanding at December 31, 2022 to purchase 7,605,492 ordinary shares issuable upon at a weighted average exercise price of A\$0.48 per ordinary share.
- the vesting of outstanding performance rights under our Performance Rights and Option Plan outstanding at December 31, 2022 that will convert into 22,800,000 ordinary shares subject to the satisfaction of certain vesting conditions.

Except as otherwise noted, all information in this prospectus reflects and assumes (i) no exercise of outstanding options issued under our Performances Rights and Option Plan and (ii) no exercise of the underwriters' option to purchase additional ADSs.

To the extent all options outstanding at December 31, 2022 are exercised, the number of ordinary shares to be outstanding immediately following the offering would increase to      and the total consideration would increase to US\$      . Our existing shareholders would hold      ordinary shares or      % of the number of ordinary shares outstanding immediately following the offering for which they paid US\$      or      % of the total consideration. The purchasers of ADSs in the offering would hold % of the number of ordinary shares outstanding immediately following the offering and would experience immediate dilution in net tangible book value of US\$      per ordinary share (or US\$      per ADS). In addition, we may in the future elect to raise additional capital as a result of favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the issuance of such securities could result in further dilution to our shareholders. See "Risk factors—Risks Related to Ownership of Our ADSs, Our Trading Market and This Offering—Our issuance of additional ordinary shares in connection with financings, acquisitions, investments, or otherwise will dilute all other ADS holders."

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements included elsewhere in this prospectus. We present our consolidated financial statements in U.S. Dollars and in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB.*

*The statements in this discussion regarding industry outlook, our expectations regarding our future performance, liquidity and capital resources and other non-historical statements are forward-looking statements. These forward-looking statements are subject to numerous risks and uncertainties, including, but not limited to, the risks and uncertainties described in "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in this prospectus. Our actual results may differ materially from those contained in or implied by any forward-looking statements.*

*Our fiscal year ends each year on June 30. Reference to a year relates to the fiscal year, ended in June 30 of the year indicated, rather than the calendar year, unless indicated by a specific date. References to "we," "us" and "our" refer to Cardiac Limited and its consolidated subsidiaries.*

### Overview

We are a commercial-stage digital healthcare company using our medical devices to redefine the way hypertension, cardiovascular disease (CVD), and other major vascular diseases are clinically diagnosed and managed. Our SphygmoCor XCEL is a vital signs and vascular biometric monitoring device that offers non-invasive assessment of the central aortic pressure waveform, including both pressures and indices of arterial stiffness, providing noninvasive measurement of arterial pressure that the heart, brain, and kidneys actually experience.

Our pioneering SphygmoCor vascular biosensing technology uses novel sensors that have been clinically validated and FDA cleared to collect digital vascular biomarkers. These biomarkers represent key indicators of vascular health including, but not limited to, central blood pressures (cBP), vascular stiffness, vascular age, and heart stress. SphygmoCor technology has been deployed in multiple clinical trials sponsored by pharmaceutical companies and healthcare systems to measure arterial health. When combined with cloud-based data analytics, we believe that our patient-friendly desktop and wearable devices built using our SphygmoCor technology enable key stakeholders throughout the healthcare ecosystem to obtain valuable health information from our digital vascular biomarkers not available from standard blood pressure devices. We believe that our consumer-facing solutions are creating a new paradigm in the diagnosis of vascular disease that is well aligned with the evolution of the healthcare industry as delivery of services becomes increasingly decentralized, patient-managed and consumer-oriented.

Our vision is to be the leading provider of home, wearable, healthcare, clinical trial, and remote patient monitoring solutions for common health disorders related to high blood pressure including hypertension, CVD, Alzheimer's disease, chronic kidney disease (CKD), and other major vascular health conditions. Our two subsidiaries, ATCOR Medical (ATCOR) and CONNEQT Health (CONNEQT), are focused on separate, but complementary, sectors of our target healthcare market. ATCOR established the SphygmoCor technology and continues to focus on servicing specialist health care providers, on-site clinical trials, research programs, and hospital networks with a variety of proprietary vascular biomarker solutions, such as our SphygmoCor XCEL system and the SunTech Oscar 2™ Ambulatory Blood Pressure Monitor with "SphygmoCor Inside". Launched in 2021, our CONNEQT business will introduce a suite of new devices and digital solutions strategically targeted to direct-to-consumer health, general health care providers, remote patient monitoring, decentralized clinical trials, and home health. We have no history of generating revenue with our CONNEQT Products. Our CONNEQT Pulse received FDA clearance in April 2023 and our CONNEQT Band is targeted for FDA clearance in the first quarter of calendar year 2024. There is no guarantee that the FDA will grant clearance to the CONNEQT Band or that it will do so on the timeline currently indicated.

Our first two products under the CONNEQT brand are our CONNEQT Pulse and CONNEQT Band (together, our "CONNEQT Products"). Our CONNEQT Products incorporate our SphygmoCor vascular biosensing technology to obtain biomarkers representing vascular health. The CONNEQT Pulse is a vascular biometric monitor we co-developed with blood pressure manufacturer Andon Health Co. Ltd. ("Andon"). It offers dual blood pressure (central and brachial) and other advanced measures of vascular health not available with traditional blood pressure monitors. The CONNEQT Band is a "medical grade" wearable device (as proposed to be designated by the FDA through its clearance process) we are co-developing with LifeQ B.V. ("LifeQ"), a developer of general health biometrics, and Shenzhen Fenda Smart Technology Limited ("Fenda"), a contract manufacturer for wearables. It captures vascular health data in patients as well as to provide general health insights to consumers using a wristband form factor. See "Business – Manufacturing, Supply and Operations" for a more detailed discussion of our relationships with LifeQ and Fenda and related agreements. We anticipate that the CONNEQT Pulse will be commercialized in the second half of 2023, having recently received FDA 510(k) clearance from the FDA in April 2023. The CONNEQT Band wearable is targeted for commercialization in the second calendar quarter of 2024, subject to obtaining 510(k) clearance from the FDA.

We incurred net losses of US\$8.6 million and US\$3.9 million for FY2022 and FY2021, respectively. As of June 30, 2022, we had accumulated losses of US\$47.2 million. We incurred net losses of US\$6.0 million and US\$3.1 million for HY2023 and HY2022, respectively. As of December 31, 2022, we had accumulated losses of US\$53.4 million.

For FY2022, we generated total revenues and other income of US\$4.0 million. For FY2021, we generated total revenues and other income of US\$4.6 million. For HY2023, we generated total revenues and other income of US\$1.3 million. For HY2022, we generated total revenues and other income of US\$2.1 million.

## **Recent Developments**

In June 2023, we commenced an offering to offshore investors of convertible notes (“Notes”) pursuant to a convertible note facility (“Note Facility”). We are seeking to raise up to A\$4.1 million (US\$2.7 million) under the Note Facility, through the issue of up to 4,100,000 Notes. Each Note will have a face value of A\$1.00 (US\$0.66) and maturity date of July 15, 2025. Each of C2 Ventures Pty Ltd, Carnethy Evergreen Pty Ltd, and Jarrod White (or his nominee) are proposing to participate in the Note Facility. The issue of Notes to each of C2 Ventures Pty Ltd, Carnethy Evergreen Pty Ltd, and Jarrod White (or his nominee) is subject to shareholder approval, which is to be sought at the next general meeting of shareholders of the Company.

## **Financial Overview**

We have incurred significant losses since our inception. We anticipate that we may continue to incur significant losses for the foreseeable future. There can be no assurance that we will ever achieve or maintain profitability. We currently generate sales revenues from the sales of our products, but as these do not currently support the operational expenses of the company, we cannot provide assurance that we will ever be profitable.

We expect our future capital requirements will continue as we:

- expand our sales, branding, marketing, clinical validation, and research and development efforts in connection with the launch of the CONNEQT Pulse and CONNEQT Band products;
- seek to identify, assess, acquire, and/or develop other product candidates and technologies;
- seek regulatory and marketing approvals in multiple jurisdictions for our product candidates that successfully complete clinical studies;
- establish collaborations with third parties for the further development and commercialization of our products;
- seek to maintain, protect and expand our intellectual property portfolio; and
- seek to attract and retain skilled personnel.

We expect that our research, clinical validation, development and design, manufacturing, and marketing expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to market our products and to continue as a going concern. Looking forward, we believe our clinical trial pipeline is strong, which, combined with the upcoming launch of the CONNEQT Pulse, gives us confidence that strong revenue growth will be achieved through FY24 and FY25.

## **Revenue**

We derive revenue as follows:

### ***Sales of goods revenue***

Our sale of goods revenue was US\$1.7 million for FY2022, an increase of US\$0.1 million from US\$1.6 million for FY2021. This increase is predominantly the result of an increase in the number of sales to customers of medical devices.

Sale of goods revenue is recognized at the point of sale, which is where the customer has taken delivery of the goods, the control is transferred to the customer and there is a valid sales contract. Amounts disclosed as revenue are net of sales returns and trade discounts.

### ***Lease revenue***

Our lease revenue was US\$0.9 million for FY2022, a decrease of US\$0.7 million from US\$1.6 million for FY2021. This decrease was primarily as a result of the end of our contract for the AVANTI heart failure trial that concluded in June 2021. In FY2022, we secured additional clinical trial contracts and we believe our pipeline for clinical trial services and contracts in the ATCOR subsidiary will contribute to increased revenue in FY2023 relative to FY2022.

### ***Royalty revenue***

Our royalty revenue was US\$42,433 for FY2022, an increase of \$1,663 from FY2021. This increase was primarily as a result of increased sales from the SunTech Oscar 2<sup>TM</sup> with “SphygmoCor Inside” medical device.

### ***Other Revenue: Data Services and Maintenance Contracts Income***

Our data services and maintenance contracts were US\$287,000 for FY2022, a decrease of \$158,000 from FY2021. This decrease was primarily as a result of the end of our contract for the AVANTI heart failure trial that concluded in June 2021.

In February 2022, we announced that we had entered into a new global Clinical Trial Services Agreement (“the Andwin Agreement”) with Andwin Scientific for both the lease of ATCOR XCEL devices and the provision of data management services for a new global clinical trial sponsored by Philip Morris.

The total revenue for the Andwin Agreement is likely to be approximately US\$1,455,987 over a 19-month period with the majority having been recognized in FY2022 and FY2023. Currently, the study is for 19 months across 40 sites. Results and any extension in the length of the trial or expansion in the number of sites will be beneficial to us and will result in an increase in services and revenue.

On December 9, 2022, CardieX announced a new clinical trial agreement with Procurement Partner, Clinichain BV. Since June 30, 2022, over US\$1.25 million has been received under this contract with a further US\$860,000 in receipts currently due and outstanding.

We are currently recruiting a new senior executive for ATCOR Medical to lead our global clinical trials, academic clinical research, and patient care businesses. We believe these global business segments will be a significant revenue generator for us going forward, especially with the anticipated launch of the CONNEQT Pulse device which provides a fully decentralized clinical trial solution for our traditional pharmaceutical partners.

### ***Other revenue; Freight Income***

Our freight income was US\$68,000 for FY2022, an increase of US\$7,000 from US\$61,000 for FY2021. This increase is primarily due to an increase in global shipping costs.

### ***Interest Revenue***

Interest revenue is accrued on a time basis by reference to the principal outstanding and at the effective interest rate applicable.

### ***Other income***

Our other income was approximately US\$1.0 million for FY2022, an increase of approximately US\$0.2 million from approximately US\$0.8 million for FY2021.

Other income primarily comprises tax incentive payments from the Australian Government's Innovation Australia Research and Development Tax Incentive Plan for research and development activities conducted in Australia in relation to our qualifying research that meets the regulatory criteria. A refundable tax offset is available to eligible companies with an annual aggregate turnover of less than A\$20.0 million. Eligible companies can receive a refundable tax offset for a percentage of their research and development spending. For FY2022, the company received US\$0.5 million under this scheme, with US\$0.4 million received during FY2021.

Other income also includes unrealized foreign exchange gains on U.S dollar deposits, plus realized gains on any foreign currency payments to our suppliers. Foreign exchange gains of US\$0.2 million and nil were recorded for FY2022 and FY2021, respectively. For FY2021, the net result of foreign exchange movements was a US\$0.4 million loss, and this was recorded in other expenses.

### ***Expenses***

*Cost of Goods Sold.* Cost of goods sold is recognized as an expense as incurred in the period in which the corresponding sales revenue is recognized. Our cost of goods sold consist primarily of:

- salaries and related overhead expenses for personnel in manufacturing functions (for example wages, salaries and associated costs such as superannuation, share-based incentives and payroll taxes, plus travel costs and recruitment fees for new hires);
- costs of components required in the manufacturing process of our devices; and
- third party costs related to royalties paid.

*Research and development.* Research and development expenditure is recognized as an expense as incurred. Our research and development expenses consist primarily of:

- product support costs, which comprise primarily salaries and related overhead expenses for personnel in research and development functions (for example wages, salaries and associated costs such as superannuation, share-based incentives and payroll taxes, plus travel costs and recruitment fees for new hires);
- third party costs, which comprise all external expenditure on our research and development programs such as fees paid to contract research organizations, or CROs, and consultants who perform research on our behalf and under our direction, rent and utility costs for our research and development facilities, and database analysis fees; and
- intellectual property support costs comprise payments to our patent attorneys to progress patent applications and all costs of renewing of our granted patents.

Our research and development expenses are not charged to specific products or programs, since the number of clinical and preclinical product candidates or development projects tends to vary from period to period and since internal resources are utilized across multiple products and programs over any given period of time. As a result, our management does not maintain and evaluate research and development costs by product or program.

*Sales and marketing.* Sales and marketing expenses are recognized as an expense as incurred. Our sales and marketing costs consist primarily of:

- salaries and related overhead expenses for personnel in sales and marketing functions (for example wages, salaries and associated on costs such as superannuation, share-based incentives and payroll taxes, plus travel costs and recruitment fees for new hires); and
- third party costs for consultants who perform sales and marketing activities on our behalf and under our direction, rent costs for our global offices, and other miscellaneous costs.

*Management and administration.* Management and administration costs are recognized as an expense as incurred. Our management and administration costs consist primarily of salaries and related costs for employees in executive, corporate and administrative functions. Other significant management and administration expenses include legal and professional services, insurance and IT services.

*Stock based compensation.* Stock based compensation expenses are recognized in line with our accounting policy for stock based compensation, which can be found at Note 21 of our consolidated financial statements. Stock based compensation expenses consist of costs related to share-based incentives granted to personnel across all functions.

*Fair value loss on financial assets.* Fair value loss on financial assets comprises the fair value adjustment applied to the investment held in inHealth. Further detail with regards to this can be found at Note 22 of our consolidated financial statements.

*Finance costs.* Finance costs relate to interest payments on the convertible note held with C2 Ventures Pty Ltd., as well as interest payments on the R&D loan facility. As of December 7, 2021 all convertible notes were converted to ordinary shares.

*Other expenses.* Other expenses comprise depreciation of fixed assets and foreign exchange losses.

Other expenses comprise unrealized foreign exchange losses on our U.S. dollar deposits plus realized losses on any foreign currency payments to our suppliers. Any unrealized foreign exchange gains on our U.S. dollar deposits or realized gains on any foreign currency payments to our suppliers would be included in other income. Foreign exchange losses was nil for FY2022 compared with US\$0.4 million for FY2021. The US\$0.4 million foreign exchange losses recognized in FY2021 was due to movements in exchange rates as the A\$ appreciated against the US\$ during FY2021.

## Results of Operations

### Comparison of our results for HY2023 and HY2022

The following table summarizes our results of operations for HY2023 and HY2022, respectively, and provides information regarding the dollar and percentage increase (or decrease) during such periods.

	For the Six-Month Periods Ended		Change	
	US\$ 2022	US\$ 2021	US\$	%
	December 31,			
	(in thousands, except per share data)			
	(unaudited)			
<b>Consolidated Income Statement Data:</b>				
Revenue:				
Sales revenue	486	682	(196)	(29)%
Lease revenue	202	580	(378)	(65)%
Other revenue	203	269	(66)	(25)%
Revenue	891	1,531	(640)	(42)%
Other income:				
Research & development tax incentive	203	223	(20)	(9)%
Foreign exchange gains	-	122	(122)	(100)%
Interest income	87	178	(91)	(51)%
Miscellaneous other income	115	4	111	NM
Other income	405	527	(122)	(23)%
Total revenue and other income	1,296	2,058	(692)	(34)%
Expenses:				
Cost of goods sold	(224)	(381)	157	(41)%
Research and development	(1,735)	(1,312)	(423)	32%
Sales and marketing	(895)	(1,202)	307	(26)%
Management and administration	(3,512)	(1,900)	(1,612)	85%
Stock based compensation	(609)	(806)	197	39%
Fair value gain/(loss) on financial assets	67	(1,011)	1,078	(107)%
Finance costs	(87)	(104)	17	(16)%
Other expenses	(189)	(88)	(101)	115%
Total expenses	(7,184)	(6,804)	(380)	6%
Loss before income tax	(5,888)	(4,746)	(1,142)	24%
Income tax expense	-	-	-	NM
Other comprehensive income for the period, net of tax – Exchange differences on translation to the presentation currency	(156)	(199)	(43)	(22)%
Loss attributable to the owners of CardieX Limited.	(6,044)	(4,945)	(1,099)	22%
<b>Loss per share attributable to the ordinary equity holders of CardieX Limited:</b>				
Basic – losses per share	(0.05)	(0.05)		
Diluted – losses per share	(0.05)	(0.05)		

\*NM = not meaningful

### Revenues

Revenues were US\$0.9 million for HY2023 compared to US\$1.5 million for HY2022, a decrease of US\$0.6 million. The following table shows movement within revenue for HY2023 and HY2022, together with the changes in those items:

	For the Six-Month Periods Ended		Change	
	US\$2022	US\$2021	US\$	%
	December 31,			
	(in thousands)			
	(unaudited)			
<b>Revenue:</b>				
Sale of goods revenue	486	682	(196)	(29)%
Lease revenue	202	580	(378)	(65)%
Other revenue	203	269	(66)	(25)%
<b>Revenue</b>	891	1,531	(640)	(42)%

The US\$0.2 million decrease in sale of goods revenue for HY2023 compared to HY2022 is due to decreased sales of medical devices to customers, which was primarily due to a timing of shipment dates.

The US\$0.4 million decrease in lease revenue for HY2023 compared to HY2022 was due to the end of our contract for two major clinical trials that concluded in December 2021.

The US\$0.1 million decrease in other revenue for HY2023 compared to HY2022 is primarily due to the decrease in lease revenue, as the largest component of other revenue is for servicing the leased devices.



### Other Income

Other income was US\$0.4 million for HY2023, compared to US\$0.5 million for HY2022. The following table shows movement within other income, together with the changes in those items:

	For the Six-Month Periods Ended December 31,		Change	
	US\$2022	US\$2021	US\$	%
	(in thousands) (unaudited)			
<b>Other income:</b>				
Research and development tax incentive scheme	203	223	(20)	(9)%
Foreign exchange gains	-	122	(122)	(100)%
Interest income	87	178	(91)	(51)%
Miscellaneous other income	115	4	111	NM
<b>Other income</b>	<b>405</b>	<b>527</b>	<b>(122)</b>	<b>(23)%</b>

NM = not meaningful

Research and development tax incentive income increased by a negligible amount when comparing HY2023 and HY2022. We have recognized incentive income pertaining to the eligible expenditure undertaken in each of these periods. At each period end management estimates the refundable tax offset available to us based on available information at the time. This estimate is also reviewed by external tax advisors.

US\$0.1 million of foreign exchange gains were recognized for HY2022 compared to nil for HY2023. For HY2022 we recognized a foreign exchange gain due to movements in exchange rates as the A\$ depreciated against the US\$ during that period. Within our Australian company, we hold certain cash and term deposit balances in US\$, resulting in foreign exchange gains on the revaluation of foreign currency denominated monetary assets and liabilities into our functional currency of A\$. For the six-month period ended HY2023 the net result of foreign exchange movements was a US\$0.1 million loss, and this loss was recorded in other expenses.

The US\$0.1 million decrease in interest revenue is due to a temporary increase in the interest rate charged on the inHealth convertible notes from 6% to 12% for the period of July 1, 2021 through February 28, 2022.

Miscellaneous other income increased by US\$0.1 million when comparing HY2023 and HY2022. This was a result of funds received on settlement of a legal dispute with a supplier.

### Cost of Goods Sold

Cost of goods sold was US\$0.2 million for HY2023, compared to US\$0.4 million for HY2022. The following table shows movement within other income, together with the changes in those items:

	For the Six-Month Periods Ended December 31,		Change	
	US\$2022	US\$2021	US\$	%
	(in thousands) (unaudited)			
<b>Cost of Goods Sold expense:</b>				
Costs of manufacture	212	285	(73)	(26)%
Royalties	11	90	(79)	(99)%
Production overhead	1	6	(5)	(83)%
<b>Cost of Goods Sold</b>	<b>224</b>	<b>381</b>	<b>(157)</b>	<b>(41)%</b>

Costs of manufacture decreased by US\$0.1 million or 26% when comparing HY2023 and HY2022. This is in line with the 29% decrease seen in sale of goods revenue for the same periods.

Royalties decreased by US\$0.1 million or 99% when comparing HY2023 and HY2022. The Company is no longer paying royalties to their supplier as the product covered by this royalty is no longer in use.

Production overhead decreased by an immaterial amount.

### Research and Development Expenses

Research and development expenses were US\$1.7 million for HY2023 compared with US\$1.3 million for HY2022, an increase of US\$0.4 million.

	For the Six-Month Periods Ended		Change	
	December 31,		US\$	%
	US\$2022	US\$2021		
	(in thousands)			
<b>Research and Development expense:</b>				
Personnel costs	414	592	(178)	(30)%
Third party costs	1,068	524	544	104%
Other research and development expenditure	253	196	57	29%
<b>Research and Development</b>	<b>1,735</b>	<b>1,312</b>	<b>423</b>	<b>32%</b>

Personnel costs decreased by US\$0.2 million for HY2023. This was as a result of outsourcing a number of research and development positions to specialized consultants and contractors in order to accelerate new product development.

Third party costs increased by US\$0.6 million for HY2023. This was as a result of additional consultants and contractors hired to accelerate new product development, primarily related to the CONNEQT brand, to position us to launch multiple new products and services to the market under this brand in FY2023.

Other research and development expenditure increased by US\$0.1 million for HY2023. This increase is driven by the increase in personnel and acceleration of new product development described above.

### Sales and Marketing Expenses

Sales and Marketing expenses were US\$0.9 million for HY2023, compared with US\$1.2 million for HY2022, a decrease of US\$0.3 million.

	For the Six-Month Periods Ended		Change	
	December 31,		US\$	%
	US\$2022	US\$2021		
	(in thousands)			
<b>Sales and Marketing expense:</b>				
Personnel costs	559	651	(92)	(14)%
Marketing expenditure	220	500	(280)	(56)%
Other sales and marketing expenditure	116	51	65	127)%
<b>Sales and Marketing</b>	<b>895</b>	<b>1,202</b>	<b>(307)</b>	<b>(26)%</b>

Personnel costs decreased by US\$0.1 million for HY2023. This was as a result of small movements in various personnel costs, as opposed to a material change in headcount.

Marketing expenditure decreased by US\$0.3 million for HY2023. This was as a result of the launch of the CONNEQT brand in FY22, the marketing for which represents the majority of the cost for HY2022. The new brand is focused on devices and solutions for home health, remote patient monitoring, and decentralized clinical trials.

Other sales and marketing expenditure, comprised of travel, sales office overheads and other sales overheads, increased by US\$0.1 million in HY2023. This is a nominal amount.

### Management and Administration Expenses

Management and administration expenses were US\$3.5 million for HY2023, compared with US\$1.9 million for HY2022, an increase of US\$1.6 million.

	For Six-Month Periods Ended December 31,		Change	
	US\$2022	US\$2021	US\$	%
	(in thousands)			
<b>Management and Administration expense:</b>				
Personnel costs	2,099	1,306	793	61%
Legal & professional fees	1,200	452	748	165%
Other management and administration expenditure	213	142	71	50%
<b>Management and Administration</b>	<b>3,512</b>	<b>1,900</b>	<b>1,612</b>	<b>85%</b>

Personnel costs increased by US\$0.8 million for HY2023. This was as a result of salary increases issued to upper management and company directors, along with an increase in headcount to support the increased activities of the company.

Legal & professional fees increased by US\$0.8 million for HY2023. This is primarily related to legal fees in connection with this offering.

Other management and administration expenditure increased by US\$0.1 million in for HY2023. This is in line with the increased headcount in this department.

### Stock Based Compensation Expenses

Stock based compensation expenses were US\$0.6 million for HY2023, compared with US\$0.8 million for HY2022, a decrease of US\$0.2 million. This decrease was as a result of performance rights expiring prior to June 30, 2022.

### Fair Value Gain/(Loss) on Financial Assets

Fair value gain/(loss) on financial assets comprises the fair value adjustment applied to the investment held in inHealth. The fair value gain for HY2023 was US\$0.1 million, compared to a fair value loss of US\$1.0 million for HY2022. The fair value adjustments are calculated with reference to an external valuation prepared by a professional valuer.

### Finance Costs

Finance costs remained flat in HY2023 and HY2022.

### Other Expenses

Other expenses were US\$0.2 million for HY2023 compared with US\$0.1 million for HY2022, an increase of US\$0.1 million. Other expenses comprise depreciation of fixed assets and foreign exchange losses. The increase is due to the fact foreign exchange losses were US\$0.1 million for HY2023, compared with nil for HY2022. The US\$0.1 million foreign exchange losses recognized in HY2023 were due to movements in exchange rates as the A\$ appreciated against the US\$ during the period.

We expect that other expenses will continue to fluctuate as a result of the movement in the Australian dollar to U.S. dollar exchange rate going forward.

### Net Losses

	For the Six-Month Periods Ended December 31,		Change	
	US\$2022	US\$2021	US\$	%
	(in thousands)			
Loss before income tax	(5,888)	(4,746)	(1,142)	24%
Income tax expense	-	-	-	NM
<b>Loss after income tax</b>	<b>(5,888)</b>	<b>(4,746)</b>	<b>(1,142)</b>	<b>24%</b>

NM = not meaningful

Loss after income tax was US\$5.9 million for HY2023 compared with US\$4.7 million for HY2022, an increase of US\$1.1 million. This increase reflects the continued development of our devices, the transition to clinical trial customers during the fiscal period, and the other factors described above.

### Cash Flows

The following table sets forth the significant sources and uses of the cash for the periods set forth below:

	For the Six-Month Periods Ended December 31,	
	US\$2022	US\$2021
	(in thousands)	
<b>Cash Flow Data:</b>		
Net cash used in operating activities	(3,072)	(3,469)
Net cash used in investing activities	(31)	(103)
Net cash provided by financing activities	4,213	4,933
Net increase in cash and cash equivalents	1,110	1,361

*Cash Flows from Operating Activities.* Net cash used in operating activities was US\$3.1 million for HY2023 compared with US\$3.5 million for HY2022, a decrease of US\$0.4 million. Outflows increased by US\$1.0 million due to an increase in payments to suppliers and employees for the advancement of our product development and as a result of increase costs in connection with this listing. Inflows increased by US\$1.4 million primarily due to cash received in advance from Clinichain for contracted clinical trial payments.

*Cash Flows from Investing Activities.* Net cash used in investing activities was US\$0.03 million for HY2023 compared with US\$0.1 million for HY2022, a decrease of US\$0.07 million. This decrease is not considered meaningful.

*Cash Flows from Financing Activities.* Net cash inflows for financing activities were US\$4.2 million for HY2023 compared with US\$4.9 million for HY2022, a decrease of US\$0.7 million. US\$1.7 million of the decrease is attributable to additional proceeds from shares issued during HY2022. US\$0.5 million of borrowings were received during HY2023, compared to nil in the prior corresponding period. Repayment of borrowings decreased by US\$0.4 million during HY2023.

## **Operating Capital Requirements**

We anticipate that we will continue to incur losses for the foreseeable future. We are subject to all of the risks incident in the development of new medical devices, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Upon the completion of this offering, we expect to incur additional costs associated with operating as a U.S. public company. We anticipate that we will need substantial additional funding in connection with our continuing operations. This may cast significant doubt over the ability of the Company to continue as a going concern.

We expect that our research and development and management and administration expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing shareholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our ordinary shares. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

### ***Purchase Commitments***

As of December 31, 2022, we had an open purchase order to the value of US\$0.3 million to procure microchips.

### ***Commitments Under License and Commercial Arrangements***

As of December 31, 2022, we had US\$0.05 million due to Andon upon FDA clearance of the CONNEQT Pulse device. The payment obligations under this agreement were triggered by the FDA clearance of the CONNEQT Pulse device in April 2023. As the achievement and timing of these payments were not probable or estimable on the December 31, 2022 balance date, such amounts have not been included in our consolidated balance sheets. As of December 31, 2022, we had US\$0.2 million due to Fenda upon the achievement of certain development milestones under the Product Development and Manufacturing Agreement with Fenda. The payment obligations under this agreement are contingent upon future events. As the achievement and timing of these future payments are not probable or estimable, such amounts have not been included in our consolidated balance sheet.

### ***Mitchell Asset Management***

As of December 31, 2022, we had US\$0.9 million due to Mitchell Asset Management under the R&D Loan Facility due by December 31, 2023.

As of December 31, 2022, we had US\$0.6 million due to Mitchell Asset Management in the form of a working capital loan facility (the "Working Capital Loan Facility"). The Working Capital Loan Facility limit is A\$880,000 and has an interest rate of 16% per annum. The Working Capital Loan Facility has a minimum interest term of six months and a maturity date of October 30, 2023.

### ***Employee Liabilities***

As of December 31, 2022, we had US\$0.4 million accrued in annual leave balances for employees of the Company.

### ***Trade and Other Payables***

As of December 31, 2022, we had US\$2.7 million in trade and other payables.

There were no other significant contractual obligations at December 31, 2022.

## Results of Operations

### Comparison of Our Audited Results for FY2022 with FY2021

The following table summarizes our results of operations for FY2022 and FY2021, together with the changes in those items in dollars and as a percentage:

	<b>For the year ended June 30,</b>		<b>Dollar Change</b>	<b>% Change</b>
	<b>US\$ 2022</b>	<b>US\$ 2021</b>		
<b>(in thousands, except per share data)</b>				
<b>Consolidated Income Statement Data:</b>				
<b>Revenue:</b>				
Sales revenue	1,695	1,573	122	8%
Lease revenue	860	1,615	(755)	(47%)
Other revenue	397	547	(150)	(27%)
Revenue	<u>2,952</u>	<u>3,735</u>	<u>(783)</u>	<u>(21%)</u>
<b>Other income:</b>				
Research & development tax incentive	480	401	79	20%
JobKeeper Covid 19 stimulus	-	47	(47)	(100%)
PPP loan forgiveness	-	174	(174)	(100%)
Foreign exchange gains	215	-	215	NM
Interest income	314	192	122	64%
Miscellaneous other income	7	5	2	40%
Other income	<u>1,016</u>	<u>819</u>	<u>197</u>	<u>24%</u>
Total revenue	<u>3,968</u>	<u>4,554</u>	<u>(586)</u>	<u>(13%)</u>
<b>Expenses:</b>				
Cost of goods sold	(705)	(676)	(29)	4%
Research and development	(2,813)	(1,310)	(1,503)	115%
Sales and marketing	(2,279)	(998)	(1,281)	128%
Management and administration	(4,725)	(3,482)	(1,243)	36%
Stock based compensation	(1,459)	(1,051)	(408)	39%
Fair value loss on financial assets	(200)	(42)	(158)	376%
Finance costs	(166)	(200)	34	(17%)
Other expenses	(192)	(664)	472	(71%)
Total expenses	<u>(12,539)</u>	<u>(8,423)</u>	<u>(4,116)</u>	<u>49%</u>
Loss before income tax	<u>(8,571)</u>	<u>(3,869)</u>	<u>(4,702)</u>	<u>122%</u>
Income tax expense	<u>-</u>	<u>-</u>	<u>-</u>	<u>NM</u>
Other comprehensive income for the period, net of tax – Exchange differences on translation to the presentation currency	<u>(128)</u>	<u>751</u>	<u>(879)</u>	<u>(117)%</u>
Loss attributable to the owners of CardieX Limited.	<u>(8,699)</u>	<u>(3,118)</u>	<u>(5,581)</u>	<u>179%</u>
<b>Loss per share attributable to the ordinary equity holders of CardieX Limited:</b>				
Basic – losses per share	(0.08)	(0.04)		
Diluted – losses per share	(0.08)	(0.04)		

\*NM = not meaningful

**Revenues**

Revenues were US\$3.0 million for FY2022 compared to US\$3.7 million for FY2021, a decrease of US\$0.8 million. The following table shows movement within revenue for FY2022 and FY2021, together with the changes in those items:

	<b>For the year ended June 30,</b>		<b>Dollar Change</b>	<b>% Change</b>
	<b>US\$2022</b>	<b>US\$2021</b>		
	<b>(in thousands)</b>			
<b>Revenue:</b>				
Sale of goods revenue	1,695	1,573	122	8%
Lease revenue	860	1,615	(755)	(47%)
Other revenue	397	547	(150)	(27%)
<b>Revenue</b>	<b>2,952</b>	<b>3,735</b>	<b>(783)</b>	<b>(21%)</b>

The US\$0.1 million increase in sale of goods revenue from FY2022 to FY2021 is due to increased sales of medical devices to customers.

The US\$0.8 million decrease in lease revenue from FY2022 to FY2021 is due to the end of our contract for the AVANTI heart failure trial that concluded in June 2021.

The US\$0.2 million decrease in other revenue from FY2022 to FY2021 is primarily due to the decrease in lease revenue, as the largest component of other revenue is for servicing the leased devices.

**Other Income**

Other income was US\$1.0 million for FY2022, compared to US\$0.8 million for FY2021, an increase of US\$0.2 million. The following table shows movement within other income for FY2022 and FY2021, together with the changes in those items:

	For the year ended June 30,		Dollar Change	% Change
	US\$2022	US\$2021		
	(in thousands)			
<b>Other income:</b>				
Research and development tax incentive scheme	480	401	79	20%
JobKeeper Covid 19 stimulus	-	47	(47)	(100%)
PPP loan forgiveness	-	174	(174)	(100%)
Foreign exchange gains	215	-	215	NM
Interest revenue	314	192	122	64%
Miscellaneous other income	7	5	2	40%
<b>Other income</b>	<b>1,016</b>	<b>819</b>	<b>197</b>	<b>24%</b>

NM = not meaningful

Research & development tax incentive income increased by US\$0.1 million from US\$0.4 million for FY2021 to US\$0.5 million for FY2022. We have recognized incentive income pertaining to the eligible expenditure undertaken in each of these periods. At each period end management estimates the refundable tax offset available to us based on available information at the time. This estimate is also reviewed by external tax advisors.

JobKeeper Covid 19 stimulus income was US\$47 thousand for FY2021 compared to nil for FY2022. The income was derived from a Covid 19 stimulus package administration by the Australia Taxation Office. JobKeeper payments ceased in September 2020.

PPP loan forgiveness income was US\$0.2 million for FY2021 compared to nil for FY2022. The loan forgiveness related to the Paycheck Protection Program administered by the U.S. Small Business Administration, and was formally forgiven in full on March 30, 2021.

US\$0.2 million of foreign exchange gains were recognized for FY2022 compared to nil for FY2021. For FY2022 we recognized a foreign exchange gain due to movements in exchange rates as the A\$ depreciated against the US\$ during FY2022. Within our Australian company, we hold certain cash and term deposit balances in US\$, resulting in foreign exchange gains on the revaluation of foreign currency denominated monetary assets and liabilities into our functional currency of A\$. For FY2022 the net result of foreign exchange movements was a US\$0.4 million loss and this loss was recorded in other expenses.

The US\$0.1 million increase in interest revenue is due to a temporary increase in the interest rate charged on the inHealth convertible notes from 6% to 12% for the period of July 1, 2021 through February 28, 2022.

### Cost of Goods Sold

There has been no meaningful change in cost of goods sold expenses in FY2022 compared with FY2021. This is in line with the increase of only US\$0.1 million in the sale of goods revenue between FY2021 and FY2022.

	For the year ended June 30,		Dollar Change	% Change
	US\$2022	US\$2021		
	(in thousands)			
<b>Cost of Goods Sold expense:</b>				
Costs of manufacture	558	489	69	14%
Royalties	137	183	(46)	(25%)
Production overhead	10	4	6	150%
<b>Cost of Goods Sold</b>	<b>705</b>	<b>676</b>	<b>29</b>	<b>4%</b>

### Research and Development Expenses

Research and development expenses were US\$2.8 million for FY2022 compared with US\$1.3 million for FY2021, an increase of US\$1.5 million.

	For the year ended June 30,		Dollar Change	% Change
	US\$2022	US\$2021		
	(in thousands)			
<b>Research and Development expense:</b>				
Personnel costs	1,218	848	370	44%
Third party costs	1,074	341	733	215%
Other research and development expenditure	521	121	400	331%
<b>Research and Development</b>	<b>2,813</b>	<b>1,310</b>	<b>1,503</b>	<b>115%</b>

Personnel costs increased by US\$0.4 million in FY2022. This was as a result of an increase in headcount in the research and development department as the company worked to accelerate new product development.

Third party costs increased by US\$0.7 million in FY2022. This was as a result of additional consultants and contractors hired to accelerate new product development, primarily related to the CONNEQT brand, to position us to launch multiple new products and services to the market under this brand in FY2023.

Other research and development expenditure increased by US\$0.4 million in FY2022. This increase is driven by the increase in personnel and acceleration of new product development described above.

### Sales and Marketing Expenses

Sales and Marketing expenses were US\$2.3 million for FY2022, compared with US\$1.0 million for FY2021, an increase of US\$1.3 million.

	For the year ended June 30,		Dollar Change	% Change
	US\$2022	US\$2021		
	(in thousands)			
<b>Sales and Marketing expense:</b>				
Personnel costs	1,161	862	299	35%
Marketing expenditure	977	103	874	849%
Other sales and marketing expenditure	141	33	108	327%
<b>Sales and Marketing</b>	<b>2,279</b>	<b>998</b>	<b>1,281</b>	<b>128%</b>

Personnel costs increased by US\$0.3 million in FY2022. This was as a result of an increase in headcount in the sales and marketing departments to drive the new branding for CONNEQT during the fiscal year.



Marketing expenditure increased by US\$0.9 million in FY2022. This was as a result of the launch of the CONNEQT brand, the marketing for which represents US\$0.7 million of the increase year-on-year. The new brand is focused on devices and solutions for home health, remote patient monitoring, and decentralized clinical trials.

Other sales and marketing expenditure, comprised of travel, sales office overheads and other sales overheads, increased by US\$0.1 million in FY2022. This is a nominal amount, and is primarily due to the launch of the CONNEQT brand during FY2022.

#### **Management and Administration Expenses**

Management and administration expenses were US\$4.7 million for FY2022, compared with US\$3.5 million for FY2021, an increase of US\$1.2 million.

	<b>For the year ended June 30,</b>		<b>Dollar</b>	<b>%</b>
	<b>US\$2022</b>	<b>US\$2021</b>		
	<b>(in thousands)</b>			
<b>Management and Administration expense:</b>				
Personnel costs	3,252	2,189	1,063	49%
Legal & professional fees	1,096	1,047	49	5%
Other management and administration expenditure	377	246	131	53%
<b>Management and Administration</b>	<b>4,725</b>	<b>3,482</b>	<b>1,243</b>	<b>36%</b>

Personnel costs increased by US\$1.1 million in FY2022. This was as a result of salary increases issued to upper management and company directors, along with an increase in headcount to support the increased activities of the company.

Legal & professional fees increased by US\$0.05 million in FY2022. This is primarily related to legal fees in connection with this offering.

Other management and administration expenditure increased by US\$0.1 million in FY2022. This is in line with the increased headcount in this department.

#### **Stock Based Compensation Expenses**

Stock based compensation expenses were US\$1.5 million for FY2022 compared with US\$1.1 million for FY2021, an increase of US\$0.4 million. This increase was as a result of the increase in employees to whom options were issued between FY2021 and FY2022.

#### **Fair Value Loss on Financial Assets**

Fair value loss on financial assets comprises the fair value adjustment applied to the investment held in inHealth. The fair value loss during FY2022 was US\$0.2 million and in FY2021 was US\$0.04 million. Further detail with regards to this can be found at Note 24 of our consolidated financial statements.

#### **Finance Costs**

Finance costs were US\$0.2 million for FY2022 and US\$0.2 million for FY2021. Finance costs relate to interest payments on the convertible note held with C2 Ventures Pty Ltd. As of December 7, 2021 all convertible notes were converted to shares.

#### **Other Expenses**

Other expenses were US\$0.2 million for FY2022 compared with US\$0.7 million for FY2021, a decrease of US\$0.5 million. Other expenses comprise depreciation of fixed assets and foreign exchange losses. The decrease is due to the fact foreign exchange losses were nil for FY2022 compared with US\$0.4 million for FY2021. The US\$0.4 million foreign exchange losses recognized in FY2021 were due to movements in exchange rates as the A\$ appreciated against the US\$ during FY2021.

We expect that other expenses will continue to fluctuate as a result of the movement in the Australian dollar to U.S. dollar exchange rate going forward.

### *Net Operating Losses*

	<b>For the year ended June 30,</b>		<b>Dollar Change</b>	<b>% Change</b>
	<b>US\$2022</b>	<b>US\$2021</b>		
	<b>(in thousands)</b>			
Loss before income tax	(8,571)	(3,869)	(4,702)	122%
Income tax expense	-	-	-	NM
<b>Loss after income tax</b>	<b>(8,571)</b>	<b>(3,869)</b>	<b>(4,702)</b>	<b>122%</b>

Loss after income tax was US\$8.6 million for FY2022 compared with US\$3.9 million for FY2021, an increase of US\$4.7 million. This increase reflects the continued development of our devices, the transition to clinical trial customers during the fiscal period, and the other factors described above.

As of June 30, 2022 and 2021, our cumulative operating losses have a potential tax benefit of US\$35.2 million and US\$29.0 million at local tax rates, respectively, which may be available for use once we are in a taxable profit position. These losses were incurred in different jurisdictions and can only be offset against profits earned in the relevant jurisdiction. Further, in order to use these tax losses it is necessary to satisfy certain tests and, as a result, we cannot assure you that the tax losses will be available to offset profits if and when we earn them.

### **Liquidity and Capital Resources**

#### *Sources of Liquidity*

We have incurred losses from operations since our initial public offering on the ASX in 2005 and as of December 31, 2022, we had an accumulated deficit of US\$53.4 million (unaudited). We expect that our research and development and management and administration expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

From our inception through December 31, 2022, we have funded our operations principally with US\$49.5 million (unaudited) in proceeds received from the sale of our ordinary shares. As of December 31, 2022, we had cash and cash equivalents of US\$1.7 million (unaudited). Cash in excess of immediate requirements is invested primarily in money market funds in order to maintain liquidity and preserve capital.

Subsequent to December 31, 2022, we completed a placement of new fully paid ordinary shares raising US\$2.7 million at an issue price of US\$0.20 per share. As part of the placement there is a 1 for 2 free attaching unlisted option, exercisable at US\$0.34, expiring one year from the date of issue.

In June 2023, we commenced an offering to raise up to A\$4.1 million (US\$2.7 million) under a convertible note facility, via the issue of up to 4,100,000 convertible notes, each with a face value of A\$1.00 (US\$0.66) and maturity date of July 15, 2025, together with up to 5,950,000 free-attaching options having an exercise price of A\$0.45 (US\$0.30) per share, to sophisticated and professional investors in Australia (including both related parties and unrelated parties). Completion of the convertible note facility, and the issue of the convertible notes and options, is subject to shareholder approval, which is to be sought at the next general meeting of shareholders of the Company.

Based on our current planned operations, we expect that our current cash, cash equivalents and short-term investments will be sufficient to fund our operations for at least 12 months after the date our most recent financial statements were issued. Our ability to continue as a going concern is dependent upon our ability to successfully secure sources of financing and ultimately achieve profitable operations. We may require additional financing to fund working capital and pay our obligations. We may seek to raise any necessary additional capital through a combination of public or private equity offerings and/or debt financings. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us, if at all. If adequate funds are not available on acceptable terms when needed, we may be required to significantly reduce operating activities, which may have a material adverse effect on our business and/or results of operations and financial condition. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing shareholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Additional capital may not be available on reasonable terms, or at all.

#### **Cash Flows**

The following table sets forth the significant sources and uses of the cash for the periods set forth below:

	<b>For the Year Ended June 30,</b>	
	<b>US\$2022</b>	<b>US\$2021</b>
	(in thousands)	
<b>Cash Flow Data:</b>		
Net cash used in operating activities	(6,640)	(2,979)
Net cash (used in)/from investing activities	(317)	272
Net cash provided by financing activities	5,381	3,946
Net (decrease)/increase in cash and cash equivalents	(1,576)	1,239

*Cash Flows from Operating Activities.* Net cash used in operating activities was US\$6.6 million for FY2022 compared with US\$3.0 million for FY2021, an increase of US\$3.6 million. Outflows increased by US\$3.3 million due to an increase in payments to suppliers and employees for the advancement of our product development. Inflows decreased by US\$0.3 million due to the decline in revenues, and as such receipts from customers, during the fiscal period.

*Cash Flows from Investing Activities.* Net cash used in investing activities was US\$0.3 million for FY2022 compared with net cash from investing activities of US\$0.3 million for FY2021, a decrease of US\$0.6 million. US\$0.5 million of the decrease was due to an inflow on repayment of convertible notes in FY2021. There was no corresponding inflow in FY2022.

*Cash Flows from Financing Activities.* Net cash inflows for financing activities were US\$5.4 million for FY2022 compared with US\$3.9 million for FY2021, an increase of US\$1.5 million. US\$0.7 million of the increase is attributable to additional proceeds from shares issued during the fiscal year. US\$0.9 million of the increase is attributable to R&D loan funding received in FY2022. Repayment of borrowings increase by US\$0.4 million, and cost of debt and equity decreased by US\$0.3 million.

#### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, other than operating leases as mentioned above, as defined under SEC rules.

## Operating Capital Requirements

Although we expect our losses to reduce in the near term as we seek to convert up to US\$7.2 million of our pipeline for clinical trials to revenue, we anticipate that we will continue to incur losses for the foreseeable future. We are subject to all of the risks incident in the development of new medical devices, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Upon the completion of this offering, we expect to incur additional costs associated with operating as a U.S. public company. We anticipate that we will need substantial additional funding in connection with our continuing operations. This may cast significant doubt over our ability to continue as a going concern.

We expect that our research and development and management and administration expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing shareholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our ordinary shares. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

## Contractual Obligations and Commitments

### *Lease Commitments: Group as Lessee*

We lease various offices under non-cancellable finance leases. The leases have varying terms, escalation clauses and renewal rights. On renewal, the terms of the leases are renegotiated.

<b>(US\$ in thousands)</b>	<b>Total</b>	<b>Less than 6 months</b>	<b>6 months to 1 year</b>	<b>1 to 5 years</b>	<b>5+ years</b>
Lease payments	709	71	74	542	22
Finance charges	(176)	(32)	(28)	(116)	-
Net present values	533	39	46	426	22

Lease commitments include amounts in AUD which have been translated to U.S. dollars as of June 30, 2022 using foreign exchange rates published by The Federal Reserve Bank of the United States.

In line with IFRS 16, where a lease is identified at inception, we recognize a right-of-use asset and a lease liability at the lease commencement date. The right-of-use asset is initially measured at cost, which comprises the ignition amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and an estimate of costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, less any lease incentives received.

In addition to the obligations in the table above, as of June 30, 2022 we also had the following significant contractual obligations described below.

#### ***Purchase Commitments***

As of June 30, 2022, we had an open purchase order to the value of US\$0.3 million to procure microchips.

#### ***Commitments Under License and Commercial Arrangements***

As of June 30, 2022, we had US\$0.05 million due to Andon Health Co. Ltd. (“Andon”) upon FDA clearance of the CONNEQT Pulse device. The payment obligations under this agreement were triggered by the FDA clearance of the CONNEQT Pulse device in April 2023. As the achievement and timing of these payments were not probable or estimable on the June 30, 2022 balance date, such amounts have not been included in our consolidated balance sheet. As of June 30, 2022, we had US\$0.2 million due to Shenzhen Fenda Smart Technology Limited (“Fenda”) upon the achievement of certain development milestones under the Product Development and Manufacturing Agreement with Fenda. The payment obligations under this agreement are contingent upon future events. As the achievement and timing of these future payments are not probable or estimable, such amounts have not been included in our consolidated balance sheet.

#### ***Mitchell Asset Management***

As of June 30, 2022, we had US\$0.9 million due to Mitchell Asset Management Pty Ltd (“Mitchell Asset Management”) in the form of an R&D loan facility (the “R&D Loan Facility”), due by December 31, 2023.

#### ***Employee Liabilities***

As of June 30, 2022, we had US\$0.4 million accrued in annual leave balances for employees of the Company.

#### ***Trade and Other Payables***

As of June 30, 2022, we had US\$1.5 million in trade and other payables.

There were no other significant contractual obligations at June 30, 2022.

#### **Certain Differences Between IFRS and GAAP**

IFRS differs from GAAP in certain respects, including differences related to revenue recognition, intangible assets, share-based compensation expense, income tax and earnings per share. Management has not assessed the materiality of differences between IFRS and GAAP. Our significant accounting policies are described in Note 1 to our consolidated financial statements and the related notes thereto included elsewhere in this prospectus.

#### **Quantitative and qualitative disclosure about market risk**

The following sections provide quantitative information on our exposure to interest rate risk, share price risk, and foreign currency exchange risk. We make use of sensitivity analyses which are inherently limited in estimating actual losses in fair value that can occur from changes in market conditions.

##### ***Credit Risk***

Credit risk arises from cash and cash equivalents, derivative financial instruments and deposits with banks and financial institutions, as well as credit exposures to customers, including outstanding receivables and committed transactions. We have no significant concentrations of credit risk. For banks and financial institutions, only independently rated and reputable parties are accepted. We have policies in place to ensure that sales of products and services are made to customers with an appropriate credit history. Terms of trade provided to creditworthy customers are between 30 and 90 days, whilst customers deemed higher risk arrange a letter of credit or prepay for goods. The maximum exposure to credit risk at the reporting date is the carrying amount of the financial assets.

##### ***Liquidity Risk***

Prudent liquidity risk management implies maintaining sufficient cash and marketable securities, the availability of funding through an adequate amount of committed credit facilities and the ability to close out market positions. We manage liquidity risk by continuously monitoring forecast and actual cash flows and matching the maturity profiles of financial assets and liabilities.

##### ***Interest Rate Risk***

The consolidated entity’s main interest rate risk arises from long-term borrowings. Borrowings obtained at variable rates expose the consolidated entity to interest rate risk. Borrowings obtained at fixed rates expose the consolidated entity to fair value risk.

##### ***Foreign Currency Exchange Risk***

Our financial results are reported in U.S. dollars. A substantial portion of our operating expenses and revenues are denominated in the U.S. dollar. During FY2022 and FY2021, we have managed our exchange rate exposure principally by purchasing currencies and maintaining foreign currency cash accounts and managing our payments from the most appropriate accounts. From time to time, we may additionally use forward exchange contracts in an effort to manage certain foreign exchange rate exposures when appropriate. See “Quantitative and Qualitative Disclosures about Market Risk” for more information.

### ***Sensitivity***

Based on the financial instruments held at June 30, 2022, had the Australian dollar weakened/strengthened by 10% against the U.S. dollar with all other variables held constant, our pre-tax result for the year would have varied by A\$10,371/(A\$11,408) (2021: A\$29,935/(A\$32,928)). Had the Australian dollar weakened/strengthened by 10% against the Euro with all other variables held constant, our pre-tax result for the year would have varied by A\$41,872/(A\$46,059) (2021: A\$52,152/(A\$57,367)).

### **Critical accounting policies and estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with IFRS as issued by the IASB. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in our consolidated financial statements appearing elsewhere in this prospectus, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

#### ***Fair Value Measurement***

##### ***Fair value measurement hierarchy***

For financial instruments that are measured on the balance sheet at fair value, IFRS 9 requires disclosure of the fair value measurements by levels of the following fair value measurement hierarchy;

- Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date;
- Level 2: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and
- Level 3: Unobservable inputs for the asset or liability. Considerable judgement is required to determine what is significant to fair value and therefore which category the asset or liability is placed in can be subjective.

Our level 3 financial assets consist of convertible notes in unlisted entities inHealth and Blumio classified as loans held at fair value through profit or loss ("FVTPL"), along with an investment in unlisted equity securities in inHealth.

Our level 3 financial liabilities consist of convertible notes owed to unlisted entity C2 Ventures Pty Ltd classified as a financial liability at fair value through profit and loss. As at June 30, 2022 the only outstanding balance on the convertible notes was unpaid interest.

The following valuation techniques are used for financial assets categorised in Level 3:

- Convertible notes (Level 3) – Our holding of convertible notes issued by inHealth are classified as loans held at FVTPL. We obtained a third party valuation of inHealth for FY2022 and FY2021, which used a Monte Carlo Simulation to value the assets.
- Shares in inHealth (Level 3) – The fair value of this investment was also determined from the third party valuation that was obtained.

#### ***Critical estimates and judgements***

##### ***Valuation of inHealth Medical Services Convertible Notes – key assumptions used in assessment***

The valuation used to support the carrying amounts of the convertible notes are, by nature, uncertain. The valuation was performed by an external independent professional valuer. The nature and basis of the key assumptions used to estimate the valuation of the convertible notes are set out below:

- The inHealth Medical Services Convertible Notes were valued with reference to the underlying note agreement.
- Control Premium – a control premium of 15% has been used in the valuation of the convertible notes. Given that conversion of the convertible notes in inHealth would give CardieX a controlling interest in the company, a premium has been calculated. This was calculated with reference to 122 deals from the overall market for latest quarter of 2022, which were noted to have an average premium of 37.6% and a median premium of 26.5%. It was also calculated with reference to other factors affecting control premiums including, but not limited to, the performance of the entity, the number of potential buyers and the size of the business.
- Discount Rate – a discount rate of 14.75% has been used in the valuation of the convertible notes. This discount rate represents the market yield of the healthcare sector as of the valuation date.
- Time until Events – is the expected amount of time that the convertible notes will be held by CardieX prior to being converted into shares of inHealth. It has been assumed that the time until events (years) is 1.419, which represents management's best estimate of when the convertibles notes will be converted.

#### ***Stock Based Compensation***

Options issues have their fair value determined with reference to an approved valuation methodology, such as the Black-Scholes valuation method. On issue, the fair value of an option is taken to the income statement as equity settled compensation, with a corresponding credit to the options reserve. This is then disclosed as other comprehensive income in the statement of comprehensive income to show other net profit position of us from a third party perspective. Shares have their value determined using the direct method of share price at date of issue multiplied by the number of shares issued.

We measure the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by using either the binomial or Black-Scholes model taking into account the terms and conditions upon which the instruments were granted. The accounting estimates and assumptions relating to equity-settled share-based payments would have no impact on the carrying amounts of assets and liabilities within the next annual reporting period but may impact profit or loss and equity.

### ***Income Tax Expense***

We are subject to income taxes in the jurisdictions in which we operate. Significant judgement is required in determining the provision for income tax. There are many transactions and calculations undertaken during the ordinary course of business for which the ultimate tax determination is uncertain. We recognize liabilities for anticipated tax audit issues based on our current understanding of the tax law. Where the final tax outcome of these matters is different from the carrying amounts, such differences will impact the current and deferred tax provisions in the period in which such determination is made.

### ***Impairment of Receivables***

The provision for impairment of receivables and the expected credit loss calculation assessment requires a degree of estimation and judgment. The level of provision is assessed by taking into account the recent sales experience, the ageing of receivables, historical collection rates and specific knowledge of the individual debtor's financial position.

### ***Impairment of Inventories***

The provision for impairment of inventories assessment requires a degree of estimation and judgement. The level of the provision is assessed by taking into account the recent sales experience, the ageing of inventories and other factors that affect inventory obsolescence.

### ***Estimation of Useful Lives of Assets***

We determine the estimated useful lives and related depreciation and amortization charges for our property, plant and equipment and finite life intangible assets. The useful lives could change significantly as a result of technical innovations or some other event. The depreciation and amortization charge will increase where the useful lives are less than previously estimated lives, or technically obsolete or non-strategic assets that have been abandoned or sold will be written off or written down.

### ***Capitalized Development Costs***

Initial capitalization of cost is based on management's judgement that technological and economic feasibility is confirmed. In determining the amounts to be capitalized, management makes assumptions regarding the expected future cash generation of the project, discount rates to be applied and the expected period of the benefits.

### **Jumpstart Our Business Startups Act of 2012**

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. We are in the process of evaluating the benefits of relying on exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if as an "emerging growth company" we choose to rely on such exemptions, we may not be required to, among other things, (i) provide an auditor's attestation report on our systems of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis), and to the extent that we no longer qualify as a foreign private issuer, (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer's compensation to median employee compensation. These exemptions will apply until we no longer meet the requirements of being an "emerging growth company." We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of US\$1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than US\$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

## BUSINESS

### Overview

We are a commercial-stage digital healthcare company using our medical devices to redefine the way hypertension, cardiovascular disease (CVD), and other major vascular diseases are clinically diagnosed and managed. Our SphygmoCor XCEL, marketed under our ATCOR brand, is a vital signs and vascular biomarker monitoring device that offers non-invasive assessment of the central aortic pressure waveform, including both pressures and indices of arterial stiffness. Our SphygmoCor XCEL provides noninvasive measurement of arterial pressure that the heart, brain, and kidneys actually experience.

Our pioneering SphygmoCor vascular biosensing technology uses novel sensors that have been clinically validated and FDA cleared to collect digital vascular biomarkers. These biomarkers represent key indicators of vascular health including, but not limited to, central blood pressures (cBP), vascular stiffness, vascular age, and heart stress. SphygmoCor technology has been deployed in multiple clinical trials sponsored by pharmaceutical companies and healthcare systems to measure arterial health. When combined with cloud-based data analytics, we believe that our patient-friendly desktop and wearable devices built using our SphygmoCor technology enable key stakeholders throughout the healthcare ecosystem to obtain valuable health information from our digital vascular biomarkers not available from standard blood pressure devices. We believe that our consumer-facing solutions are creating a new paradigm in the diagnosis of vascular disease that is well aligned with the evolution of the healthcare industry as delivery of services becomes increasingly decentralized, patient-managed and consumer-oriented.

Our vision is to be the leading provider of home, wearable, healthcare, clinical trial, and remote patient monitoring solutions for common health disorders related to high blood pressure including hypertension, CVD, Alzheimer's disease, chronic kidney disease (CKD), and other major vascular health conditions. Our two subsidiaries, ATCOR Medical (ATCOR) and CONNEQT Health (CONNEQT), are focused on separate, but complementary, sectors of our target healthcare market. ATCOR established the SphygmoCor technology and continues to focus on servicing specialist health care providers, on-site clinical trials, research programs, and hospital networks with a variety of proprietary vascular biomarker solutions, such as our SphygmoCor XCEL system and the SunTech Oscar 2™ Ambulatory Blood Pressure Monitor with "SphygmoCor Inside." Launched in 2021, our CONNEQT business will introduce a suite of new devices and digital solutions strategically targeted to direct-to-consumer health, general health care providers, remote patient monitoring, decentralized clinical trials, and home health.

Our first two products under the CONNEQT brand are our CONNEQT Pulse and CONNEQT Band (together, our "CONNEQT Products"). Our CONNEQT Products incorporate our SphygmoCor vascular biosensing technology to obtain biomarkers representing vascular health. The CONNEQT Pulse is a vascular biometric monitor we co-developed with blood pressure manufacturer Andon Health Co. Ltd. ("Andon"). It offers dual blood pressure (central and brachial) and other advanced measures of vascular health not available with traditional blood pressure monitors. The CONNEQT Band is a "medical grade" wearable device (as proposed to be designated by the FDA through its clearance process) we are co-developing with LifeQ B.V. ("LifeQ"), a developer of general health biometrics, and Shenzhen Fenda Smart Technology Limited ("Fenda"), a contract manufacturer for wearables. It captures vascular health data in patients as well as to provide general health insights to consumers using a wristband form factor. See "Business – Manufacturing, Supply and Operations" for a more detailed discussion of our relationships with LifeQ and Fenda and related agreements. We anticipate that the CONNEQT Pulse will be commercialized in the second half of 2023, having recently received FDA 510(k) clearance from the FDA in April 2023. The CONNEQT Band wearable is targeted for commercialization in the second calendar quarter of 2024, subject to obtaining 510(k) clearance from the FDA.

#### *Our History*

ATCOR was originally founded in Sydney, Australia by Professor Michael O'Rourke who pioneered the technology to non-invasively assess central aortic pressure and indices of arterial stiffness. Subsequently named "SphygmoCor," this technology was based on insights generated from more than 40 years of hemodynamic studies Prof. O'Rourke conducted along with University of Florida Medicine Professor, Wilmer Nichols.

Our SphygmoCor technology has been independently validated by researchers worldwide and supported studies that resulted in over 2,000 peer-reviewed clinical publications since 1998. Our technology has also supported global pharmaceutical companies in 46 clinical trials. The current SphygmoCor XCEL is the third generation of our device. The 510(k) FDA clearance for the first generation SphygmoCor PX system was granted in 2002.



The (ASX:CDX) listed parent company AtCor Medical Limited, was rebranded to CardieX Limited (CardieX) in 2018, with newly-branded ATCOR continuing as a fully-owned subsidiary. This restructuring included reorganizing the executive team, and a new strategic vision to develop health solutions leveraging the foundational SphygmoCor technology. Since 2018, CardieX has developed a new ecosystem and portfolio of assets, medical & consumer devices, and digital health platforms targeted at detecting and managing the treatment of large-scale vascular health disorders. Our solutions provide both patients and health practitioners with the key information they need to better manage patient outcomes. We believe our SphygmoCor technology, as well as our intellectual property and patents, provide us with a competitive advantage as we enter new markets and develop new products.

#### ***Our Success Factors***

We believe the following factors differentiate our company and will continue to be significant components of our success and growth:

- **Pioneering technology.** Our patented SphygmoCor vascular biosensing technology non-invasively extracts high fidelity arterial signals at the heart and other major organs from multiple sensor formats including cuff- based pressure sensors, finger-based PPG sensors for advanced vascular health insights, and wrist-based PPG sensors for additional health and fitness parameters. Our FDA-cleared cuff-based sensor device (SphygmoCor XCEL) has been independently validated by researchers worldwide and has supported studies that have resulted in over 2,000 peer-reviewed clinical publications.
- **Industry trusted actionable data.** Our patented algorithms extract actionable medical and consumer health parameters not available from traditional blood pressure devices and wearables. These data drive better decision making and patient outcomes and impacts multiple disease states beyond hypertension. Our SphygmoCor technology is deployed in more than 4,500 installations worldwide, and it has been used in clinical trials sponsored by pharmaceutical companies in trial areas as diverse as pregnancy, diabetes, kidney disease, cardiovascular disease, heart failure, and the impact of cigarette smoking. Specifically, our flagship SphygmoCor XCEL device has been used in 46 pharmaceutical clinical trials to-date, spanning over 1,700 global study sites.
- **Proven track record of innovation.** SphygmoCor technology is hardware agnostic with applications across multiple device platforms including medical devices, consumer wearables, home health and clinical care, consumer devices, computers and portable technology, smartwatches and connected fitness. Our proven track record in developing new products that leverage the SphygmoCor technology will continue to differentiate us. The current SphygmoCor XCEL is the third generation of this device dating back to 2002 when the initial 510(k) FDA clearance for the first generation SphygmoCor PX system was granted. XCEL and the SunTech Oscar 2™ Ambulatory Blood Pressure Monitor with “SphygmoCor Inside”, are the only FDA cleared devices for full arterial waveform analysis and reimbursement in adults. Designed, manufactured and marketed by SunTech Medical, the Oscar 2™ incorporates our SphygmoCor technology.
- **Versatility of CONNEQT ecosystem.** Through the CONNEQT cloud we are expanding our existing proven technology into significant new markets including complete arterial health remote patient monitoring, home health and wearable devices and decentralized clinical trials. Our first two products under the CONNEQT brand are our CONNEQT Pulse, a vascular biometric monitor, and our CONNEQT Band, a medical grade wearable for vascular health. The CONNEQT Pulse device, received FDA 510(k) clearance in April 2023. For the CONNEQT Band wearable device, we anticipate receiving FDA clearance in the first quarter of 2024. If FDA clearance of the CONNEQT Band is granted allowing the device to be marketed as a medical grade vascular health wearable, this would be the first of its kind. However, there is no guarantee that the FDA will grant clearance to the CONNEQT Band or that it will do so on the timeline currently indicated.
- **Management.** Proven management team with diverse sector expertise and world recognized scientific expertise and research pioneers.

## ***Our Growth Strategies***

Our goal is to be the leading provider of home, wearable, healthcare, clinical trial, and remote patient monitoring solutions for common health disorders related to high blood pressure including hypertension, CVD, Alzheimer's disease, chronic kidney disease (CKD), and other major vascular health conditions. To achieve our growth plan, we expect to employ the following growth strategies:

- **Expand CONNEQT through our existing partner ecosystem.** We aim to capture a significant untapped opportunity with our CONNEQT devices by incorporating the SphygmoCor vascular biosensing technology in wearables, in-clinic patient monitoring solutions for general practitioners, remote patient monitoring, and decentralized clinical trials. Combined with the CONNEQT Patient Management Portal (CONNEQT Portal) that integrates with electronic medical records, we will be able to offer a value proposition to patients, consumers, health care providers, and, importantly, our existing pharmaceutical and healthcare industry clients.
- **Regulatory process.** We are the only company with an FDA-cleared technology capable of providing a non-invasive cBP reading with full pulse waveform output features and analysis in all adult populations. We received FDA clearance for the CONNEQT Pulse in April 2023. For the CONNEQT Band, we anticipate receiving FDA clearance in the first quarter of calendar year 2024. With the FDA clearance of our CONNEQT Pulse device, we believe we are well positioned to address the significant limitations of traditional blood pressure monitors. The CONNEQT Pulse will allow us to expand our existing "on-site" product offering to pharmaceutical and biotechnology companies already using our SphygmoCor XCEL technology to also include decentralized clinical trials where patient vascular health data is uploaded to the cloud from home or, wherever the patient is located. Along with these devices we expect to begin offering SaaS subscriptions for access to cloud-based data, our CONNEQT Portal, purchase or lease options for the device, and data management services.
- **Building a health ecosystem and brand.** In addition to our SphygmoCor vascular health parameters, the CONNEQT Band will also be a comprehensive lifestyle wearable incorporating a suite of features and health insights, derived from a wrist-based PPG sensor, thereby enabling users to obtain a complete 360-degree view of their health and fitness status. When paired with the CONNEQT App, the CONNEQT Band will continuously track users' heart health, support 24/7 practitioner monitoring and apply advanced intelligent analytics (our Arty Heart Health platform) to evaluate their health data in order to provide actionable insights regarding their unique vascular and health status. We intend to continue expanding indications and clinical use cases for our solutions in untapped patient populations at risk for vascular disease through our clinical and market development efforts. We believe we have a compelling opportunity to build a disruptive healthcare brand. We also believe that despite the existence of many sellers of traditional blood pressure devices, no other company has our technology advantage, nor have they been able to create a household brand-name in the vascular health sector.
- **Expand payor coverage and reimbursement.** A key component in ensuring whether the appropriate payment amount is received for physician and other services, including those procedures using our products, is the existence of a Current Procedural Terminology (CPT) code to describe the procedure in which the product is used. To receive payment, health care practitioners must submit claims to insurers using these codes for payment for medical services. CPT codes are assigned, maintained and annually updated by the American Medical Association and its CPT Editorial Board. Our SphygmoCor XCEL system is the only device we are aware of that can fully leverage the CPT code for assessment of digital vascular biomarkers, including central aortic pressures, augmentation index, and the use of pulse wave analysis (PWA) in all adult populations. On launch of the CONNEQT Pulse and CONNEQT Band, subject to regulatory authorization, it is expected that physicians and other health care providers will be able to bill health insurance companies for certain procedures under applicable CPT codes, including those related to remote patient management depending on the type and location of the service.
- **Continue to scale our operations in the United States to accelerate the growth of ATCOR and CONNEQT Products.** We expect to continue to scale our business in the United States by hiring additional U.S.-based managers as well as sales and marketing and end-user support personnel to enhance our ability to acquire customers and retain and grow these relationships. We expect that by expanding our U.S. team, we will acquire additional commercial expertise that will enable us to grow our customer and revenue base by continuing to cultivate satisfied customers and building key relationships with U.S. medical societies, which we believe will position us to create the value and tools required to win in an evolving competitive healthcare landscape. We plan to accelerate our sales efforts across all our business divisions while also increasing our digital marketing and online lead generation. While our current commercial focus is on the U.S. market, we also plan to initiate efforts that will allow for future expansion into other international geographies, including Asia, Europe, and the Middle East.
- **Growth through partnerships and acquisitions.** While we continue to accelerate our internal organic sales growth, we will also monitor opportunities to expand our business through select partnerships and acquisitions, especially as we look to drive value through a more vertically integrated product offerings in our target markets.

## **Our Market Opportunities**

Patient blood pressure is generally monitored either in a healthcare facility or in a patient's home to diagnose, guide, and manage hypertension, the leading cause of cardiovascular disease and premature death worldwide. Recent studies suggest that the use of digital vascular biomarkers including cBP in hypertension management may be more cost-effective and require less use of medications than current methods of hypertension management. We believe we are at the forefront of a paradigm shift where blood pressure measurement, one of the four key vital signs, will increasingly refer to cBP now that technologies that measure it noninvasively can be accessed outside of healthcare facilities. We further believe that the use of digital vascular biomarkers will become part of the standard practice in the management of cardiovascular health, patient monitoring, and ensuring patient safety during clinical trials as described below.

We believe that our focus on creating cloud-enabled devices under the CONNEQT brand will enable us to commercialize a compelling solution for those markets. As both the patient monitoring and the clinical trials markets increasingly rely on the remote collection of vital signs such as blood pressure, the clinical evidence that have been generated from our SphygmoCor technology over the past two decades enables us to create a unique and competitive value proposition in the blood pressure monitoring, remote patient monitoring, and clinical trials markets described below.

## **Blood Pressure Monitoring**

### ***Overview of "Cuff-Based" Blood Pressure Opportunity***

Blood pressure is traditionally taken in-clinic by a physician or nurse practitioner or at home by a patient. The market for standard blood pressure devices is estimated to reach US\$3.2 billion in 2028 according to *Fortune Business Insights*. The current, widely adopted use of standard blood pressure devices is a cuff-based device that provides limited insight into the overall vascular health of a patient.

Traditional blood pressure devices are singularly focused on hypertension through a single data output of systolic and diastolic pressure providing a generalized diagnostic reading based solely on population guidelines. When used by physicians for diagnosing and managing patients who are suspected of having hypertension, limitations of traditional blood pressure devices can lead to under- or over-treatment and potentially add further harm to the patients.

We believe that we are well positioned with our CONNEQT Pulse device to address the significant limitations of traditional blood pressure monitors when used in-clinic. The CONNEQT Pulse is the fourth generation device that incorporates SphygmoCor parameters from our existing FDA-cleared SphygmoCor XCEL device. Importantly, our patented algorithms extract actionable medical and consumer health parameters not available from traditional blood pressure devices and wearables.

#### ***Overview of Wearable “Cuff-Less” Blood Pressure Opportunity***

We believe that there are no FDA-cleared wrist-worn devices for blood pressure measurement that are truly “cuffless.” Cuffless blood pressure monitors rely on sensors integrated into wearable devices to capture pulsatility (a function of maximum flow rate) from the heart and translate that into blood pressure values. These devices passively capture and record blood pressure and related heart health data from individuals as they go about their daily activities. Today, no FDA-cleared cuffless wrist-worn blood pressure monitor exists on the market.

Under development is our CONNEQT Band, a cuffless wearable that will provide health data for the accurate measurement of blood pressure and other SphygmoCor biometric parameters.

Subject to FDA clearance, our vision for the CONNEQT Band is to create a “*SphygmoCor for the Wrist*”, that is suitable for clinical use. However, there is no guarantee that the FDA will grant clearance to the CONNEQT Band or that it will do so on the timeline currently indicated.

#### ***Overview of Ambulatory Blood Pressure Monitoring Opportunity***

Ambulatory Blood Pressure Monitoring (“ABPM”) is a cuff-based blood pressure monitor used to confirm a diagnosis of hypertension and designed to be worn as a patient goes about their daily activities. Unfortunately, ABPM’s share similar constraints as traditional cuff-based blood pressure devices. The need to wear the device for an extended period of time further reduces a patient’s willingness to undergo ABPM screening. Patients also reported discomfort and that monitoring disturbed their everyday activities, including 55% of patients reporting interference with sleep, 41% reporting pain, and 17% having a local skin reaction. Other patients found that the device was heavy, bulky to wear, and drew unwanted attention. The logistics of undergoing an ABPM study can also be challenging, as it may require multiple visits to the clinic. Subject to FDA clearance, it is anticipated that our CONNEQT Band will combine the comfort of a wrist wearable with our SphygmoCor parameters and will be capable of sending ambulatory blood pressure data directly into our CONNEQT Portal, with integrations directly into the patient’s electronic medical record. Since we have not commercialized any of our CONNEQT products, we do not have any revenues from them at this stage.

#### ***Overview of Remote Patient Monitoring Opportunity***

The growing prevalence of chronic diseases have led to an increased need for continuous ambulatory monitoring of vital signs, making it possible for healthcare providers to obtain patient data in their usual settings and timely management of sickness and chronic illnesses. Remote patient monitoring (“RPM”) is a subset of telehealth that facilitates patient monitoring and the timely transfer of patients-generated vital signs data from connected blood medical devices (blood pressure monitors, glucometers, pulse oximeters, electrocardiograms and more) from patient to care team and back to the patient. RPM provides a holistic view of a patient’s health over time, may increase visibility into a patient’s adherence to a treatment, and may enable timely intervention before a costly care episode.

We believe the CONNEQT Pulse, combined with the CONNEQT Portal, will offer an RPM solution that can provide a holistic view of how a patient is responding to treatment and enable a clinician to react to an adverse outcome in a timely manner.

#### ***Overview of Clinical Trials and Healthcare Research Opportunity***

With rising geriatric populations worldwide and the growing burden of chronic disorders, there has been increased demand for the development of novel noninvasive therapies that can increase patient monitoring with the goal of improving health outcomes and reducing the burden on health care systems. The increased demand for novel noninvasive therapies that can increase patient monitoring is further fueled by the increasing number of biologics on the market and the demand for contract research organizations (CROs) to manage clinical studies.

There are currently over 105,000 new and actively recruiting clinical trials published on ClinicalTrials.gov registry, the world’s largest clinical trials database containing clinical trials information from 220 countries. Multiple global pharmaceutical companies and public and private research institutions have used our SphygmoCor parameters in their clinical trials and over 2,000 studies using our technology have been published in peer-reviewed clinical publications.

### ***Conventional Trial Model***

Conventional clinical trials rely heavily on patients traveling to the trained study personnel and intermediaries for data collection. Our SphygmoCor XCEL device has been used by global pharmaceutical companies in 46 pharmaceutical clinical trials to-date, spanning over 1,700 global study sites, supporting trials related to pregnancy, diabetes, kidney disease, cardiovascular disease, heart failure, and cigarette smoking. Global clinical trials were valued at US\$47 billion in 2021, according to a report by Grand View Research.

### ***Decentralized Clinical Trial Model***

The COVID-19 pandemic has significantly catalyzed the adoption of decentralized clinical trials (“DCTs”) as wearable devices and remote patient monitoring have enabled more procedures to occur away from research sites. Respondents of an EY-Parthenon survey estimate that 50% of clinical trials will be hybrid or decentralized by 2024. *MarketResearch* estimates the global market for decentralized clinical trials to reach US\$14.2 billion by 2026.

With just 5% of eligible patients participating in clinical research according to a study lead by researchers at THREAD Research, trial decentralization broadens trial sponsors’ access to a larger and a more diverse pool of patients. A 2021 McKinsey & Company survey reported that 100% of pharma and CROs expected to include virtual trial methodologies within their drug trials, and of those surveyed, 89% reported they would run trials from patient’s homes. Decentralization can also reduce the workload for trial investigators, since traditional site activities (such as vital signs measurements) can be performed remotely by trial participants themselves.

We believe that DCTs offer a significant opportunity for our technology in wearables and remote patient monitoring. The CONNEQT Pulse is a connected vascular biometric monitor designed with decentralized clinical trials in mind that will offer a full suite of novel vascular health insights. We also believe our solution will be further strengthened with the CONNEQT Band currently under development, designed to capture ambulatory vital signs data.

### **Our Technology**

Our two subsidiary companies, ATCOR and CONNEQT are focused on separate, but complementary sectors of our target healthcare markets. ATCOR’s product line has typically focused on servicing specialist health care providers (cardiologists, nephrologists etc.), on-site clinical trials (where trial participants are required to visit a clinic), research programs, and hospital networks. Subject to FDA clearance of the CONNEQT Band, CONNEQT will introduce a suite of new devices and digital solutions strategically directed to general health care providers, remote patient monitoring, hybrid clinical trials, decentralized clinical trials (where trial participants can be remotely monitored at wherever they are located), and home health. A core driver to launch CONNEQT is to democratize access to our FDA-cleared SphygmoCor central waveform technology with a suite of connected devices, paired with a consumer-first digital experience focused on vascular health education and personalized actionable insights.

## SphygmoCor XCEL

The SphygmoCor XCEL is a vital signs and vascular biometric monitoring device that offers non-invasive assessment of the central aortic pressure waveform, including both pressures and indices of arterial stiffness, providing noninvasive measurement of arterial pressure that the heart, brain, and kidneys actually experience. The current SphygmoCor XCEL is the third generation of this device.

The SphygmoCor XCEL derives the central aortic pressure waveform using a blood pressure cuff on the arm. The procedure can be conducted in the office setting and is easy to perform, painless, and reproducible.

Health assessment using our SphygmoCor technology enables:

- Reimbursement to physicians and other qualifying health care providers' for Pulse Wave Analysis (CPT 93050). Payor coverage may vary from plan to plan.
- Non-invasive measurement of pressures at the major organs.
- Multiple medical grade vascular health insights beyond traditional blood pressure readings.
- Aid in the identification of "white-coat" hypertension (in-office blood pressure measurements elevated relative to home-based readings).



**The CONNEQT Brand**

Our focus is creating cloud-enabled devices that straddle both the clinical and consumer market. The CONNEQT Pulse is a connected vascular biometric monitor. The CONNEQT Pulse will be launched under the new CONNEQT brand accessible to both consumers and for clinical use. Subject to FDA clearance, we also expect to launch a consumer and patient targeted wearable band, the CONNEQT Band, a 24/7 dual-PPG sensing wearable which combines both our patent pending SphygmoCor finger-based PPG sensor for vascular health measurements and a wrist-based PPG sensor to capture additional health and fitness parameters.



We believe our central blood pressure technology and companion digital solutions have the potential to replace traditional blood pressure technology and become the primary first-line monitoring option for consumers and physicians alike. With our launch of the CONNEQT brand we believe will be creating a new category centered around vascular health which has many sub-markets for us to address including heart health, vascular health, and kidney, brain, maternal, and sexual function. Each of these arenas broadens our outreach to the health market with tailored condition-specific digital solutions.



**CONNEQT Pulse**

The CONNEQT Pulse is the first connected vascular biometric monitor to incorporate our SphygmoCor technology for home, decentralized clinical trials, and remote patient monitoring. The CONNEQT Pulse will offer dual blood pressure (central and brachial) and other advanced measures of vascular health. In addition, it will be the first connected vascular biometric monitor to enable a discrete physiological profile which personalizes each vascular health parameter reference to the patient, a feature not available with traditional blood pressure monitors.

Our CONNEQT Pulse incorporates our SphygmoCor parameters and can be customized based on an individual's specific health condition enabling patients to specifically focus on the unique vascular health insights that directly impact them. Using our CONNEQT Pulse, consumers will be able to view a real-time customizable dashboard of their data, have access to science-based educational content and health programming, and enable a share function that enables data to be disseminated to friends, family, health care providers and clinical research managers.

For in-clinic readings or on-site clinical trial testing, the CONNEQT Pulse will interface with our CONNEQT Portal, a custom-built tablet application that supports device customization by clinicians, patient/subject lookup and which is the central data dashboard for each reading session.

### ***CONNEQT Band***

The CONNEQT Band is a wearable “cuffless” device designed to monitor vascular health in patients as well as to provide general health insights to consumers. Cuffless blood pressure monitors rely on sensors integrated into wearable devices to capture pulsatility from the heart and translate that into blood pressure values. These devices passively capture and record blood pressure and related heart health data from individuals as they go about their daily activities. Today, no FDA-cleared cuffless wrist-worn blood pressure monitor exists on the market.

We believe that we are well positioned with our CONNEQT Band, subject to FDA clearance, to launch the first cuffless wearable that will provide health data for the accurate measurement of blood pressure and other SphygmoCor parameters.

We have already successfully integrated a subset of our SphygmoCor technology into the Mobvoi TicWatch GTH Pro smartwatch using a finger-based PPG sensor on the smartwatch to extract a limited suite of consumer-focused heart health features. This successful translation of our SphygmoCor cuff-based algorithms into a finger-based PPG sensor allowed us to evolve our sensing capabilities in a non-FDA cleared, consumer smartwatch in partnership with Mobvoi. Subject to FDA clearance, our CONNEQT Band will be the first wearable to feature our patent-pending SphygmoCor finger-based PPG side-sensor technology providing a full suite of medical grade SphygmoCor biomarkers to our users in an FDA-cleared device. The use of a finger-based PPG side-sensor is necessary for the superior resolution of the arterial biometric features that can be extracted from a finger, as compared to the wrist. A user simply places a finger on the side-sensor of the CONNEQT Band for 5 to 10-seconds to obtain insights into the user’s vascular health.

Subject to FDA clearance, in addition to incorporating our SphygmoCor vascular health parameters, the CONNEQT Band will also be a comprehensive lifestyle wearable incorporating a suite of features and health insights, derived from the wrist-based PPG sensor, enabling users to obtain a 360-degree view of their health and fitness status. When paired with the CONNEQT App, the CONNEQT Band will continuously track users’ heart health, support 24/7 practitioner monitoring and apply advanced intelligent analytics (our Arty Heart Health platform) to evaluate their health data to provide actionable insights regarding their unique vascular and health performance.

Our CONNEQT Band is a medical grade vascular health wearable currently in development and targeted for commercialization in the second calendar quarter of 2024, subject to obtaining 510(k) clearance from the FDA. However, there is no guarantee that the FDA will grant clearance to the CONNEQT Band or that it will do so on the timeline currently indicated.

### ***CONNEQT App***

Our CONNEQT App will be a key part of the digital ecosystem for our CONNEQT devices and will be the main engagement interface for consumers and patients interacting with all our CONNEQT devices. The foundation of our app is the Arty Heart Health platform.



Arty is a heart health analytics platform and ecosystem that lives within the CONNEQT App. Arty will leverage our SphygmoCor technology and vascular health algorithms to provide consumers and patients with a proprietary suite of unique biomarkers, contextually aware health education tools. The CONNEQT App will also provide for health record and data sharing with physicians and caregivers and allows users to fully customize the CONNEQT Pulse’s screens and health insights depending on your specific health concerns.

### **CONNEQT Patient Management Portal (the “CONNEQT Portal”)**

Our CONNEQT Portal, powered by the CONNEQT Cloud, will be the primary platform for physician reimbursement for remote physiological monitoring, as well as reimbursement for “arterial waveform analysis” as a result of a reading obtained and analyzed via one of our SphygmoCor enabled devices. Combined with the CONNEQT Pulse and the CONNEQT Band, the CONNEQT Portal will provide us with a compelling value proposition both for (i) physicians looking to remotely monitor their patients, and (ii) clinical trial sponsors looking to regularly monitor their trial participants’ vital signs remotely for safety, leveraging the many benefits associated with decentralized clinical trials. While we have a long history of our partners utilizing SphygmoCor XCEL devices in past on-site clinical trials, we believe the use of that same technology in a decentralized trial environment will provide us with a competitive advantage for us in our partnerships with drug and medical device developers.

**For Healthcare Providers** the CONNEQT Portal will support in-clinic office readings as well as remote physiological monitoring, collating all patient data into a singular dashboard view to assess in-office readings, monitor remote patient data and reimbursement compliance, create reimbursement reports and manage device inventory/updates.

**For Clinical Trial Managers** the CONNEQT Portal will support both on-site clinical endpoint readings as well as remote physiological readings for decentralized clinical trials. A patient subject list can either be bulk uploaded into the CONNEQT Portal via a pre-formatted csv file or entered manually. The CONNEQT Portal for decentralized clinical trials will have additional levels of security, administrative roles and data permissions to ensure that the patient data is secure, anonymized, and unbiased.

### **CONNEQT Cloud**

The backbone of our connected ecosystem is our CONNEQT Cloud which empowers our Arty Heart Health analytics platform and data repository for our CONNEQT Portal (a health care provider and clinical trial manager facing web-enabled interface), and consumer-facing CONNEQT App.

The CONNEQT Cloud will be the foundation to our digital health ecosystem, a HIPAA compliant infrastructure allowing for the secure transfer of data from our devices to a series of purpose built web-enabled and mobile app solutions (CONNEQT Portal and CONNEQT App). It will also host our Arty Heart Health platform, and with the support of our Arty analytics engine will provide real-time data analysis and personalized actionable insights with relevant educational content, coaching, and notifications to support our consumers.





### ***CONNEQT Touchpoint™***

CONNEQT Touchpoint is our vision for the incorporation of our technology across an ecosystem of consumer and connected fitness devices, smartphones, and computers. Our patent-pending SphygmoCor finger-based PPG technology that will be incorporated into our CONNEQT Band allows any device that has a “touch point” to be enabled with our technology. Our vision is to enable multiple devices with health analytics that could be accessed by just “touching” a non-intrusive sensor allowing constant, contextual rich health insights to be integrated into an individual’s daily life. We believe the computer and laptop market is a lower barrier to entry for us in this sector given the existing prevalence and adoption of finger-based ID verification on computing devices.

### ***SunTech Oscar 2™ ABPM with “SphygmoCor Inside”***

The SunTech Oscar 2™ ABPM with “SphygmoCor Inside”, is an ambulatory blood pressure monitor that also captures a suite of unique vascular health features and health insights developed by our ATCOR subsidiary.

ABPM’s are blood pressure monitoring devices that are prescribed by a physician and worn by a patient in order to monitor blood pressure during a defined period. ABPM’s generally take a blood pressure reading every 30 minutes over a period of 24-hours without any action required by the patient.

Designed, manufactured and marketed by SunTech Medical, the Oscar 2™ ABPM with “SphygmoCor Inside” provides valuable diagnostic information that traditional ABPMs are incapable of measuring.

The Oscar 2™ ABPM with “SphygmoCor Inside” obtained 510(k) FDA clearance in 2016. “Oscar 2” is a trademark of SunTech Medical. The device is owned and manufactured by SunTech. We sell our SphygmoCor IC firmware chip to SunTech for incorporation into the device and receive a revenue share on all sales.

#### ***Mobvoi TicWatch GTH Pro Smartwatch***

The TicWatch GTH Pro, our collaboration with Mobvoi Information Technology Co. Ltd, is a smartwatch incorporating a suite of vascular health features and health insights developed by ATCOR specifically for the watch. The TicWatch GTH Pro was also the first wearable to feature our patent pending SphygmoCor finger-based PPG sensor technology for arterial feature collection.

While the TicWatch GTH Pro is not being marketed as a medical device, by leveraging our SphygmoCor technology, the TicWatch GTH Pro is the world’s first smartwatch capable of providing unique PPG-based heart and vascular health parameters which act as key points of differentiation in the smartwatch market.

#### ***SphygmoCor Parameters***

ATCOR’s intellectual property based on PWA is the main driver for our proprietary SphygmoCor parameters. Currently our PWA algorithms are either embedded into our in-house programmed microchips, which are then integrated into our devices. For our wearable devices, the algorithms are embedded directly into the firmware for easy collection of waveform data.

The algorithm outputs the following list of vascular biomarkers. We consider these parameters to be “medically reliable” as they have been validated in clinical studies against invasive arterial catheterization and cleared by the FDA.

***Central Systolic and Diastolic Blood Pressure*** is the pressure in the ascending aorta, just outside the left ventricle. It is the pressure that the target organs are exposed to and, due to arterial pressure amplification, is lower than brachial cuff pressures.

***Brachial Systolic and Diastolic Blood Pressure*** is the pressure of blood at the brachial artery in the upper arm.

***Heart Rate*** is the beat-to-beat heart rate measurement on par with standard ECG-based methods. A consistently high resting heart rate may be a sign of coronary heart disease.

**Augmentation Pressure** is the added pressure from the backward reflected pressure wave. A measure of the extra work the heart must generate to eject oxygenated blood to the body. The measure is a reflection of arterial stiffness, a consequence of aging and disease. Accelerated arterial stiffness is a marker of an abnormal vascular pathophysiology.

**Augmentation Index (AIx)** is a measure of the percentage of the blood pressure on the heart not related to blood pumping, but to arteries stiffness. This is indicative to the extra load on the heart which is shown to be a risk factor for major cardiovascular diseases.

**Central Pulse Pressure** is the amount of pressure on the heart during the cardiac cycle. This pressure differs significantly from the pressure measured by the conventional cuff blood pressure devices. The central pulse pressure is indicative of major organ risk.

**Central Mean Pressure** is the average arterial pressure throughout one cardiac cycle, systole, and diastole. It is influenced by cardiac output and systemic vascular resistance. When the mean pressure is too low, vital organs do not receive the required blood supply and can lead to organ failure.

**Subendocardial Viability Ratio (SEVR)** is a measure which reflects the cardiac ability to supply oxygen to the body during high demand. This non-invasive assessment can provide early indications of heart disease and identify patients with underlying heart disease who may be at a very high risk of serious adverse events (e.g., angina and myocardial infarction).

#### **Arty Heart Health Parameters**

We have also developed a set of consumer-friendly parameters to distill and convey the insights gathered from the clinical- and medical-centric nature of the SphygmoCor parameters. We refer to these as Arty Heart Health parameters and we leverage these parameters in our consumer-facing solutions.

**Arty Score™** combines several vascular health parameters into a comprehensive, personal heart and vascular health score for easy, frequent review. Based on proprietary algorithms derived from arterial waveform analysis, our Arty Score quantifies each individual's unique cardiovascular profile, thereby offering individualized data, insights, and trends that can be used to monitor overall vascular health.

**ArtyAge™** measures the "stiffness" of an individual's arteries and indicates cardiovascular health relative to biological age. ArtyAge can be used to motivate a person to implement lifestyle changes aimed at improving their ArtyAge score.

**Exercise Capacity™ (eCAP™)** is an indicator of fitness and directly measures blood flow to the inner muscle of your heart, which is important for overall heart health. Targeting a high eCAP is particularly important for individuals with a history of sub-optimal heart health to ensure the heart has adequate supply of blood to meet demand.

**Heart Stress Index™ (HSX™)** is a measurement of the extra load placed on the heart due to the stiffening of the arteries. Targeting a low HSX is important for overall and long-term heart health.

**TruHR™** is a highly accurate measurement of the heart rate that is similar to how heart rate is calculated from an electrocardiogram.

**Arterial Stiffness Factor™** indicates the stiffness of the main arterial and vascular system that supply blood to the main organs (e.g., brain and kidney). The stiffness of these arteries is one of the major underlying causes of vascular and heart diseases.

**Vitals Risk™** indicates an individual's risk of heart, brain, kidney, and other major organ damage based on the supplied blood pressure on these organs.

### *Our SphygmoCor Technology*

The technology to non-invasively measure central aortic blood pressures (referred to as SphygmoCor technology) was enabled by more than 40 years of hemodynamic studies of the cardiovascular system led by the founder of our ATCOR subsidiary Professor Michael O'Rourke, and University of Florida Medicine Professor, Wilmer Nichols. These studies established the fundamental principles and laws governing blood pressure and flow pulses along the arterial tree.

These studies also showed the clinical significance of measuring arterial blood pressure close to the heart, and specifically, at the aortic artery. Prof. O'Rourke's pioneering studies are summarized in Prof. O'Rourke's co-authored textbook: "McDonald's Blood Flow in Arteries: Theoretical, Experimental and Clinical Principles, 5th Edition. This classic text, first published in 1960, introduced at that time an entirely new approach to the study of arterial hemodynamics and provided a theoretical basis to understanding blood flow.

Even though measuring central aortic blood pressure was always considered clinically beneficial, it was not considered for routine out-patient clinical use as it previously required an invasive catheterization procedure with a pressure sensor inserted into the aorta.

In the first trial of its type, Prof. O'Rourke was able to reproduce an equivalent central aortic pressure pulse to that obtained invasively using a non-invasive peripheral (brachial or radial) pulse using a generalized transfer function (which governs the relationship between peripheral and central pulses). Prof. O'Rourke concluded that one transfer function can be generalized to all adults (a "general transfer function") and set the foundation for the measurement of central aortic pressures and associated arterial health features which was subsequently published in the journal Hypertension in 2001.

SphygmoCor technology uses the general transfer function estimated from invasive evaluations and non-invasive peripheral pulse recordings to reconstruct central aortic pressure pulse along with cardiovascular related physiologic variables with the objective of providing additional information about the status (or health) of the vascular system. The features are detected by the pulse wave analysis proprietary algorithm implemented in our SphygmoCor devices. This method, which has been validated through invasive studies and FDA cleared and has been implemented in non-invasive blood pressure devices and used in clinical research studies since 1996.

The vascular biomarkers produced by SphygmoCor have been studied and reported in numerous peer-reviewed publications with the clinical focus being on cardiovascular risk and the status (health) of the vascular system. The assessment is predictive of end-organ damage (e.g., heart, brain, kidney), disease outcomes (e.g., heart failure, ischemic heart disease, stroke) and for guidance in monitoring of therapeutic interventions. It is our belief that incorporation of these variables into primary and specialty care can profoundly impact management and outcome.



The key areas of health practice management that can be impacted with potential examples are as follows:

- **Identifying patients at increased risk for hypertension and vascular related disease.** Patients with isolated elevations in central pressures may identify a specific risk not otherwise found. Patients with borderline elevations in brachial pressure where risk may not be clear can be diagnosed with more confidence in the setting of increased central variables, such as central systolic pressure and augmentation index (identifying increased arterial stiffness).

- **Refining monitoring requirements.** It is evident from numerous research publications that central and peripheral pressures are not redundant and provide independent yet complementary information allowing physicians to enhance or reduce monitoring depending upon risk. High risk and unstable pressure readings may lead to prescription for increased monitoring while improved and stable central aortic pressure responses to a therapeutic plan could lead to reduced recommendations for monitoring. In addition, changes in variables such as SEVR in the setting of suspected or known cardiac disease may further guide targeted investigations (e.g., imaging).

- **Reducing over-treatment.** Perhaps the most compelling example is the problem of white-coat hypertension. A normal or low central pressure suggests white-coat hypertension and a management decision to follow a patient with life-style recommendations without immediately initiating pharmacotherapy. In treated hypertension patients, a slightly elevated brachial BP might lead to increased drug treatment, which may not be needed if central pressures are normal or low. More aggressive treatment than necessary could lead to adverse effects related to over-treatment (i.e., hypotension, syncope, falls, organ damage).

- **Improving under-treatment.** In patients where there is a hesitancy to initiate or increase medication, the concurrent elevation of brachial and central pressures or where other centrally derived variables identify significant increases in risk can inform health care providers to more confidently, although always judiciously, increase treatment.

SphygmoCor technology PWA is the only FDA cleared medical device for non-invasive central aortic PWA analysis for all adults. We believe that the physiologic insights from the unique clinically relevant information that are provided from central aortic PWA (not available through monitoring of brachial pressures alone) can help guide treatment decisions.

We believe that our solutions will have profound benefits for all members of the health care community as follows:

**For Healthcare Providers:** Enabling physicians to make more informed treatment decisions based on clinically relevant vascular health data.

**For Patients:** Give patients the tools to make better decisions about their own health.

**For Payors and Pharmaceutical Companies:** Generate reliable, real-world, clinically relevant outcomes data to support payor review/reimbursement of drug products.

A dual arterial pressure monitoring system consisting of brachial blood pressure and the central aortic pressure parameters (using PWA) allows health care professionals to optimize care for patients with hypertension, hypertension related end-organ damage (e.g., heart, brain, kidney) and numerous vascular disorders where arterial pressures and health have a directly affect by providing additional unique information beyond standard brachial pressure alone.

***Applying the Science of SphygmoCor to Wearables and Non-Cuff-Based Sensors***

Subject to FDA clearance, our goal with the launch of the CONNEQT Band and our other sensor-based devices is to replicate our FDA-cleared SphygmoCor parameters by way of a non-pressure based signal extracted from either or a combination of the finger or the wrist.

In July 2020, we lodged a new U.S. Provisional Patent Application 63/031,645 that describes a system and method of measuring medically reliable heart and vascular health indicators from PPG light sensor on a wearable device such as a smartwatch or mobile phone when a user places his or her finger on the sensor. The determination of a central aortic pulse with significant heart and vascular health indicators by way of our pending patent could previously only be obtained invasively or via a medical device in a clinical setting.

In June, 2021 we subsequently lodged USPTO application No 17/331,873 and WIPO application No. PCT/IB2021/054655 expanding the earlier provisional patent application to cover a system and method for obtaining those same heart and vascular health indicators from PPG sensors in a multitude of electronic devices including laptops and computer ID sensors, mouse devices, computer gaming controls, and keyboards.

With the launch of the TicWatch GTH Pro in March 2022 in partnership with Google-backed smartwatch company Mobvoi, we demonstrated that we could reproduce meaningful vascular health parameters in a consumer watch based on our patent-pending PPG side-sensor technology. The next phase is to extend that research and technology in order to implement it into our CONNEQT Band medical grade wearable that can be recommended for clinical use.

We are currently continuing research studies to develop an algorithm to detect blood pressure from the derived PPG signals validated against ambulatory blood pressure devices. We believe this technology has the potential for application across multiple device formats including consumer technology, connected fitness, as well as its core application in wearables.

## Our Revenue

We derive a mix of sales, data, and management services revenues from our existing ATCOR business unit. With the launch of our CONNEQT brand we are seeking to expand our revenue base in new market channels to also include device sales, SaaS and app subscription revenues, revenue share, and premium digital content revenue. The following tables present our total revenue by geographic area for each year presented (in thousands):

<b>2022</b>	<b>Americas</b>	<b>Europe</b>	<b>Asia Pacific</b>	<b>Inter-segment eliminations/ unallocated</b>	<b>Consolidated</b>
Sales to external customers	2,300	343	309	-	2,952
Intersegment sales	-	-	759	(759)	-
<b>Total sales revenue</b>	<b>2,300</b>	<b>343</b>	<b>1,068</b>	<b>(759)</b>	<b>2,952</b>
Interest revenue	-	-	314	-	314
<b>Total segment revenue/income</b>	<b>2,300</b>	<b>343</b>	<b>1,382</b>	<b>(759)</b>	<b>3,266</b>

<b>2021</b>	<b>Americas</b>	<b>Europe</b>	<b>Asia Pacific</b>	<b>Inter-segment eliminations/ unallocated</b>	<b>Consolidated</b>
Sales to external customers	3,150	291	294	-	3,735
Intersegment sales	-	-	969	(969)	-
<b>Total sales revenue</b>	<b>3,150</b>	<b>291</b>	<b>1,263</b>	<b>(969)</b>	<b>3,735</b>
Interest revenue	-	-	192	-	192
<b>Total segment revenue/income</b>	<b>3,150</b>	<b>291</b>	<b>1,455</b>	<b>(969)</b>	<b>3,927</b>

### ATCOR Revenue

We market our SphygmoCor vascular health solutions in the United States and globally through a direct sales organization comprised of sales management, field billing specialists, and territory managers. Our physical sales coverage includes the U.S., Europe, China, Australia, Canada and the Middle East. We also use in-bound digital lead generation through our websites and “search engine marketing” to drive leads. Territory managers focus on both initial introduction into new accounts and penetration across a sales region and conveying our message of clinical and economic value to hospital administrators, research organizations, and other clinical departments. We anticipate increasing the size of our global sales organization to expand the current customer account base and increase utilization of our ATCOR suite of products and services. In addition, we will continue exploring sales and marketing expansion opportunities in international geographies.

We market our SphygmoCor XCEL device and data services to a variety of physician specialties including cardiologists, nephrologists and other physician specialists who diagnose and manage care for patients with vascular related diseases. We have found success focusing on integrated delivery networks (“IDNs”), in which large networks of facilities and providers work together to offer a continuum of care to a specific geographic area or market. Focusing on sales to IDNs gives us the opportunity to conduct a holistic sale for health systems interested in making value-based purchasing decisions.

We also target academic research institutions as part of our marketing efforts. We maintain close ongoing contact with major U.S., Canadian, Australian and European research hospitals and other related institutions to monitor opportunities for RFPs (Requests for Proposals) for devices and solutions to support research projects, NIH, NIA, NIGMS, and VA GRECC funded large and specialized academic research centers. We do this through ongoing direct sales contact as well as through the monitoring of public databases for potential opportunities to supply our solutions.

Our Clinical Trial Solutions (CTS) group also actively monitors the public databases of new clinical trials in order to identify new sales opportunities for our solutions for existing and recruiting trials. We also actively participate in public forums (conferences, industry events) and direct marketing efforts to pharmaceutical and biotechnology companies, CRO's, and our existing client database to drive sales leads. With recent new additions to leadership in this sector we expect our CTS group to be a significant revenue growth area for us moving forward.

Our ATCOR division does business on 6 continents, in 34 countries, and with an installed base of over 4,500 SphygmoCor systems. ATCOR currently derives revenue from the following sources:

1. **Academic Research Institutions.** We sell ATCOR's SphygmoCor technology to global academic research institutions for use in clinical and benchmarking studies. We are currently involved in 120 global studies with SphygmoCor technology. Our business model is a mix of direct sales and lease of equipment.
2. **Pharmaceutical and Biotechnology Companies.** We derive revenue from our pharmaceutical clients through both the lease of SphygmoCor devices and the provision of data management and other services over the course of the trial. We also receive a mix of set-up, training, and provisioning revenue depending on the nature of the trial and geographic location.

Historically, ATCOR has enabled 46 global trials with trial partners, in trial areas as diverse as hypertension, diabetes, smoking, gout, obesity, arthritis, and COPD. The vascular health parameters in our SphygmoCor XCEL are used to support clinical trial endpoints such as demonstrating a drug's effect on central blood pressure and arterial stiffness. This business unit is the highest contributor to the overall group revenues of the Company with the highest net profit margins. Our SphygmoCor XCEL devices are provided principally for use "on-site" by the clinician trial lead, where the monitoring device is housed in a physician's/clinical office. A "decentralized" trial refers to monitoring devices being located in a trial participant's home setting and being managed remotely and is the principal use-case for our CONNEQT Pulse (see below).

3. **Clinical Research Organizations.** CROs support clinical trials sponsored by pharmaceutical and biotechnology companies. We have supplied our SphygmoCor systems to CROs, such as Clario (ERT), Clinichain, and Covance (Labcorp) for utilization in clinical trials that they have independently managed. We currently sell to four CROs and are in four clinical studies. We derive revenue from our pharmaceutical clients through both the lease of SphygmoCor devices and the provision of data management and other services over the course of the trial. We also receive a mix of set-up, training, and provisioning revenue depending on the nature of the trial and geographic location.
4. **Integrated Delivery Networks (IDN's) and Specialist Physician Practices.** We work with physician specialists with expertise in cardiology, nephrology and endocrinology. We sell to physicians either in private practices or as part of an IDN, including the Cleveland Clinic, Massachusetts General Hospital, Johns Hopkins, Emory, Alexian Brothers, Ascension Health, Northwestern, and NYU. Physicians that treat hypertension use our SphygmoCor XCEL to diagnose, personalize, and tailor therapy. The largest portion of this business is in concierge medicine, anti-aging practices, and top-ranking institutional hypertension clinics. Physicians bill CPT codes pertaining to our services and are reimbursed for using our devices. We sell or lease our equipment to the physician's practice, IDN, or clinic.
5. **Medical and Consumer Device Joint Ventures & Licensing.** We selectively license or partner with non-competitive companies for the provision of our vascular health algorithms for use in their devices.

Our ATCOR division supplies SunTech with specially manufactured microchips which contain proprietary firmware developed by ATCOR. SunTech utilizes these microchips in the manufacturing of Oscar 2™ with "SphygmoCor Inside" devices under the SunTech brand; and both parties share revenue on the sale of Oscar 2™ with "SphygmoCor Inside" devices on a worldwide basis.

ATCOR and Mobvoi co-developed the TicWatch GTH Pro device; Mobvoi is responsible for the commercialization of TicWatch GTH Pro; and Mobvoi compensates ATCOR with a royalty fee that is based on net volume of TicWatch GTH Pro devices sold in recurring sales periods. Additionally, ATCOR has the option to distribute TicWatch GTH Pro in non-competitive channels.

With the commercialization of our CONNEQT suite of products, and a general increase in awareness of our proprietary technologies and algorithms for heart health, we expect new licensing opportunities for ATCOR in other applications such as gaming, portable computing, and connected fitness may present themselves.

#### **CONNEQT Division Revenue**

The CONNEQT business will benefit from being principally reliant on online and digital marketing in order to drive sales leads. Our [conneqthealth.com](http://conneqthealth.com) website will be the principal platform to generate professional healthcare provider leads that will be converted through a team of specialist sales personnel trained in our target business segments for these products. In addition, our CONNEQT home solutions will be directly available to purchase through the website. We have engaged a number of healthtech focused specialist media, data analytics, and marketing agencies to assist us in this process and to build an analytics and lead generation engine in order to maximize our sales conversions and in order to optimize our marketing spend per sales lead. By using a proprietary "SWOOP®" patient analytics engine we have been able to aggregate a deep data set of our addressable market and customer profile that we will be implementing with both our consumer and professional marketing programs at launch.

Supporting our sales efforts for all our businesses will be an accelerated brand, marketing, event, and media program aimed at building the profile of our businesses and the impact of our solutions on global health.



Our CONNEQT brand is currently in various stages of development on multiple new products and digital platforms. Our CONNEQT Pulse device received FDA clearance in April 2023 and we anticipate receiving FDA clearance for the CONNEQT Band in the first quarter of calendar year 2024. When the FDA will grant clearance for any of our premarket submissions is uncertain, as the FDA can delay, limit, or deny clearance of a device for many reasons, including, for examples, if the FDA identifies deficiencies in our regulatory submissions, requires us to submit additional data or conduct additional testing or studies to demonstrate safety and effectiveness of a device, or if the FDA disagrees with our interpretation of the data. Our business model for our new CONNEQT products and services is predicated on the following revenue sources:

*CONNEQT Pulse – Vascular biometric monitor, CONNEQT App, and CONNEQT Patient Management Portal.*

1. **Pharmaceutical and biotechnology companies operating decentralized clinical trials.** Decentralized clinical trials, where telehealth and remote monitoring capabilities are employed to gather data, are rapidly gaining acceptance due to efficiency, cost-effectiveness and improved patient experience. The FDA cleared CONNEQT Pulse will allow us to expand our existing “on-site” offering to pharmaceutical and biotechnology companies (currently enabled with our SphygmoCor XCEL) to also include decentralized trials where patient vascular health data is uploaded to the cloud from home or, wherever the patient is located.
2. **Clinical Research Organizations.** Similar to pharmaceutical and biotechnology companies, the addition of CONNEQT Pulse which can be used in the patient’s home, is expected to drive increased sales to CROs.
3. **Physician Practices.** The addition of CONNEQT Pulse and its companion CONNEQT Portal is expected to increase sales to physicians for in-clinic use but also drive sales to physicians who may require remote monitoring of vascular health parameters in order to better manage their patients’ conditions. It is anticipated that the revenue model in this instance will be predicated on a mix of:
  - a. Physicians billing and receiving reimbursement from payors for in-clinic pulse wave analysis using our devices, and physician practices purchasing and/or leasing the CONNEQT Pulse device from CONNEQT.
  - b. Physicians billing and receiving reimbursement from payors for remote patient monitoring using our devices, and physician practices purchasing and/or leasing the CONNEQT Pulse device from CONNEQT.
  - c. Subscription revenue for use of our cloud-based HIPAA compliant and globally compliant CONNEQT Portal.
4. **Home health use.** Patients or general consumers wanting to monitor their vascular health will be able to purchase the CONNEQT Pulse with a prescription from their primary care physician or via a telehealth consultation, a process that will also be enabled online through [www.conneqthealth.com](http://www.conneqthealth.com). Our business model in this scenario is predicated on the patient also downloading and subscribing to the CONNEQT App, either on a monthly or annual membership basis. We also anticipate premium services, coaching, wellness programs, and other educational tools being made available to patients for an additional premium subscription fee.



**CONNEQT Band - Wearable**

Pricing for the CONNEQT Band has not been determined; however we expect our revenues to be a mix of product sales, app subscription, and membership fees for premium services. The CONNEQT Band will also be a key part of our professional offering to our clinician, physician, and pharmaceutical partners who require an ambulatory (wearable) solution for their respective monitoring programs.

### **Reimbursement**

We do not receive revenue directly from payors however our business is partially dependent on payor reimbursement to physicians.

It is critical for commercial success in the healthcare industry that services utilizing medical devices be reported with an appropriate code. For procedures performed in an office setting, procedures are reported with Current Procedural Terminology or CPT code. CPT is managed by the American Medical Association (AMA).

#### *ATCOR Reimbursement*

In 2016, the AMA approved a Category I CPT code for PWA which was submitted by the Renal Physicians Association (RPA). PWA performed with our SphygmoCor XCEL physician in-office setting is reported with this code:

- *CPT Code 93050: Arterial pressure waveform analysis for assessment of central arterial pressures, includes obtaining waveform(s), digitization, and application of nonlinear mathematical transformations to determine central arterial pressures and augmentation index, with interpretation and report, upper extremity artery, non-invasive*

#### *CONNEQT Reimbursement*

At launch, the CONNEQT Pulse and associated physician portal are anticipated to provide greater location flexibility. It is expected that physicians and other health care providers will be able to bill health insurance companies with a variety of CPT codes based on the type and location of the service (office or home).

It is expected that the CONNEQT Pulse, may be used for PWA in a physician office setting and CPT Code 93050 may be used to report this service.

CONNEQT Pulse may also be used in a patient's home. If the physician orders remote physiologic monitoring (RPM) as part of a treatment plan, the services may be reported and reimbursed with the RPM codes. If the patient tracks and reports their blood pressure, the self-measured blood pressure (SMBP) CPT codes may also be used.

RPM allows patients to be monitored in their homes while physicians and health care providers track physiologic parameters such as blood pressure or central blood pressure and implement changes to treatment as appropriate. RPM is billed monthly (with a minimum of 16 days of data transmission out of 30 days). Two CPT codes are available to report set up and monitoring with the device and two codes for cumulative physician time during the month. A summary of these codes is as follows:

- *99453 Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment.*
- *99454 Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days.*
- *99457 Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes.*
- *99458 Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure).*

To support the Target BP Program developed by the AMA and AHA, 2 CPT codes were created in 2020 for SMBP measurement. These codes cannot be reported in the same period as RPM codes and cannot be reported on the same day as a regular office visit, also known as an evaluation and management service.

- *99473 Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration*
- *99474 Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient*

When physicians or other health care providers bill for RPM or SBMP, it is reported on a claim form to the patient's insurance company. Depending on the patient's health benefits, and if the physician is in-network or out-of-network, the insurance company will pay the physician for the service and charge the patient a co-payment. The co-payment amount depends on the patient's plan. The typical Medicare co-payment amount is 20%.

Both RPM and SMBP codes are relatively new, created in 2019 and 2020, respectively. The benefits of virtual care were established during the pandemic, and it is our belief that payor coverage of RPM will expand. Our goal is to achieve nationwide payor reimbursement RPM using our technology by demonstrating clinical value in specific patient populations, such as hypertensive disorders of pregnancy and CKD, where there may be serious consequences of unmanaged hypertension, and for inclusion of vascular health parameters in clinical practice guidelines.

#### ***On-Going Clinical Research Utilizing SphygmoCor XCEL***

We are currently involved in ongoing several studies through the provision of SphygmoCor XCEL devices.

***The CARTESIAN study*** is the world's largest study on hypertension and COVID-19 and is sponsored by The Artery Society (an international organization promoting the advancement of knowledge and dissemination of information concerning the pathophysiology, pharmacology, epidemiology, detection, investigation and treatment of arterial structure and function). A total of 60 investigational centers in 30 countries are involved. The objective is to study the medium- and long-term effects (3-6 months and 1 year) of SARS-CoV-2 on arterial stiffness and central hemodynamics. SphygmoCor XCEL was selected to assess subjects' central pressure hemodynamics. A long-term (5 and 10-year) clinical follow-up will be planned to evaluate the risk of CV events related to arterial stiffness and central hemodynamics in COVID-19 survivors.

***Philip Morris*** is conducting a study to evaluate effects of switching from cigarette smoking to tobacco heating system (THS) use for at least two years compared to cigarette smoking with the hypothesis that THS will lead to improvements in multiple endpoints. Central hemodynamics, specifically augmentation index, as measured by our SphygmoCor XCEL is included as an endpoint. ATCOR has been contracted to provide SphygmoCor XCEL systems and data management. This study is in the process of expanding its scope with the potential for an additional 18 sites in an additional three countries added to their recruitment activity. This study has just expanded to an additional 18 sites across three countries to expedite their recruitment and trial enrollment.

***UK's National Health Services*** is assessing the effects of arterial stiffness on patients with heart failure and chronic kidney disease. The ATCOR SphygmoCor System provides Arterial Stiffness and Central Aortic Blood Pressure parameters as part of the overall assessment of patients.

***AstraZeneca Panacea Trial*** is a single site trial for 150 adult patients (male and female) with heart failure and left ventricle <50%. This trial uses the SphygmoCor system for visit data collection.

## Engineering, Research & Development

We maintain our principal engineering facility in our Sydney-based head office in Australia. We also have two research and development facilities located in Sydney. One research facility, located in our Sydney head office is focused on general research and development for our SphygmoCor enabled devices, solutions, and integrations. Our research and development activities are focused on:

- **Improvements and extensions to existing products and services.** We are continuously working to improve the medical accuracy, validation, and scientific foundation for all our products and solutions.
- **Advancing our technology offering.** Our product pipeline includes multiple new product offerings in home, medical, and wearable solutions. A significant part of our research and development is dedicated to the underlying scientific validation of these new products including biometric sensor research.
- **Physician workflow optimization.** We have internal initiatives that are focused on optimizing workflow in the healthcare practice through easier patient enrollment and integration of our reports directly into electronic health records.
- **Data analytics.** We are focused on improving and enhancing our digital and SaaS based solutions, backend machine-learned analytic platform, and building on our core competency in vascular health analytics.
- **Developing clinical evidence.** We are involved in clinical & patient studies to further validate the benefits of central blood pressure and related parameters, and to expand indications for use.
- **Continuing to solidify our footprint in digital healthcare.** We are continuing to look for ways to create unique and disruptive opportunities in digital healthcare, including expansion of indications for our technology and new, potential therapeutic applications.

We also utilize the Blood Pressure and Arterial Function (BPAF) Laboratory at Macquarie University, a department that we work with on a contractual, as-needed basis, to serve as an independent body to recruit human subjects and validate the performance of our wearable and cuffless blood pressure solutions.

Our research and development department consists of software development, algorithm and product development, regulatory affairs, and clinical research. We spent US\$2.8 million and US\$1.3 million on research and development for FY2022 and FY2021, respectively. Our research and development expenditure for the last two years is as follows:

	<u>2022</u>	<u>2021</u>
	US\$	US\$
<b>Research &amp; development</b>		
Personnel costs	1,217,555	848,479
Third party costs	1,197,242	341,016
Production overhead	398,542	120,670
<b>Total Research &amp; development</b>	<b>2,813,339</b>	<b>1,310,165</b>
Cash Payments for InHealth Investment* - US based investment	-	-
<b>TOTAL EXPENDITURE ON INVESTMENTS</b>	<b>2,813,339</b>	<b>1,310,165</b>

\* Balance of inHealth payments as well as Blumio investment payments made prior to FY2021.

The personnel costs expense is largely comprised of hiring and maintaining research and development staff and consultants. The increase in personal costs in FY2022 was mainly due to investment in a US product development team.

The third party costs expense is comprised of external software development, contract manufacturer co-development costs. These expenses are predominantly US based, with some Australian expenditure. The third party cost expense also includes co-development costs paid to Andon and Fenda.

The production overhead expense was predominantly Australian based in FY2021. This expense increased in FY2022 mainly due to investment in US product development operations.

The research and development expenses are predominantly financed from Company equity raises. The Company also received a 43.5% rebate of some of its Australian based research and development expenditure, of which finance facilities have been used in order to secure funds prior to the required expenditure.

## Competition

We operate in a large and fragmented industry, subject to change and affected by new product introductions, results of clinical research, corporate combinations and other factors. For our ATCOR business, we view as competitors those companies whose primary business is developing and marketing central blood pressure and arterial stiffness measurement devices and services for research and clinical trials. We principally compete with 80 Beats Medical, Uscom Limited and IEM GmbH. For our CONNEQT business, we view as competitors those companies whose primary business is developing and marketing blood pressure monitoring devices and services targeting in-office, home, and remote patient monitoring applications. We principally compete with GE HealthCare, Philips Healthcare, Hill-Rom Holdings, Inc (which was acquired by Baxter International), A&D Medical, OMRON Corporation, Withings, and iHealth Labs.

We are also aware of some small start-up companies developing wearable “cuff-less” blood pressure monitoring devices such as Biobeat and Aktiia. Large medical device companies may continue to acquire or form alliances with these smaller companies in order to diversify their product offering and participate in the digital health space. Many of our competitors have substantially greater financial, manufacturing, marketing and technical resources than we do. Furthermore, many of our competitors have well-established brands, widespread distribution channels, broader product offerings and an established customer base. Competition may also emerge from large technology companies, such as Apple, Amazon, Facebook, Google, or Microsoft, who may wish to develop their own blood pressure monitoring solutions.

We believe our principal competitive advantages in our market include:

- Opportunities for physician billing with Category 1 CPT codes for non-invasive central PWA and RPM;
- FDA-cleared SphygmoCor technology capable of providing both non-invasive central blood pressure measurement and central aortic pulse waveform analysis in all adult populations;
- Scientific and research expertise in vascular biomarkers;
- Robust patent portfolio covering critical components and applications for cuff and sensor methods, including a novel wearable sensor method (patent pending) for vascular health assessment;
- Our focus on “medical grade” wearables that produce measurement and data that can demonstrate clinical validation and achieve FDA clearance, compared to our competitors who are more focused on general consumer health devices;
- Our focus on markets not serviced by our competitors in which we are well positioned due to our technology differentiation;
- Our brand and marketing expertise to be applied in creating what we believe to be a new category around “vascular health” with our CONNEQT brand; and
- Existing SphygmoCor customer base to market new CONNEQT products and solutions.

#### **Intellectual Property**

Our success depends in part on our ability to obtain, maintain, protect, and enforce our intellectual property rights, including our patent rights, preserve the confidentiality of our trade secrets, operate without infringing, misappropriating or otherwise violating the intellectual property rights of others and prevent others from infringing, misappropriating or otherwise violating our intellectual property rights. We rely on a combination of patent, trademark, trade secret, copyright and other intellectual property rights and measures, including invention assignment agreements and protective contractual provisions with our employees, contractors, consultants, suppliers, partners and other third parties, to protect the products and technology that we consider important to our business. We also rely on know-how and continuing technological innovation to develop and maintain our competitive position.

Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the U.S. and in jurisdictions outside of the U.S. related to our technology, inventions, improvements and products that are important to the development and implementation of our business. Our patent portfolio covers various aspects of our core technology and related devices and methods, as well as technology for future product lines.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. Generally, in the U.S., issued patents are granted a term of 20 years from the earliest claimed non-provisional or Patent Cooperation Treaty (“PCT”) filing date. In certain instances, a patent term can be adjusted to recapture a portion of delay by the U.S. Patent and Trademark Office (“USPTO”) in examining the patent application (patent term adjustment, or PTA). The adjusted term may be shortened if a patent is terminally disclaimed over another commonly owned patent. However, the life of the patent, and the protection it affords, is limited. In addition, we cannot provide any assurance that any patents will be issued from our pending or future applications or that any issued patents will adequately protect our current and future products. We also cannot predict the breadth of claims that may be allowed or enforced in our patents or whether such claims, if issued, will cover our products, provide sufficient protection from competitors or otherwise provide any competitive advantage. Any issued patents that we may own or in-license in the future may be challenged, invalidated, narrowed, held unenforceable, infringed or circumvented.

Our patent portfolio as of December 31, 2022 includes approximately 10 owned issued and non-expired U.S. patents, 3 pending non-provisional U.S. patent applications, 9 issued and non-expired foreign patents, 1 pending PCT application and 3 other pending foreign patent applications. These owned patents, and the patents, if any, that issue from these patent applications are projected to expire between 2025 and 2042, in each case without taking into account any possible PTA and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. Issued European Patent 2566387 is presently subject to opposition proceedings in the European Patent Office. We have received a preliminary ruling and based on such preliminary ruling, we do not expect the opposition proceedings to result in significant loss of patent scope, if any.

**Issued patent portfolio:**

Jurisdiction	Patent No.	Issuance Date	Expiration Date
US	7,628,758	12/8/2009	6/7/2025
US	7,442,169	10/28/2008	3/4/2025
US	8,273,030	9/25/2012	11/27/2026
US	8,679,025	3/25/2014	1/6/2031
US	8,112,150	2/7/2012	12/27/2029
US	9,314,170	4/19/2016	3/27/2032
US	9,974,450	5/22/2018	5/5/2031
US	9,220,903	12/29/2015	12/16/2034
US	11,006,842	5/18/2021	4/10/2039
US	10,835,132	11/17/2020	6/13/2039
Japan	JP5893006	3/4/2016	5/6/2031
Japan	JP7123070	8/12/2022	3/16/2038
Japan	JP7187493	12/2/2022	2/28/2038
Japan	JP7160832	10/17/2022	4/3/2038
China	CN201880032292.3	08/02/2022	3/15/2038
China	CN201880036028.7	8/23/2022	4/2/2038
China	201880028771.8	10/11/2022	2/27/2038
Europe	EP2566387	9/16/2020	5/6/2031
Australia	2018235369	11/03/2022	03/16/2038

**Pending patent portfolio:**

Jurisdiction	Application No.
US	17/832,885
US	17/331,873
US	17/220,200
Australia	2018227095
Australia	2018252273
Europe	18784766.0
WO	PCT/IB2021/054655

Our patent portfolio, including issued patents and patent applications, is generally directed to: non-invasive central blood pressure monitoring, clinically reliable non-invasive assessment of cardiac and arterial functions, the accuracy of blood pressure monitoring using harmonic waveform pulse analysis and data collected from the general adult population, and adaptations of this core technology to enable use in wearable and cloud applications.

Our trademark portfolio as of December 31, 2022 contains 11 U.S. trademark registrations, 5 pending U.S. trademark applications, 27 international trademark registrations, and 10 pending international trademark applications.

*List of trademarks:*

- Arty

<b>Jurisdiction</b>	<b>Registration / Application No.</b>
Australia	2055054 (Pending)
Canada	1999071 (Pending)
China	43780747
EU	018164105
Japan	6331803
Mexico	2114050
United States	6,336,081

- ArtyAge

<b>Jurisdiction</b>	<b>Registration / Application No.</b>
Australia	1663385
China	1663385
EU	1663385
New Zealand	1663385 (Pending)
United States	90/639,448 (Pending)
WIPO	1663385

- ASF

<b>Jurisdiction</b>	<b>Registration / Application No.</b>
United States	6,584,473

- BPV+

<b>Jurisdiction</b>	<b>Registration / Application No.</b>
United States	6,366,001

- CONNEQT

<b>Jurisdiction</b>	<b>Registration / Application No.</b>
Australia	1692985 (Pending)
Canada	1692985 (Pending)
China	1692985 (Pending)
EU	1692985 (Pending)
Japan	1692985 (Pending)
Mexico	1692985 (Pending)
New Zealand	1692985 (Pending)
United Kingdom	1692985 (Pending)
United States	90/686,910 (Pending)
WIPO	1692985

- CompleteBP

<b>Jurisdiction</b>	<b>Registration / Application No.</b>
Australia	1582773
Canada	1173993
China	1582773
France	224857087 (Pending)
Italy	302022000065765 (Pending)
Japan	1582773 (Pending)
New Zealand	1174563
Spain	4166718 (Pending)
United Kingdom	1582773
United States	6992149
WIPO	1582773

- eCAP

<b>Jurisdiction</b>	<b>Registration / Application No.</b>
Australia	1663142 (Pending)
China	1663142 (Pending)
EU	1663142
New Zealand	1211124
United States	6,365,999
WIPO	1663142



- Exercise Capacity

<b>Jurisdiction</b>	<b>Registration / Application No.</b>
Australia	1663390 (Pending)
China	1663390 (Pending)
EU	1663390 (Pending)
New Zealand	1663390 (Pending)
United States	6,311,129
WIPO	1663390

- Heart Performance Index

<b>Jurisdiction</b>	<b>Registration / Application No.</b>
United States	6,303,086

- HPX

<b>Jurisdiction</b>	<b>Registration / Application No.</b>
United States	6,412,706

- HSX

<b>Jurisdiction</b>	<b>Registration / Application No.</b>
Australia	1663383
China	1663383
EU	1663383
New Zealand	1211146
United States	97/094,978 (Pending)
WIPO	1663383

- SphygmoCor

<b>Jurisdiction</b>	<b>Registration / Application No.</b>
United States	2,193,986

- Track What Matters

<b>Jurisdiction</b>	<b>Registration / Application No.</b>
Australia	2273954
EU	1663636 (Pending)
New Zealand	1663636 (Pending)
United States	97/139,016 (Pending)
WIPO	1663636

- truHR

<b>Jurisdiction</b>	<b>Registration / Application No.</b>
Australia	1663389
China	1663389
EU	1663389 (Pending)
New Zealand	1211149
United States	6,366,000
WIPO	1663389

- truHRV

<b>Jurisdiction</b>	<b>Registration / Application No.</b>
United States	6,714,389

- VitalsRisk

<b>Jurisdiction</b>	<b>Registration / Application No.</b>
United States	6,584,474



<b>Jurisdiction</b>	<b>Registration / Application No.</b>
Australia	1692760 (Pending)
Canada	1692760 (Pending)
China	1692760 (Pending)
EU	1692760
Japan	1692760 (Pending)
Mexico	1692760 (Pending)
New Zealand	1692760 (Pending)
United Kingdom	1692760
United States	90/741,045 (Pending)
WIPO	1692760



<b>Jurisdiction</b>	<b>Registration / Application No.</b>
Australia	2083976
Canada	2024482 (Pending)
China	44137828
China	45786340
China	45786339
EU	018236258
Japan	6391111
Mexico	2221288
Mexico	2117917
Mexico	2221289
United States	6,442,185
United States	88/899,792 (Pending)

We also seek to maintain certain intellectual property and proprietary know-how as trade secrets, and generally require our partners to execute non-disclosure agreements prior to any substantive discussions or disclosures of our technology or business plans. Our trade secrets include proprietary algorithms and operational processes.

### Manufacturing, Supply & Operations

#### Overview

Due to the nature of the products in our portfolio, we strategically and flexibly leverage third-party manufacturing resources based on their respective technical and operational expertise.

<u>Product</u>	<u>Type</u>	<u>Marketed Under</u>	<u>Legal Manufacturer*</u>	<u>Contract Manufacturer*</u>
SphygmoCor XCEL	Medical	ATCOR	ATCOR Medical Pty Ltd	CircuitWise Electronics Manufacturing
CONNQQT Pulse	Medical	CONNQQT	ATCOR Medical Pty Ltd	Andon Health Co. Ltd.
CONNQQT Band	Medical	CONNQQT	ATCOR Medical Pty Ltd	Shenzhen Fenda Smart Technology Limited
Oscar 2™ with “SphygmoCor Inside”	Medical (OEM)	SunTech Medical	SunTech Medical	N/A
TicWatch GTH Pro	Consumer (OEM)	Mobvoi	Mobvoi	N/A

\*The Legal Manufacturer is the manufacturing party that bears all responsibility as relates to quality management of a product to ensure it complies with the regulatory requirements. Until a company gets to a certain size where its production volume warrants creation of a manufacturing facility, a Legal Manufacturer would outsource the manufacturing function to a Contract Manufacturer to produce a physical product at scale.

#### *SphygmoCor XCEL*

SphygmoCor XCEL is a medical device that is marketed under the ATCOR brand, and ATCOR Medical Pty Ltd is the legal manufacturer that is responsible for the Quality Management System (QMS) under which the manufacturing and release of SphygmoCor XCEL devices are controlled. ATCOR Medical Pty Ltd has received ISO 13485:2016 certification for its QMS. Manufacturing of the components of SphygmoCor XCEL is provided by an electronics manufacturing service provider, CircuitWise Electronics Manufacturing (CircuitWise). We have a Quality and Manufacturing Services Agreement with CircuitWise. CircuitWise has received ISO 13485:2016 and ISO 9001:2015 certifications for its QMS, and its manufacturing process for the product is compliant with the QMS put in place by ATCOR Medical Pty Ltd. There are certain critical components and sub-assemblies sourced by other vendors. The vendors for these materials are qualified through stringent evaluation and testing of their performance.

We implement a strict no-change policy with our contract manufacturers for critical components to ensure that key components are not changed without our approval.

### ***CONNEQT Pulse***

The CONNEQT Pulse is a medical device that will be marketed under the CONNEQT brand, and Andon Health Co., Ltd. (“Andon”), based in Tianjin, China, is the legal manufacturer that is responsible for the QMS under which the manufacturing and release of the CONNEQT Pulse devices will be controlled. Andon has received EN ISO 13485:2016 certification for its QMS. This product integrates SphygmoCor technology through a specially manufactured chip which contains proprietary firmware developed by ATCOR Medical Pty Ltd.

We entered into a Co-Development and Purchasing Agreement (“Co-Development Agreement”) with Andon on August 30, 2020 for the development of CONNEQT Pulse and Andon’s purchase of certain manufactured chips from us in connection with Andon’s development activities. We are the sole and exclusive owner of all intellectual property rights related to the CONNEQT Pulse. The Co-Development Agreement does not grant Andon any license, interest, or right in respect of any of our intellectual property. We will pay Andon a Target Development Cost (as defined in the Co-Development Agreement) in four payments based on certain development milestones. As of June 21, 2023, we have paid Andon an aggregate of \$207,000 in fees, with another \$62,000 expected over the course of the next 12 months. In connection with Andon’s purchase of our chips, Andon pays us a per unit price subject to certain bulk discounts and a minimum order quantity. The term of the Co-Development Agreement is three years, and may be renewed or extended upon the written agreement of the parties at least three months before the end of the term. Either party may terminate the Co-Development Agreement (a) upon sixty days written notice to the other party in the event that certain development activities cannot be successfully completed, (b) for an uncured material breach on thirty days prior written notice, and (c) certain insolvency matters.

### ***CONNEQT Band***

Subject to FDA clearance, the CONNEQT Band will be a medical device that will be marketed under the CONNEQT brand, and ATCOR Medical Pty Ltd will be the legal manufacturer that is responsible for the QMS under which vendors for manufacturing and release of the CONNEQT Band devices will be controlled. ATCOR Medical Pty Ltd has received EN ISO 13485:2016 certification for its QMS. There is no guarantee that the FDA will grant clearance for the CONNEQT Band or that it will do so on the timeline that we have indicated.

We currently have, as of September 16, 2021, a Product Development and Manufacturing Agreement (the “Development Agreement”) in place with Shenzhen Fenda Smart Technology Limited (“Fenda”) under which Fenda designs, develops and manufactures our CONNEQT Band devices based on product specifications provided by us, and we commit to purchase certain quantities of CONNEQT Band devices from Fenda. Under the terms of this agreement, we are required to pay Fenda for design and development work as well as any tooling, samples, certifications, etc. that are needed. As of June 21, 2023, we have paid Fenda an aggregate of \$341,000 in fees, with another \$226,000 expected over the course of the next two years. Fenda has agreed to provide us with a minimum six-month rolling forecast of our monthly product requirements. We place purchase orders with Fenda at least three months prior to the expected delivery date of said order, where such purchase orders are paid on a per unit basis and may be subject to a minimum order quantity. We own all designs, copyrights, patents, technology, know-how and other intellectual property rights arising from and subsisting in the Product (as defined in the Development Agreement). The term of the Development Agreement is three years and either party may terminate the Development Agreement may terminate for an uncured material breach on thirty days prior written notice. Upon termination, we are obligated to purchase Product subject to a purchase order. The manufacturing process of Fenda for the CONNEQT Band will be compliant with the QMS put in place by Fenda, who has received EN ISO 13485:2016 certification for its QMS.

On November 5, 2021 we entered into a Collaboration Agreement with LifeQ B.V. (“LifeQ”), a provider of on-device and cloud-based health information metrics derived from PPG sensors, to co-develop the CONNEQT Band. We and LifeQ each contribute certain health parameters into the CONNEQT Band through a CONNEQT mobile application developed by us with input from LifeQ. We are responsible for developing and creating the CONNEQT Band and leading the joint development of the CONNEQT mobile application. LifeQ is responsible for developing and creating certain general health biometrics to run on the CONNEQT Band and a cloud based health information system that is utilized by us in the CONNEQT mobile application to provide a selection of health parameters, biometrics, and health solutions. We are responsible for determining the commercialization strategies for the CONNEQT Band, subject to certain LifeQ consultation with respect to certain joint promotional assets, and we control sales and distribution of the CONNEQT Band. In connection with LifeQ’s collaboration, we are required to pay LifeQ an initial one-time consulting services fee in and three installments scheduled according to certain development events. As of June 21, 2023, we have paid LifeQ an aggregate of \$50,000 in fees, with another \$150,000 expected over the course of the next two years. Upon commercialization of the CONNEQT Band and related CONNEQT mobile application services, we are entitled to recoup the foregoing consulting services fee through sales of the CONNEQT Band and subscriptions to the CONNEQT mobile applications and, thereafter, share any subscription revenue generated by CONNEQT mobile application services depending on which parties’ platform generates the subscription revenue. LifeQ grants to us a world-wide, non-exclusive, irrevocable, sublicensable, fully paid license, under any and all intellectual property rights owned, licensable, or otherwise controlled by LifeQ to exploit the CONNEQT Band and CONNEQT mobile application. The initial term of the Collaboration Agreement is five years, and the term automatically renews for successive periods of one year unless terminated by either party with six months written notice prior to the end of the then-current term. Either party may terminate for an uncured material breach on sixty days prior written notice or certain insolvency matters.

### ***Oscar 2™ with “SphygmoCor Inside”***

SunTech Oscar 2™ with “SphygmoCor Inside” is a medical device that is marketed under the SunTech brand, and SunTech is the legal manufacturer and owner that is responsible for the QMS under which the manufacturing and release of the SunTech Oscar 2™ with “SphygmoCor Inside” devices are controlled. This product integrates SphygmoCor technology through a specially manufactured chip which contains proprietary firmware developed by ATCOR Medical Pty Ltd.

The manufacturing operations above for medical devices are subject to regulatory requirements of the FDA’s Quality System Regulation, or QSR, for medical devices sold in the U.S., set forth at 21 CFR part 820, and the Medical Devices Directive 93/42/EEC, or MDD, which is required for doing business in the European Union, or EU. The FDA enforces the QSR through periodic unannounced inspections that may include our manufacturing partners’ facilities or those of our suppliers. We are audited in compliance with EU MDD and MDSAP (Medical Device Single Audit Program). Our EU Notified Body for SphygmoCor XCEL, the British Standards Institution, or BSI, (Notified Body #2797) enforces the MDD (compliant with the transitional provisions of MDR) through both scheduled and unscheduled inspections of our manufacturing facilities. Our EU Notified Body for CONNEQT Pulse, iHealth Labs Europe SAS (Notified Body #0197) will enforce the MDR through both scheduled and unscheduled inspections of Andon’s manufacturing facilities. The EU Notified Body for CONNEQT Band will be determined in the near future.

Our failure or the failure of our manufacturing partners and suppliers to maintain compliance with either the QSR or MDD/MDR requirements could result in the shutdown of our manufacturing operations or the recall of our products, which would harm our business. In the event that one of our suppliers fails to maintain compliance with our or governmental quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result.

BSI, an accredited certifying body, inspected our manufacturing operations for SphygmoCor XCEL, including manufacturing activities at CircuitWise and the QMS maintenance at ATCOR Medical Pty Ltd, in May 2022 as part of an annual surveillance audit. Along with this, BSI ensured compliance with EU MDD and MDSAP (except for Brazil and Japan). No non-conformance was identified at the manufacturing site during the audit that required any remedial action. There were four non-conformances identified with respect to the QMS maintenance, all of which have been duly addressed to the satisfaction of the certification body.

### ***TicWatch GTH Pro***

The TicWatch GTH Pro, which features Arty Heart Health, is a consumer product that is marketed under the Mobvoi brand, and Mobvoi is the legal manufacturer for TicWatch GTH Pro. This is the only product in our current device portfolio which is not subject to requirements intended for medical devices as regulated by the FDA, EU notified bodies and other regulators. Arty Heart Health is a consumer-facing derivative of our proprietary SphygmoCor software and firmware.

In all cases, order quantities and lead times for components purchased from suppliers are based on our forecasts derived from historical demand and anticipated future demand. Lead times for components may vary significantly depending on the size of the order, time required to fabricate and test the components, specific supplier requirements and current market demand for the components and subassemblies.

***All Products***

Certain of our products, such as the SphygmoCor XCEL and CONNEQT Pulse, contain specially-programmed microchips that act as the central processor in these products. These microchips are programmed with proprietary firmware using off-the-shelf (OTS) microcontroller units (MCU). From a design viewpoint, these specific OTS MCUs are used for their embedding versatility, speed to market and overall cost-effectiveness when compared to creating in-house MCUs.

Currently, we are supplied with our MCUs from one supplier. We do not have a formal contract with this supplier because all MCUs are OTS and orders are fulfilled using purchase orders. We are not materially dependent on this supplier for the supply of MCUs, nor is this supplier the only distributor that we can engage for the procurement of the MCUs. We are aware of several reputable distributors that also carry the specific MCU. Additionally, we can create the MCU in-house if we need to. However, we have found that it is impractical to create bespoke MCU designs internally due to high engineering expenses and slow speed to market.

We do not source specific raw materials for our SphygmoCor XCEL. The microchips come fully assembled from our supplier. As we have seen availability of the microchips fluctuate, we have implemented a policy of purchasing large bulk orders of microchips. We typically review our forecasts for the volume of SphygmoCor XCEL products and purchase enough to support that amount of builds. The price of microchips has also fluctuated, especially during and since the COVID pandemic. This price fluctuation has led to an increase in cost and lead time. We manage these price fluctuations by ordering approximately 12 months in advance to ensure we pay a lower price.

For supporting global customers of SphygmoCor XCEL, we have a centrally located site in Naperville, Illinois, which manages the sales and distribution worldwide. The SphygmoCor XCEL devices are manufactured by CircuitWise and shipped to Naperville for inventory and global distribution management.

For supporting customers of CONNEQT brand products in the U.S., we plan to set up a fulfillment center based in Orange County, California. For instance, our CONNEQT Pulse devices are planned to be manufactured in China, shipped to the Port of Long Beach via ocean freight, and transported to our fulfillment center in Orange County. This Southern California facility is expected to ship orders for the West Coast and the Midwest. Additionally, we plan to utilize Amazon's Multi-Channel Fulfillment (MCF) platform for East Coast orders. Leveraging the MCF network will shorten transit time for orders while minimizing logistical overhead.

***Our commercial products and products in development***

The following table summarizes the Company's products and the marketing authorization(s) in applicable countries or jurisdictions:

<b>Product</b>	<b>Authorized Markets</b>
SphygmoCor XCEL	United States, EU Countries, United Kingdom, Australia, Canada, People's Republic of China, Japan
SunTech Oscar 2™ with "SphygmoCor Inside"*	United States, EU Countries, United Kingdom, Australia, Canada, People's Republic of China, Japan
CONNEQT Pulse	United States, EU Countries (in preparation), Australia (in preparation), People's Republic of China (in preparation), other countries to follow
CONNEQT Band	United States (anticipated), other countries to follow

\* SunTech Oscar 2™ with "SphygmoCor Inside" is a device that is owned and manufactured by SunTech Medical.

### *FDA regulation of medical devices*

Our products and operations are subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations, as well as other federal, state and local regulatory authorities in the United States, as well as foreign regulatory authorities. The FDA regulates, among other things, product design and development, pre-clinical and clinical testing, manufacturing, packaging, labeling, storage, record keeping and reporting, clearance or approval, marketing, distribution, promotion, import and export, and post-marketing surveillance in the United States to assure the safety and effectiveness of medical products for their intended use.

Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FDCA, also referred to as a 510(k) clearance, or approval from the FDA of a PMA application. Both the 510(k) clearance and PMA processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees, unless an exemption is available.

FDA classifies medical devices into one of three classes – Class I, Class II or Class III – depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I devices are those for which safety and effectiveness can be reasonably assured by adherence to the FDA's general controls for medical devices, which include compliance with the applicable portions of FDA's current good manufacturing practices for devices, as reflected in of the Quality System Regulation, or QSR, establishment registration and device listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices, also called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the FDA's general controls and any other special controls deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, patient registries, product-specific FDA guidance documents, special labeling requirements and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. Due to the level of risk associated with Class III devices, the FDA's general controls and special controls alone are insufficient to assure their safety and effectiveness. Devices placed in Class III generally require the submission of a PMA application, demonstrating the safety and effectiveness of the device which must be approved by the FDA prior to marketing, or the receipt of a 510(k) de novo classification, which provides for the reclassification of the device into Class I or II. The PMA process is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.



If a new medical device does not qualify for the 510(k) premarket notification process because no predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the “Request for Evaluation of Automatic Class III Designation,” or the de novo classification process. This process allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. The FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk and requires PMA or that general controls would be inadequate to control the risks and special controls cannot be developed.

Obtaining FDA marketing authorization, de novo down-classification, or approval for medical devices is expensive and uncertain, and may take several years, and generally requires significant scientific and clinical data.

#### ***Investigational device process***

In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an IDE application. Some types of studies deemed to present “non-significant risk” are deemed to have an approved IDE once certain requirements are addressed, and IRB approval is obtained. If the device presents a “significant risk” to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials, and although the FDA’s approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product’s safety and effectiveness, even if the trial meets its intended success criteria.

All clinical trials must be conducted in accordance with the FDA’s IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA’s good clinical practice regulations for institutional review board approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA.

The results of clinical testing may be unfavorable, or, even if the intended safety and effectiveness success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- The FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- Patients do not enroll in clinical trials at the rate expected;
- Patients do not comply with trial protocols;
- Patient follow-up is not at the rate expected;

- Patients experience adverse events;
- Patients die during a clinical trial, even though their death may not be related to the products that are part of the trial;
- Device malfunctions occur with unexpected frequency or potential adverse consequences;
- Side effects or device malfunctions of similar products already in the market that change the FDA's view toward approval of new or similar PMAs or result in the imposition of new requirements or testing;
- Institutional review boards and third-party clinical investigators may delay or reject the trial protocol;
- Third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreement, investigational plan, good clinical practices, the IDE regulations, or other FDA or IRB requirements;
- Third-party investigators are disqualified by the FDA;
- We or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans, or otherwise fail to comply with the IDE regulations governing responsibilities, records, and reports of sponsors of clinical investigations;
- Third-party clinical investigators have significant financial interests related to us or our study such that the FDA deems the study results unreliable, or we or investigators fail to disclose such interests;
- Regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- Changes in government regulations or administrative actions;
- The interim or final results of the clinical trial are inconclusive or unfavorable as to safety or effectiveness; or
- The FDA concludes that our trial design is unreliable or inadequate to demonstrate safety and effectiveness.

#### *The 510(k) clearance process*

Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent," as defined in the statute, to a legally marketed predicate device.

A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. A device is considered to be substantially equivalent if, with respect to the predicate device, it has the same intended use, and has either (i) the same technological characteristics; or (ii) different technological characteristics, but the information provided in the 510(k) submission demonstrates that the device does not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes, but not always, required to support substantial equivalence.

Before the FDA will accept a 510(k) premarket notification for substantive review, the FDA will first assess whether the submission satisfies a minimum threshold of acceptability. If the FDA determines that the 510(k) submission lacks necessary information for substantive review, the FDA will issue a "Refuse to Accept" letter which generally outlines the information the FDA believes is necessary to permit a substantive review and to reach a determination regarding substantial equivalence. An applicant must submit the requested information before the FDA will proceed with additional review of the submission. If a 510(k) submission is accepted for substantive review, the Medical Device User Fee Amendments sets a performance goal of 90 days for FDA review of a 510(k) submission, but the review time can be delayed if FDA raises questions or requests additional information during the review process. As a practical matter, clearance often takes longer, and clearance is never assured. Thus, as a practical matter, clearance often takes longer than 90 days. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not “substantially equivalent” to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA process, or seek reclassification of the device through the de novo process. A manufacturer can also submit a petition for direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

Medical devices can only be marketed for the indications for which they are cleared or approved. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application or de novo classification. The determination as to whether or not a modification constitutes such a change is initially left to the manufacturer using available FDA guidance; however, the FDA may review this determination to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until new 510(k) clearance or PMA is obtained. If the FDA disagrees with a manufacturer’s determination regarding whether a new premarket submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

#### ***The PMA process***

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the substantive review. The FDA, by statute and by regulation, has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant’s response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (e.g., major deficiency letter) within a total of 360 days. Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee’s recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- The device may not be shown safe or effective to the FDA’s satisfaction;
- The data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- The manufacturing process or facilities may not meet applicable requirements; and
- Changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may also require post-market surveillance for certain devices cleared under a 510(k) notification, such as implants or life-supporting or life-sustaining devices used outside a device user facility. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use. Significant modifications to the manufacturing process, labeling and design for a device which has received approval through the PMA process may require submission of a new PMA application or PMA supplement prior to marketing.

#### ***Ongoing regulation by the FDA***

Even after the FDA permits a device to be marketed, numerous regulatory requirements apply, including but not limited to:

- establishment registration and device listing;
- the QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation, and other quality assurance procedures during the manufacturing process;
- labeling regulations, advertising and promotion requirements, restrictions on sale distribution or use of a device, each including the FDA general prohibition against the promotion of products for any uses other than those authorized by the FDA, which are commonly known as "off label" uses;
- the Medical Device Reporting, or MDR regulation, which requires that manufactures report to the FDA if their device may have caused or contributed to a death or serious injury or if their device malfunctioned and the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;
- medical device corrections and removal reporting regulations, which require that manufactures report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the FD&C Act that may present a risk to health;
- recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- an order of repair, replacement or refund;
- device tracking requirements; and
- post market study and surveillance requirements.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) or possibly a PMA. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with our determination not to seek a new 510(k) clearance, the FDA may retroactively require us to seek 510(k) clearance or possibly a PMA. The FDA could also require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or a PMA is obtained. Also, in these circumstances, we may be subject to significant regulatory fines and penalties.

Some changes to an approved PMA device, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new PMA application or PMA supplement, as appropriate, before the change can be implemented. Supplements to a PMA often require the submission of the same type of information required for an original PMA application, except that the supplement is generally limited to that information needed to support the proposed change from the device covered by the original PMA. The FDA uses the same procedures and actions in reviewing PMA supplements as it does in reviewing original PMA applications.

FDA regulations require us to register as a medical device manufacturer with the FDA. Additionally, some states also require medical device manufacturers and/or distributors doing business within the state to register with the state or apply for a state license, which could subject our facility to state inspection as well as FDA inspection on a routine basis for compliance with the QSR and any applicable state requirements. These regulations require that we manufacture our products and maintain related documentation in a prescribed manner with respect to manufacturing, testing and control activities. Further, the FDA requires us to comply with various FDA regulations regarding labeling. Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or state authorities, which may include any of the following sanctions:

- warning or untitled letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications, voluntary or mandatory recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- delay in processing, clearing or approving submissions or applications for new products or modifications to existing products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries;
- suspension or withdrawal of FDA approvals or clearances that have already been granted; and
- criminal prosecution.

Newly discovered or developed safety or effectiveness data may require changes to a product's labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory clearance or approval of our products under development.

Our facilities, records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. Failure to comply with the applicable United States medical device regulatory requirements could result in, among other things, warning letters, untitled letters, fines, injunctions, consent decrees, civil penalties, unanticipated expenditures, repairs, replacements, refunds, recalls or seizures of products, operating restrictions, total or partial suspension of production, the FDA's refusal to issue certificates to foreign governments needed to export products for sale in other countries, the FDA's refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product clearances or approvals and criminal prosecution.

When the FDA conducts an inspection, the inspectors will identify any deficiencies they believe exist in the form of a notice of inspectional observations, or Form FDA 483. If we receive a notice of inspectional observations or deficiencies from the FDA following an inspection, we would be required to respond in writing, and would be required to undertake corrective and/or preventive or other actions in order to address the FDA's or other regulators' concerns. Failure to address the FDA's concerns may result in the issuance of a warning letter or other enforcement or administrative actions.

#### *International medical device premarket authorization process*

The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Our products are regulated in the European Union as medical devices per European Union Directive 93/42/EEC, also known as the Medical Device Directive, or MDD. The MDD sets out the basic regulatory framework for medical devices in the European Union. The system of regulating medical devices operates by way of a certification for each medical device. Each certified device is marked with the CE mark which shows that the device has a Certificat de Conformité. There are national bodies known as Competent Authorities in each member state which oversee the implementation of the MDD within their jurisdiction. The means for achieving the requirements for the CE mark vary according to the nature of the device. Devices are classified in accordance with their perceived risks, similarly to the U.S. system. The class of a product determines the conformity assessment required before the CE mark can be placed on a product. Conformity assessments for our products are carried out as required by the MDD. Each member state can appoint Notified Bodies within its jurisdiction. If a Notified Body of a one-member state has issued a Certificat de Conformité, the device can be sold throughout the European Union without further conformance tests being required in other member states. The CE mark is contingent upon continued compliance with the applicable regulations and the quality system requirements of the ISO 13485 standard.

The new European Union Medical Devices Regulation 2017/745, or EU MDR, which was published in May 2017 with a transition period of three years, replaces the MDD and will expand and modify the pre-market and post-market obligations of the MDD. The EU MDR entered into application on May 26, 2021. The EU MDR imposes additional requirements on clinical evaluation process, safety, classification and performance of medical device products. We are currently preparing our submission for MDR and plan to submit in calendar year 2023. In addition to inspections by the FDA and other regulatory entities, we are also subject to periodic inspections by applicable European Notified Body with respect to regulatory requirements that apply to medical devices designed and manufactured by us and clinical trials sponsored by us. We are also certified to the Medical Device Single Audit Program (MDSAP) for the jurisdictions of the United States, Canada, and Australia which allows for one single audit performed by Notified Body to cover those jurisdictions with respect to quality systems.

### *Other U.S. regulatory matters*

Medical device companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Manufacturing, sales, promotion and other activities following product clearance or approval are subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the CMS, other divisions of the Department of Health and Human Services, the Department of Justice, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. For example, in the United States, sales, marketing and scientific and educational programs also must comply with state and federal fraud and abuse, anti-kickback false claims, transparency, government price reporting, anti-corruption, and health information privacy and security laws and regulations. Internationally, other governments also impose regulations in connection with their healthcare reimbursement programs and the delivery of healthcare items and services. These laws include the following:

- U.S. federal healthcare fraud and abuse laws generally apply to our activities because our products are covered under federal healthcare programs such as Medicare and Medicaid. The Anti-Kickback Statute is particularly relevant because of its broad applicability. The federal Anti-Kickback Statute makes it illegal for any person, including a prescription medical device manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular medical device, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Almost any financial arrangement with a healthcare provider, patient or customer could implicate the Anti-Kickback Statute. Statutory exceptions and regulatory safe harbors protect certain arrangements if specific requirements are met. The government can exercise enforcement discretion in taking action against arrangements that do not fit within a safe harbor. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Penalties for violations of the Anti-Kickback Statute include, but are not limited to, criminal, civil and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from Medicare, Medicaid and other federal healthcare programs. Our exclusion would mean that procedures using our products would no longer be eligible for reimbursement under federal healthcare programs;
- Another development affecting the healthcare industry is the increased use of the federal Civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. In recent years, the number of suits brought against healthcare companies by private individuals has increased dramatically. The federal civil and criminal false claims acts, including the civil FCA, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. No specific intent to defraud is required under the civil FCA. The criminal FCA provides for criminal penalties for submitting false claims, including imprisonment and criminal fines;
- The Civil Monetary Penalty Act of 1981 and implementing regulations impose penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- HIPAA prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- The FDCA, which prohibits, among other things, the adulteration or misbranding of medical devices;

- The federal Physician Payment Sunshine Act and its implementing regulations, which require applicable manufacturers of covered drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (CMS) of the U.S. Department of Health and Human Services (HHS) information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- The Foreign Corrupt Practices Act (FCPA) prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, if any, and to devise and maintain an adequate system of internal accounting controls for international operations;
- Analogous state and foreign laws and regulations, such as state anti-kickback, anti-referral, and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require certain biotechnology, pharmaceutical, and medical device companies to comply with the industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require applicable manufacturers to disclose or report certain information related to payments and other transfers of value to doctors and entities or sales, marketing, pricing, clinical trials, marketing expenditures and activities, and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions or safe harbors, it is possible that some of our activities, such as stock-option compensation paid to doctors that have entered into consulting agreements with us, could be subject to challenge under one or more of such laws. The growth of our business and sales organization and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to various interpretations. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. Also, we may be subject to private “qui tam” actions brought by individual whistleblowers on behalf of the federal or state governments. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant civil, criminal and administrative penalties, including damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.



### ***United States health care reform***

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage for the procedures associated with the use of our products or result in lower reimbursement for those procedures. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could significantly reduce our revenues from the sale of our products. Changes in healthcare policy, including changes in the implementation or the repeal of the ACA in the United States, could increase our costs, decrease our revenue and impact sales of and reimbursement and coverage for our current and future products. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. In particular, on December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and held oral arguments in November 2020. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, upholding the ACA. It is unclear how this Supreme Court decision, future litigation, other efforts to repeal and replace the ACA, and healthcare measures of the Biden administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers, which will remain in effect through 2031, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. Moreover, there recently has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

We believe that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third-party payors. Current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

### **Data privacy and security**

Medical device companies may be subject to U.S. federal and state health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon “covered entities” (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to the U.S. Department of Health and Human Services, or HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, or PHI, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance.

Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Personally identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California enacted the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA, among other things, created new data privacy obligations for covered companies and provided new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also created a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach.

Additionally, in November 2020, California voters passed the California Privacy Rights Act of 2020, or CPRA. The CPRA, which is expected to take effect on January 1, 2023 and create additional obligations with respect to certain data relating to consumers, significantly expands the CCPA, including by introducing additional obligations such as data minimization and storage limitations, granting additional rights to consumers, such as correction of personal information and additional opt-out rights, and creates a new entity, the California Privacy Protection Agency, to implement and enforce the law. The CCPA and CPRA may increase our compliance costs and potential liability. In addition to the CCPA, numerous other states' legislatures have passed or are considering similar laws that will require ongoing compliance efforts and investment.

The EU also has laws and regulations dealing with the collection, use and processing of personal data obtained from individuals in the EU, namely the EU General Data Protection Regulation, or GDPR. These regulations are often more restrictive than those in the United States and may restrict transfers of personal data to the United States unless certain requirements are met. The GDPR provides that EU member states may make their own further laws and regulations limiting the processing of genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition. Further, the United Kingdom's decision to leave the European Union has created uncertainty with regard to data protection regulation in the United Kingdom. As of January 1, 2021, we are also subject to the UK General Data Protection Regulation and UK Data Protection Act of 2018, which retains the GDPR in the United Kingdom's national law. Failure to comply with any of these obligations could expose us to significant fines.

### **Company Information**

We were formed in 1994 as ATCOR Medical, an Australian company, by Dr. Michael O'Rourke. In November 2005, we completed an initial public offering of our ordinary shares and listing of these shares on the Australian Securities Exchange, or the ASX, under the symbol "ACG." In May 2018, we changed our name to CardieX Limited, and began trading on the ASX under the symbol "CDX." We have four wholly-owned subsidiaries, including AtCor Medical Pty Limited incorporated under the laws of Australia, AtCor Medical Inc. incorporated under the laws of the state of Delaware, CardieX (Shanghai) Medical Technology Co., Ltd. incorporated under the law of China, and CONNEQT, Inc. incorporated under the laws of the state of Delaware. Our principal executive offices are located at Suite 301, 55 Lime St, Sydney 2000 and 184 Shuman Blvd #515, Naperville, IL 60563. Our Australian telephone number is +61 (2) 9874-8761, and U.S. telephone number is (630) 228-8871. Our principal website addresses are [www.cardiex.com](http://www.cardiex.com), [www.atcormedical.com](http://www.atcormedical.com), and [www.conneqthealth.com](http://www.conneqthealth.com). The information on, or that may be accessed through, our website is not incorporated by reference into this prospectus and should not be considered a part of this prospectus.

**Employees**

As of June 30, 2023, we had 43 full-time employees. None of our employees are represented by a labor union or is a party to a collective bargaining agreement and we believe that our employee relations are good. As of June 30, 2023, 8 of our employees were based in Australia, of which 6 are in our research and development department and 2 are in our general and administrative department, 31 of our employees were based in the U.S., of which 11 are in our research and development department and 20 are in our general and administrative department, 3 of our employees were based in Asia of which all three are in our general and administrative department, and 1 of our employees was based in Europe and also in our general and administrative department.

**Facilities**

In Sydney, Australia we lease 2,000 square feet for our Australian research and development center and corporate headquarters. This lease terminates in September 2024, with the option to renew for a further lease period that terminates in September 2027.

In Naperville, Illinois, U.S. we lease 2,916 square feet for the global sales office and distribution center for ATCOR. The lease terminates in August 2024.

We believe that these existing and planned facilities are and will be sufficient to meet our current and anticipated future needs.

**Legal Proceedings**

We are not currently a party to any material legal proceedings. From time to time we may be involved in legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business.

## MANAGEMENT

### Directors and Senior Management

The table below sets forth the certain information relating to our directors and senior management as of the date of this prospectus.

<b>Name</b>	<b>Age</b>	<b>Position</b>
<i>Board Members</i>		
Craig R. Cooper, BEc., LLB (Hons)	60	Chief Executive Officer & Director
Niall Cairns, BEc., CA ANZ, FAICD	59	Executive Chairman & Director
Jarrod White	36	Director, Interim Chief Financial Officer
R. King Nelson, BA, MBA	65	Director
Lesa Musatto	56	Director
<i>Senior Management and Key Employees</i>		
Steven Kesten, M.D.	64	Chief Medical Officer
Mark Gorelick, Ph.D.	48	Chief Product Officer
Ahmad Qasem, Ph.D.	59	Chief Science & Research Officer
Catherine Liao	44	Chief Strategy Officer
Josh Stevens	49	President, CONNEQT

### *Board Members*

**Craig Cooper, BEc., LLB (Hons)** has served as our Chief Executive Officer and a member of our board of directors since December 2017. Mr. Cooper co-founded Boost Mobile USA, a wireless service provider, and NRG Asia-Pacific Ltd., a private electricity supplier. Mr. Cooper has previously served in various leadership positions, including Managing Director, Founder, and Head of Venture Capital at Saban Ventures, a venture capital fund formed with Forbes 400 media entrepreneur Haim Saban, founding Partner in the Softbank Capital Technology Fund, a venture capital fund backed by Masayoshi Son, the Korean-Japanese billionaire technology entrepreneur, and a founding director of EBT Mobile, a Chinese mobile phone retail chain. Mr. Cooper is also a Director and shareholder of C2 Ventures Pty Ltd, the largest shareholder in CardieX, and the Chief Executive Officer of CardieX's subsidiaries, ATCOR and CONNEQT Health. Mr. Cooper holds a Bachelor of Economics and a Bachelor of Laws (Honors) from the University of Sydney in Australia.

We believe Mr. Cooper is qualified to serve as a member of our board of directors because of his extensive corporate, venture capital, and business experience as well as his deep understanding of the Company's market and growth opportunities, and his vision for the Company.

**Niall Cairns, BEc., CA ANZ, FAICD** has served as our Executive Chairman since August 2019 and was originally appointed as a Director in December 2017. Since January 1994, Mr. Cairns has served as co-founder and Managing Director of Kestrel Capital, a private equity and venture capital investment company, where he has raised and managed institutional and private funds, assisted in multiple mergers and acquisitions, initial public offerings, and public and private exit transactions. Mr. Cairns serves as Non-Executive Chairman of Tambla Limited and Director of Consolidated Financial Holdings Limited, DTS Limited, Kestrel Growth Companies Ltd and the St. Andrews College Foundation Limited. Mr. Cairns is a Director and shareholder of C2 Ventures Pty Ltd, the largest shareholder in CardieX. Mr. Cairns holds a BEc. in Economics, Accounting and Law from the University of Sydney.

We believe Mr. Cairns is qualified to serve as a member of our board of directors because of his extensive Australian and global experience serving on the boards of public and private companies, his substantial investment, corporate development and business strategy expertise gained in global/ANZ emerging growth companies, as well as his deep understanding of the Company's growth opportunities.

**Jarrold White** has served as a member of our board of directors since May 2020 and is currently serving as our Interim Chief Financial Officer since May 2023. Mr. White also served as our former Chief Financial Officer from June 2018 to December 2022. Since May 2009, Mr. White has served as Managing Director of Traverse Accountants Pty Ltd, a public practice chartered accounting firm providing taxation, accounting, and outsourced Chief Financial Officer services. Since June 2014, Mr. White has served as Chief Financial Officer of High Peak Royalties Limited (ASX:HPR), a company engaged in building a portfolio of diversified high value resource royalties around the world. Mr. White has served as the Chief Financial Officer and Chief Executive Officer of multiple ASX listed entities in a range of sectors and has been engaged in the capital markets for over 15 years. As a Chartered Accountant with a specialty in corporate finance, Mr. White has been involved in the advisory and financing mandates of multiple initial public offerings, mergers and corporate transactions. Mr. White holds a B.A. in Business and Accounting from the University of Technology Sydney, and is a Chartered Accountant (ICAAANZ) and Chartered Tax Advisor (TIA).

We believe Mr. White is qualified to serve as a member of our board of directors because of his financial expertise and his experience with Australian private and public company financial accounting matters and risk management.

**R. King Nelson** has served as a member of our board of directors since November 2015. Since October 2019, Mr. Nelson has served as Chief Executive Officer of Q'Apel Medical, a medical device company focused on neurovascular disease. From April 2007 to July 2016, Mr. Nelson served as President and Chief Executive Officer of Uptake Medical Corporation, a company focused on treatments for emphysema and lung cancer. Mr. Nelson has also previously served as President and Chief Executive Officer of Kerberos Proximal Solutions, a medical device company which was acquired by FoxHollow Technologies, and as President and Chief Executive Officer of VenPro Corporation, a heart valve business acquired by Medtronic. Mr. Nelson holds a B.S. in Communications from Texas Tech University and a M.B.A. in International Business from the University of Miami.

We believe Mr. Nelson is qualified to serve as a member of our board of directors because of his years of experience and knowledge of the healthcare industry, his experience serving on the boards of public and private medical technology companies and his perspective and expertise in healthcare leadership and business development.

**Lesla Musatto** has served as a member of our board of directors since April 2022. Since July 2021, Ms. Musatto has served as the Chief Marketing Officer at Auction Technology Group (ATG:LSE), a marketplace and auction services company. From July 2016 to July 2021, Ms. Musatto served as Chief Marketing Officer, Head of Technology and Head of Sales at Backroads, Inc., an active travel company. From April 2015 to July 2016, Ms. Musatto served as Chief Revenue Officer at Nuelle, Inc, a medical technology company. Ms. Musatto holds a B.A. in Political Science and French from the University of Minnesota.

We believe Ms. Musatto is qualified to serve as a member of our board of directors because of her extensive expertise in global brand development, direct to consumer businesses and go-to-market business development and implementation.

## **Senior Management and Key Employees**

**Steven Kesten, M.D.** has served as our Chief Medical Officer since December 2020. Since January 2016, Dr. Kesten has provided consulting services to drug and medical device companies through SKC Life Sciences. Previously, Dr. Kesten served as President and Chief Medical Officer of Pneuma Respiratory, Inc., an inhaled drug and medical device development company, from March 2018 to December 2018, and Executive Vice President and Chief Medical Officer of Cytori Therapeutics, Inc. (NASDAQ: PSTV), a cell therapy and cell processing device company, from 2013 to 2016. Dr. Kesten has also previously served in various executive and senior management positions in the pharmaceutical and medical device industries, including at Uptake Medical and Boehringer Ingelheim Pharmaceuticals. Dr. Kesten also served as the Medical Director at The Toronto Lung Transplant Program, a staff pulmonologist at Toronto General Hospital and Toronto Western Hospital, and Medical Director of the Advanced Lung Disease Program at Rush Presbyterian St. Luke's Medical Center in Chicago. Dr. Kesten holds an M.D. from the University of Toronto, received Royal College of Physicians and Surgeons of Canada certification in Internal Medicine and Pulmonary Medicine, and is Board Certified in Internal Medicine.

**Mark Gorelick, Ph.D.** has served as our Chief Product Officer since December 2020. Since 2007, Mr. Gorelick has served as Managing Director of XPhys Technologies, Inc., a fitness, health and wellness product company. From 2018 to 2019, Mr. Gorelick served as Vice President – Digital Health at Performance Lab Technologies, a software development company. From 2015 to 2018, Mr. Gorelick served as Chief Science Officer at PAI Health (formerly Mio Global), a health technology software company. Mr. Gorelick holds a BSc in Kinesiology from Dalhousie University, a MSc in Kinesiology from Dalhousie University, and a Ph.D. in Biomedical Science from University of Wollongong.

**Ahmad Qasem Ph.D.** has served as Chief Science and Research Officer of ATCOR Medical Pty Ltd. since 2021 and prior to serving in such position Mr. Qasem served in various roles at ATCOR Medical, including Director of Research and Applications, Principal Scientist, Manager, Clinical Applications and Research, and Clinical Application Development Specialist, beginning in 2002. Mr. Qasem has more than 22 years of experience in the fields of cardiovascular dynamics, mathematical modelling, non-invasive cardiovascular assessment methods, and biomedical signal analysis and processing. Mr. Qasem holds a B.S. in Electrical Engineering from the University of Massachusetts Dartmouth, a M.S. in Electrical Engineering from the University of Massachusetts Dartmouth, and a Ph.D. in Biomedical Engineering from the University of New South Wales.

**Catherine Liao** has served as our Chief Strategy Officer since September 2022. Previously, Ms. Liao served as Chief Executive Officer of Blumio, Inc., a medical device company, from February 2016 to September 2022, where she assisted with fundraising, constructed a leadership and advisory team with expertise across healthcare innovations, enterprise technology, and sensor technology, and designed and executed multiple research studies. Ms. Liao holds a BSc in Management Information Systems from Excelsior College, an MBA in Business Administration from Imperial College of London, and a MSc in Health Economics from London School of Economics.

**Josh Stevens** has served as President of CONNEQT Health since April 2023. Previously, Mr. Stevens served as President & Chief Growth Officer of DayTwo Inc, a diabetes management company, from December 2017 to June of 2022. Prior to DayTwo, Mr. Stevens served as the Chief Executive Officer of Keas, a benefits administration company for employers and payers from November 2012 to November 2016. Since 2018, Mr. Stevens has served on the board of directors of The Presbyterian Pension Fund as a member of the Executive Committee, Chair of the Audit Committee, and member of the Investment Committee. Since 2017, Mr. Stevens has been an advisor and limited partner with Crosslink Capital, in San Francisco, focusing on healthcare, health IT, and technology investments. Since January 2012, Mr. Stevens has provided management consulting services to healthcare and technology companies through Asymptote Partners. Mr. Stevens holds a BA in History from Wesleyan University, in Middletown, Connecticut.

There are no family relationships among any of our directors and senior management. The business address of each of our directors and senior management is CardieX Limited, 55 Lime Street, Suite 301, Sydney, NSW, 2000, Australia.

## Board of Directors

Our board of directors currently consists of five (5) members, including our Chief Executive Officer. We believe that each of our directors has relevant industry experience. The membership of our board of directors is directed by the following requirements:

- our Constitution specifies that there must be a minimum of three (3) directors and a maximum number is to be determined by the board of directors, which until otherwise determined by the board of directors is ten (10);
- it is the intention of our board of directors that its membership consists of a majority of independent directors who satisfy the criteria for independence recommended by the ASX's Corporate Governance Principles and Recommendations;
- the chairperson of our board of directors may be an independent director who satisfies the criteria for independence recommended by the ASX's Corporate Governance Principles and Recommendations; and
- our board of directors should, collectively, have the appropriate level of personal qualities, skills, experience, and time commitment to properly fulfill its responsibilities or have ready access to such skills where they are not available.

Our board of directors is responsible for, and has the authority to determine, all matters relating to our corporate governance, the policies, practices, management and operation. The principal roles and responsibilities of our board of directors are to:

- facilitate board of directors and management accountability to our company and its shareholders;
- ensure timely reporting to shareholders;
- provide strategic guidance to us, including contributing to the development of, and approving, the corporate strategy;
- oversee management and ensure there are effective management processes in place;
- monitor:
- organizational performance and the achievement of our strategic goals and objectives;
- financial performance including approval of the annual and half-year financial reports and liaison with our auditors;
- progress of major capital expenditures and other significant corporate projects including any acquisitions or divestments;

- compliance with our code of conduct;
- progress in relation to our diversity objectives and compliance with its diversity policy;
- review and approve business plans, the annual budget and financial plans including available resources and major capital expenditure initiatives;
- approve major corporate initiatives;
- enhance and protect the reputation of the organization;
- oversee the operation of our system for compliance and risk management reporting to shareholders; and
- ensure appropriate resources are available to senior management.

### *Committees*

To assist our board of directors with the effective discharge of its duties, it has established a Remuneration & Nomination Committee and an Audit & Risk Committee. Each committee operates under a specific charter approved by our board of directors.

*Remuneration & Nomination Committee.* The members of our Remuneration & Nomination Committee are Messrs. Nelson and Cairns, one of whom is an independent, non-executive director. The Remuneration & Nomination Committee is a committee of our board of directors, and is primarily responsible for making recommendations to our board of directors on:

- Board appointments;
- Non-executive director fees;
- The executive remuneration framework;
- Remuneration of executive directors, including the CEO and other key executives;
- Short-term and long-term incentive awards; and
- Share ownership plans.

The committee's objective is to ensure remuneration policies are fair and competitive and in line with similar industry benchmarks while aligned with our objectives. The Remuneration & Nomination Committee seeks independent advice from remuneration consultants as and when it deems necessary. See "—Remuneration."

*Audit & Risk Committee.* The members of our Audit & Risk Committee are \_\_\_\_\_, \_\_\_\_\_, and \_\_\_\_\_, of whom \_\_\_\_\_ are an independent, non-executive director. This committee will oversee, review, act on and report on various auditing and accounting matters to our board of directors, including the selection of our independent accountants, the scope of our annual audits, fees to be paid to the independent accountants, the performance of our independent accountants and our accounting practices. In addition, the committee will oversee, review, act on and report on various risk management matters to our board of directors.

It is our objective to appropriately balance, protect and enhance the interests of all of our shareholders. Proper behavior by our directors, officers, employees and those organizations that we contract to carry out work is essential in achieving this objective.



We have established a Code of Business Conduct, which sets out the standards of behavior that apply to every aspect of our dealings and relationships, both within and outside CardiacX. Our Code of Business Conduct is available under the Corporate Governance section of our website at <https://cardiacx.com>. In addition, we intend to post on our website all disclosures that are required by law or Nasdaq Capital Market listing standards concerning any amendments to, or waivers from, any provision of our Code of Business Conduct. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

## **Remuneration**

### **Principles used to determine the nature and amount of remuneration**

#### ***Non-Executive Director Compensation***

Fees and payments to non-executive directors reflect the demands which are made on, and the responsibilities of, the directors. Non-executive directors' fees and payments are reviewed annually by the board of directors. The board of directors also refers to external surveys to ensure non-executive directors' fees and payments are appropriate and in line with the market. The Chairman's fees are determined independently of the fees of non-executive directors based on comparative roles in the external market. The Chairman is not present at any discussions relating to determination of his own remuneration. Non-executive directors are entitled to receive options, following approval by the shareholders of the Company.

Non-executive directors' fees are determined within an aggregate non-executive directors' fee pool limit, which is periodically recommended for approval by shareholders. The pool was increased to A\$500,000 per annum at the 2021 annual general meeting of shareholders, excluding share-based payments that are subject to separate shareholder approval.

#### ***Executive Compensation***

The objective of our executive reward framework is to ensure reward for performance is competitive and appropriate for the results delivered. The framework aligns executive reward with achievement of strategic objectives and the creation of value for shareholders. The board of directors ensures that the following is considered for good governance practices:

- competitiveness and reasonableness;
- acceptability to shareholders;
- performance linkage / alignment of executive compensation;
- transparency; and
- capital management.

The board of directors considers the following for alignment to shareholders' interests:

- has Company growth as a core component of plan design;
- focuses on sustained long-term growth in shareholder wealth; and
- attracts and retains high caliber executives.

The board of directors considers the following for alignment to program participants' interests:

- rewards capability and experience;
- reflects competitive reward for contribution to growth in Company value;
- provides a clear structure for earnings rewards; and
- provides recognition for contribution.

Details of the compensation of our individual directors and executive management in the aggregate for FY2023 are set out below (amounts are presented in United States dollars):

	Short-Term Benefits		Post-Employment Benefits Super-annuation	Long-Term Benefits Long-Service Leave	Share-Based Payments and Options(1)	Other Termination Benefits	Total
	Salary and Fees	Cash Bonus					
Craig Cooper	420,000	100,000	-	-	476,203	-	996,203
Niall Cairns	202,068	-	-	-	476,203	-	678,271
R. King Nelson	50,000	-	-	-	79,644	-	129,644
Jarrold White	62,506	-	-	-	174,661	-	237,167
Lesa Musatto	-	-	-	-	60,620	-	60,620
Steven Kesten	134,364	-	-	-	25,840	-	160,204
Mark Gorelick	250,008	-	-	-	13,393	-	263,401
Ahmad Qasem	127,976	-	-	13,438	2,494	16,072	159,980
Catherine Liao	186,703	-	-	-	17,282	-	203,985
Toni Hofhine(2)	184,035	59,343	-	-	17,282	-	260,660
Josh Stevens	91,362	-	-	-	-	-	91,362

(1) The amounts in this column reflect the aggregate grant date fair value of performance rights awards and stock options granted to our individual directors and executive management in FY2023, as determined under International Reporting Standards.

(2) As of June 23, 2023, Ms. Hofhine is no longer with the Company.

Details of the compensation of our individual directors and executive management in the aggregate for FY2022 are set out below (amounts are presented in United States dollars):

	Short-Term Benefits			Post-Employment Benefits Super-annuation	Long-Term Benefits Long-Service Leave	Share-Based Payments and Options(1)	Other Termination Benefits	Total
	Salary and Fees	Cash Bonus	Non-Monetary Benefits					
Craig Cooper	420,000	100,000	-	-	-	362,426	-	882,426
Niall Cairns	188,716	-	-	-	-	362,426	-	551,142
R. King Nelson	40,585	-	-	-	-	22,387	-	62,972
Jarrold White	84,559	-	-	-	-	136,086	-	220,645
Lesa Musatto	-	-	-	-	-	-	-	-
Steven Kesten	124,029	-	-	-	-	55,548	-	179,577
Mark Gorelick	250,008	-	-	-	-	78,312	-	328,320
Ahmad Qasem	142,406	-	-	14,241	3,163	37,873	-	197,683

(1) The amounts in this column reflect the aggregate grant date fair value of performance rights awards and stock options granted to our individual directors and executive management in FY2022, as determined under International Reporting Standards.

#### Director Compensation

Directors were paid the following amounts in FY2023 (all amounts are in United States dollars):

Name	Salary and director fees (US\$)	Share based payment benefits (US\$)(1)	Total (US\$)
Niall Cairns(2)	202,068	476,203	678,271
Craig Cooper	520,000	476,203	996,203
R. King Nelson	50,000	79,644	129,644
Jarrold White	62,506	174,661	237,167
Lesa Musatto	-	60,620	60,620
<b>Total</b>	<b>834,574</b>	<b>1,267,331</b>	<b>2,101,905</b>

(1) The amounts in this column reflect the aggregate grant date fair value of performance rights awards and stock options granted to our individual directors and executive management in FY2023, as determined under International Reporting Standards.

(2) Director fees are paid to Carnethy Investments Pty Limited of which Mr. Cairns is the sole owner.

Directors were paid the following amounts in FY2022 (all amounts are in United States dollars):

Name	Salary and director fees (US\$)	Share based payment benefits (US\$)(1)	Total (US\$)
Niall Cairns(2)	188,716	362,426	551,142
Craig Cooper	520,000	362,426	882,426
R. King Nelson	40,585	22,387	62,972
Jarrold White	84,559	136,086	220,645
Lesa Musatto	-	-	-
<b>Total</b>	<b>833,860</b>	<b>883,325</b>	<b>1,717,185</b>

(1) The amounts in this column reflect the aggregate grant date fair value of performance rights awards and stock options granted to our individual directors and executive management in FY2022, as determined under International Reporting Standards.

(2) Director fees are paid to Carnethy Investments Pty Limited of which Mr. Cairns is the sole owner.

Shares held by directors and their affiliates:

<u>Name</u>	<u>Balance at June 30, 2023</u>	<u>Balance at June 30, 2022</u>
Niall Cairns	26,634,394(1)	23,559,394(2)
Craig Cooper	26,124,394(1)	23,099,394(2)
R. King Nelson	15,385	15,385
Jarrod White	1,028,880	576,551
Lesa Musatto	-	-
<b>Total</b>	<b>53,803,053</b>	<b>47,250,724</b>

(1) A total of 3,025,000 shares acquired by Mr. Cairns and Mr. Cooper in the period are indirectly held by C2 Ventures Pty Limited, of which Mr. Cairns and Mr. Cooper are directors. These shares are subject to the Restriction Agreement and Deed of Undertaking as approved by shareholders at the Extraordinary General Meeting held on May 28, 2018 (the "Restriction Agreement").

(2) A total of 4,775,193 shares acquired by Mr. Cairns and Mr. Cooper in the year are indirectly held by C2 Ventures Pty Limited, of which Mr. Cairns and Mr. Cooper are directors. These shares are subject to the Restriction Agreement.

Options held by directors and their affiliates:

The following sets forth the number of options granted in FY2023, their vesting conditions, their exercise price, and the applicable expiration date:

<u>Name</u>	<u>Number of Options</u>	<u>Vesting Conditions</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
Niall Cairns(1)	1,000,000	Vested on issue	A\$ 0.45	December 16, 2023
Craig Cooper(1)	1,000,000	Vested on issue	A\$ 0.45	December 16, 2023
R. King Nelson(2)	500,000	Vested on issue	A\$ 0.50	December 16, 2027
Jarrod White(3)	111,444	Vested on issue	A\$ 0.45	December 16, 2023
Lesa Musatto(4)	150,000	Vested on issue	A\$ 0.50	April 26, 2027
Lesa Musatto(4)	350,000	Vested on issue	A\$ 0.50	December 16, 2027

(1) Directors Mr. Cairns and Mr. Cooper hold 1,150,000 options indirectly through C2 Ventures Pty Limited, of which they are both directors. As of June 30, 2023, Mr. Cairns and Mr. Cooper each held 1,150,000 options.

(2) As of June 30, 2023, Mr. Nelson held 650,000 options.

(3) As of June 30, 2023, Mr. White held 261,444 options.

(4) As of June 30, 2023, Ms. Musatto held 500,000 options.

The following sets forth the number of options granted in FY2022, their vesting conditions, their exercise price, and the applicable expiration date:

<u>Name</u>	<u>Number of Options</u>	<u>Vesting Conditions</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
Niall Cairns(1)	-	-	-	-
Craig Cooper(1)	-	-	-	-
R. King Nelson(2)	-	-	-	-
Jarrod White(2)	-	-	-	-
Lesa Musatto	-	-	-	-

(1) As of June 30, 2022, directors Mr. Cairns and Mr. Cooper each held 150,000 options indirectly through C2 Ventures Pty Limited, of which they are both directors.

(2) As of June 30, 2022, directors Mr. Nelson and Mr. White each held 150,000 options.

Performance Rights held by key management personal and their affiliates:

On November 30, 2022, shareholders approved the issue of performance rights to be issued to the Directors under the Company's Performance Rights and Option Plan. These performance rights total 6,750,000 and expire on November 30, 2027. The terms of the Director rights on issue are as follows:

Tranche	Number of performance rights	Vesting conditions
Tranche 1	2,250,000	Vest upon the Company successfully achieving a Secondary Listing on a US exchange
Tranche 2	2,250,000	Vest upon the Company achieving an audited A\$10 million in Revenue from third parties in any financial year prior to the expiry date
Tranche 3	2,250,000	Vest upon the Company achieving an audited A\$20 million in Revenue from third parties in any financial year prior to the expiry date

On December 11, 2020, the Company's shareholders approved the issue of performance rights to be issued to the directors under the Performance Rights and Option Plan. These performance rights total 16,050,000 and expire on December 11, 2023. The terms of the directors' rights on issue are as follows:

Tranche	Number of performance rights	Will vest if share price trades at or above:	Expiration date of performance milestone
Tranche 1	1,100,000	A\$1.20	11/12/2023
Tranche 2	1,100,000	A\$1.50	11/12/2023
Tranche 3	2,450,000	A\$2.00	11/12/2023
Tranche 4	5,700,000	A\$2.50	11/12/2023
Tranche 5	5,700,000	A\$5.00	11/12/2023

Name	Balance at June 30, 2023	Balance at June 30, 2022
Niall Cairns	9,800,000	6,800,000
Craig Cooper	9,800,000	6,800,000
R. King Nelson	350,000	350,000
Jarrold White	2,850,000	2,100,000
Lesa Musatto	-	-
<b>Total</b>	<b>22,800,000</b>	<b>16,050,000</b>

#### Executive Compensation

Executives were paid the following amounts in FY2023 (all amounts are in United States dollars):

Name	Salary and director fees (US\$)	Share based payment benefits (US\$(1))	Total (US\$)
Steven Kesten	134,364	25,840	160,204
Mark Gorelick	250,008	13,393	263,401
Ahmad Qasem	143,908	16,072	159,980
Toni Hofhine (2)	243,378	17,282	260,660
Catherine Liao	186,703	17,282	203,985
Josh Stevens	91,362	-	91,362
<b>Total</b>	<b>1,049,723</b>	<b>89,869</b>	<b>1,139,592</b>

(1) The amounts in this column reflect the aggregate grant date fair value of performance rights awards and stock options granted to our individual directors and executive management in FY2023, as determined under International Reporting Standards.

(2) As of June 23, 2023, Ms. Hofhine is no longer with the Company.

Executives were paid the following amounts in FY2022 (all amounts are in United States dollars):

Name	Salary and director fees (US\$)	Share based payment benefits (US\$(1))	Total (US\$)
Steven Kesten	124,029	55,548	179,577
Mark Gorelick	250,008	78,312	328,320
Ahmad Qasem	159,810	37,873	197,683
<b>Total</b>	<b>533,847</b>	<b>171,733</b>	<b>705,580</b>

(1) The amounts in this column reflect the aggregate grant date fair value of performance rights awards and stock options granted to our individual directors and executive management in FY2022, as determined under International Reporting Standards.

Shares held by executives and their affiliates:

Name	Balance at June 30, 2023	Balance at June 30, 2022
Steven Kesten	-	-
Mark Gorelick	110,428	110,428
Ahmad Qasem	24,700	24,700
Toni Hofhine(1)	-	-
Catherine Liao	-	-
<b>Total</b>	<b>135,128</b>	<b>135,128</b>

(1) As of June 23, 2023, Ms. Hofhine is no longer with the Company.

The following sets forth the number of options granted in the year ended June 30, 2023, their vesting conditions, their exercise price, and the applicable expiration date:

<b>Name</b>	<b>Number of Options</b>	<b>Vesting Conditions</b>	<b>Exercise Price</b>	<b>Expiration Date</b>
Steven Kesten(1)	-	-	-	-
Mark Gorelick(2)	-	-	-	-
Ahmad Qasem(3)	-	-	-	-
Toni Hofhine(4)(5)	500,000	Vesting quarterly over 3 years	A\$ 0.50	December 16, 2027
Catherine Liao(6)	500,000	Vesting quarterly over 3 years	A\$ 0.50	December 16, 2027
Catherine Liao(6)	500,000	Vesting quarterly over 3 years	A\$ 0.50	June 30, 2028
Josh Stevens(7)	1,000,000	Vesting quarterly over 3 years	A\$ 0.50	June 30, 2028

(1) As of June 30, 2023, Mr. Kesten held 400,000 options.

(2) As of June 30, 2023, Mr. Gorelick held 250,000 options.

(3) As of June 30, 2023, Mr. Qasem held 400,000 options.

(4) As of June 30, 2023, Ms. Hofhine held 500,000 options.

(5) As of June 23, 2023, Ms. Hofhine is no longer with the Company.

(6) As of June 30, 2023, Ms. Liao held 1,000,000 options.

(7) As of June 30, 2023, Mr. Stevens held 1,000,000 options.

The following sets forth the number of options granted in FY2022, their vesting conditions, their exercise price, and the applicable expiration date:

<b>Name</b>	<b>Number of Options</b>	<b>Vesting Conditions</b>	<b>Exercise Price</b>	<b>Expiration Date</b>
Steven Kesten(1)	-	-	-	-
Mark Gorelick(2)	-	-	-	-
Ahmad Qasem(3)	-	-	-	-

(1) As of June 30, 2022, Mr. Kesten held 400,000 options.

(2) As of June 30, 2022, Mr. Gorelick held 250,000 options.

(3) As of June 30, 2022, Mr. Qasem held 400,000 options.

#### **Key Terms of Service Agreements**

Remuneration and other terms of the Chief Executive Officer and other key management personnel's service relationship with the Company are formalized in employment and consulting agreements. Each of these agreements provide for the provision of performance related cash bonuses, other benefits including health insurance and car allowances, and participation, when eligible, in the Performance Rights and Option Plan. Other major provisions of the agreements relating to remuneration are set out below. Details of the compensation of our individual directors and non-director senior management in the aggregate for FY2022 are set out below.

All contracts with executives may be terminated early by either party with variable notice periods, subject to termination payments as detailed below.

#### **Craig Cooper – Chief Executive Officer**

Mr. Cooper's consultancy agreement with the Company commenced on December 1, 2017, which was later replaced and extended with a new agreement to re-affirm various contractual changes since that initial contract, with the replacement agreement being entered into in September 2021 with CooperativeHealth, LLC, an entity for which Mr. Cooper is sole owner. Those changes as formally documented in the replacement agreement provide for annualized consultancy fees due to CooperativeHealth, LLC being US\$420,000. Under the agreement there are potential bi-annual bonuses, each of which will be targeted up to 25% of CooperativeHealth, LLC's annualized consultancy fees, that are paid based upon performance reviews which are conducted by the remuneration & nomination committee. Under the agreement, CooperativeHealth, LLC also receives a separate healthcare payment of \$24,000 annually that is paid on a monthly basis. If CooperativeHealth, LLC is terminated by the Company other than for Cause (as defined in the agreement), death or Disability (as defined in the Agreement), or CooperativeHealth, LLC terminates the contract for Good Reason (as defined in the agreement), then, subject to the terms of the agreement, CooperativeHealth, LLC will receive (i) 12 months of continuing payments of consulting fees and (ii) a lump sum payment equal to CooperativeHealth, LLC's target bonus in effect in the year of termination, prorated for the number of days CooperativeHealth, LLC contracted with the Company in the year of termination. The Company reimburses Mr. Cooper for all reasonable expenses incurred in running the U.S. business. These expense reimbursements are paid on a monthly basis. Mr. Cooper receives stock and performance share-based compensation subject to certain corporate and share price based milestones. See "Related Party Transactions" for more information regarding payments made to Mr. Cooper.

#### **Niall Cairns – Executive Chairman and Director**

Mr. Cairns is the sole owner of Carnethy Investments Pty Limited, who entered into a consulting services agreement with the Company which commenced on June 8, 2018, which was later replaced and extended with a new agreement to re-affirm various contractual changes since that initial contract, with the replacement agreement being entered into in July 2023. Those changes as formally documented in the replacement agreement provide for annualized consultancy fees due to Carnethy Investments Pty Limited being A\$300,000 and the opportunity to receive bonuses at the Company's discretion. The Company reimburses Carnethy Investments Pty Limited for all reasonable expenses incurred. Mr. Cairns also receives stock and performance share-based compensation subject to certain corporate and share price based milestones. See "Related Party Transactions" for more information regarding payments made to Mr. Cairns.

*R. King Nelson – Non-Executive Director*

Mr. Nelson's current letter of appointment as an independent non-executive director with the Company was executed and commenced on July 17, 2023. Mr. Nelson receives an annual base salary of US\$50,000.

*Jarrod White – Director, Interim Chief Financial Officer*

Mr. White is the principal of Traverse Accountants Pty Ltd, who holds an engagement with us covering CFO services, Company Secretarial services, corporate finance support, and other general accountancy services. Mr. White received A\$35,000 in shares for the prior reporting year for his services as a director of the Company. In addition, there were fees paid to Traverse Accountants Pty Ltd, including A\$48,000 per annum for retained CFO services and A\$24,000 for retained Company Secretarial services. Additional fees were paid to Traverse Accountants on an arms' length service basis for additional accounting and financial function support that are not considered to be part of Mr. White's personal executive remuneration. Additionally, Mr. White entered into an Executive Director Service Agreement with the Company in July 2023, which provides for an annual base salary of A\$35,000 and the opportunity to receive bonuses at the Company's discretion. The Company reimburses Mr. White for all reasonable expenses incurred. Mr. White also receives stock and performance share-based compensation subject to certain corporate and share price based milestones. See "Related Party Transactions" for more information regarding payments made to Mr. White.

*Lesia Musatto – Non-Executive Director*

Ms. Musatto is paid in options for her services as a Non-Executive director, initially through June 30, 2023 after which it may be amended by mutual agreement.

*Steven Kesten – Chief Medical Officer*

Mr. Kesten's Consulting Services Agreement with the Company was entered into on December 1, 2020. During the term of his agreement, Mr. Kesten is paid a base retainer of US\$5,000 per month. Mr. Kesten is also paid US\$400 for any time worked over 13 hours a month, up to a cap of US\$8,000 a month. Mr. Kesten is reimbursed all reasonable, out of pocket expenses incurred in connection with his approved activities for the Company.

*Mark Gorelick – Chief Product Officer*

Mr. Gorelick's Consulting Services Agreement was entered into on December 8, 2020 under the entity named XPhys Technologies Inc. Mr. Gorelick's Revised Offer and Contract of Employment with the Company was entered into as of June 29, 2021. Commencing on July 1, 2021, Mr. Gorelick is paid an annual base salary of US\$250,000. Mr. Gorelick has also been granted US\$50,000 of fully vested stock in CardieX Limited.

*Ahmad Qasem – Chief Science and Research Officer*

Mr. Qasem entered into an employment agreement on October 11, 2000 with the Company as Applications Development Executive. Mr. Qasem's current base salary is A\$190,000 and commenced on July 1, 2021, when the Company changed Mr. Qasem's title to "Chief Science and Research Officer (CSRO)." Mr. Qasem is also eligible for consideration for participation in a discretionary share bonus program based on new product releases.

*Toni Hofhine – President, ATCOR*

Ms. Hofhine's employment agreement with the Company commenced on October 10, 2022 and ended on June 23, 2023. Ms. Hofhine's annual base salary was US\$250,000 and Ms. Hofhine was entitled to receive grants of 1,000,000 options under the Performance Rights and Options Plan. Ms. Hofhine was entitled to receive a 4% commission on sales receipts from new clinical trial contracts not already under negotiation, contracted or commenced on her start date. Ms. Hofhine also was entitled to receive a 2.5% commission on gross receipts from existing clinical trials or trials that were in negotiation as of her start date.

*Catherine Liao – Chief Strategy Officer*

Ms. Liao entered into an employment agreement on September 20, 2022 with the Company as Chief Strategy Officer. Ms. Liao's annual base salary is US\$250,000 and Ms. Liao has been granted 1,000,000 options under the Performance Rights and Options Plan.

*Josh Stevens – President, CONNEQT*

Mr. Stevens entered into an employment agreement on February 28, 2023 with the Company as President, CONNEQT. Mr. Stevens annual base salary is US\$250,000 and Mr. Stevens has been granted 1,000,000 options under the Performance Rights and Options Plan.

### **Equity Awards**

Equity awards for executives and employees are provided under the Performance Rights and Option Plan.

Participation in this plan is at our board of directors' discretion and no individual has an ongoing contractual right to participate in the plan or to receive any guaranteed benefits. For key appointments, an initial allocation of equity may be offered as a component of their initial employment agreement. The structure of equity awards is under the active review of the Nomination & Remuneration Committee to ensure it meets good corporate practice for a company of our size, nature and company lifecycle.

The following describes the material terms of the Performance Rights and Option Plan.



### *Performance Rights and Option Plan*

The purpose of the Performance Rights and Option Plan is to assist in the reward, retention and motivation of eligible participants (defined below); to link the reward of eligible participants to performance and the creation of shareholder value; to align the interests of eligible participants more closely with the interests of shareholders by providing an opportunity for eligible participants to receive ordinary shares of CardieX; to provide eligible participants with the opportunity to share in any future growth in value of CardieX and to provide greater incentive for eligible participants to focus on CardieX's long term goals. 1,200,000 shares were issued to employees under the Performance Rights and Option Plan during FY2022 as a result of conversion of existing performance rights.

Eligible Participant	An eligible participant is a person that is: (i) director (whether executive or non-executive) of any group company; a full or part time employee of any group company; a casual employee or contractor of a group company to the extent permitted by the Australian Securities & Investments Commission; or a prospective participant; and (ii) has been declared by CardieX's board of directors to be eligible to receive awards under the Performance Rights and Option Plan.
Non-residents of Australia	<p>CardieX's board of directors may adopt additional rules of the Performance Rights and Option Plan applicable in any jurisdiction outside of Australia. Any additional rule must conform to the basic principles of the Performance Rights and Option Plan.</p> <p>When an award is granted to a person who is not a resident of Australia, the provisions of the Performance Rights and Option Plan apply subject to alterations and additions as CardieX's board of directors determines having regard to any securities, exchange control or taxation laws or regulation or similar factors which may apply to the participant or any group company in relations to the awards.</p> <p>CardieX's board of directors expects to adopt a U.S. Sub-Plan for use under the Performance Rights and Option Plan to issue awards of restricted stock units (which constitute performance rights under the Performance Rights and Option Plan) and stock options to individuals subject to U.S. tax law. Pursuant to the U.S. Sub-Plan, up to _____ shares may be issued subject to options that constitute incentive stock options within the meaning of Section 422 of the U.S. Internal Revenue Code.</p>
Awards	The Performance Rights and Option Plan defines an award as either an option to subscribe for an ordinary share of CardieX ("option") or a right to acquire an ordinary share of CardieX subject to the satisfaction of any vesting conditions ("performance right").
Administration of Plan	The Performance Rights and Option Plan is administered by CardieX's board of directors or a committee appointed by the board of directors.
Termination & Amendment	<p>CardieX's board of directors may terminate the Performance Rights and Option Plan at any time. Termination of the Performance Rights and Option Plan does not affect the rights or obligations of a participant or CardieX which have arisen under the Performance Rights and Option Plan before the date of termination.</p> <p>Subject to express restrictions set out in the Performance Rights and Option Plan and complying with the Corporations Act 2001 (Cth), ASX Listing Rules and any other applicable law, CardieX's board of directors may at any time by resolution amend or add to all or any of the provisions of the Performance Rights and Option Plan, or the terms or conditions of any award granted under the Performance Rights and Option Plan including giving any amendment retrospective effect.</p>

Offer of Awards	CardieX's board of directors may, from time to time, in its absolute discretion, make a written offer to any eligible participant (including an eligible participant who has previously received an offer) to apply for awards, upon the terms set out in the Performance Rights and Option Plan and such additional terms and conditions as CardieX's board of directors determines. In determining whether to offer an award to an eligible participant, CardieX's board of directors may take into consideration (without limitation) the eligible participant's length of service, contributions made, potential contributions or any other matter they deem relevant. The number and type of award offered is determined by CardieX's board of directors.
Issue price	Performance rights granted under the Performance Rights and Option Plan will be issued for nil cash consideration.  Unless the options are quoted on ASX, options issued under the Performance Rights and Option Plan will be issued for no more than nominal cash consideration.
Option Exercise Price	If the award offered is options, CardieX's board of directors may determine the option exercise price in their discretion
Vesting Conditions	CardieX's board of directors, in its discretion, determines the vesting conditions of an award (if any).
Grant of Awards on acceptance of offer	An eligible participant (or permitted nominee) may accept an offer in whole or in part, by signing and returning an acceptance form to CardieX.
Awards not transferable	Subject to the ASX Listing Rules, an award is only transferable, assignable or able to be otherwise disposed or encumbered: (i) in special circumstances or a change of control, with the consent of CardieX's board of directors (which may be withheld in its absolute discretion); or (ii) by force of law upon death to the participant's legal personal representative or upon bankruptcy to the participant's trustee in bankruptcy.
Vesting and exercise of awards	An award will not vest and be exercisable unless the vesting conditions (if any) attaching to that award have been satisfied (or waived by CardieX's board of directors in special circumstances or on winding up).  Subject to the Corporations Act 2001 (Cth), the ASX Listing Rules, the Performance Rights and Option Plan and the offer, following valid exercise of a vested award, CardieX will issue to the participant the number of ordinary shares to which the participant is entitled.
Rights attaching to Shares	A participant will, from and including the issue date of ordinary shares, be the legal owner of the ordinary shares and will be entitled to dividends and to exercise voting rights attached to those shares.  All ordinary shares of CardieX issued under the Performance Rights and Option Plan will, subject to any restrictions on dealing, rank equally with all other shares of the same class on issue, except with regards to any rights attaching to the shares by reference to a record date prior to the date of their issue.

Restriction on Dealing in Shares	CardieX's board of directors may, in its discretion, determine at any time up until exercise of an award that a restriction period will apply to some or all of the ordinary shares of CardieX issued to a participant on exercise of those awards, up to a maximum of 5 years from the date that the award is granted, such period the restriction period. In addition, CardieX's board of directors may, in its discretion, having regard to the circumstances at the time, waive the restriction period. Participants who have had a restriction period applied to their ordinary shares must not dispose of or otherwise deal with those ordinary shares during the restriction period.
Lapse of Awards	An award granted under the Performance Rights and Option Plan will lapse upon the earlier of (i) an unauthorized dealing in, or hedging of, the award; (ii) when a vesting condition in relation to the award is not satisfied by the due date or becomes incapable of satisfaction (as determined by CardieX's board of directors at its discretion); (iii) in respect of an unvested award only, an eligible participant ceasing to be eligible; (iv) in respect of unvested awards only, an eligible participant ceasing to be eligible and, where required by CardieX's board of directors, the vested performance right is not exercised within a 1 month period (or another period that CardieX's board of directors determines); (v) CardieX's board of directors deems that the award lapses due to fraud, dishonesty or other improper behavior of the eligible participant; (vi) CardieX undergoes a change in control or winding up resolution or order is made and the award does not vest in accordance with the Performance and Options Rights Plan; or (vii) the award expires.
No Participation Rights	There are no participation rights or entitlements inherent in the awards and participants will not be entitled to participate in new issues of securities offered to shareholders during the currency of the awards, unless the awards are validly exercised before the applicable record date.
Reorganization	If, at any time, the issued capital of CardieX is reorganized (including consolidation, subdivision, reduction or return), all rights of a participant are to be changed in a manner consistent with the Corporations Act 2001 (Cth) and the ASX Listing Rules at the time of the reorganization.

#### ***Compensation Consultants***

During the year, the Remuneration & Nomination Committee of our board of directors engaged Egan Associates Pty Ltd, to provide a report on non-executive directors' fees, including equity components, for appropriately similar companies both in Australia and the United States. They were paid A\$10,290 for providing this report.

## PRINCIPAL SHAREHOLDERS

The following table sets forth information regarding the beneficial ownership of our ordinary shares at June 30, 2023 by:

- each of our directors and senior management; and
- each person known by us to own more than 5% of our ordinary shares.

We have determined beneficial ownership in accordance with the rules of the SEC. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the persons named in the following table have sole voting and investment power with respect to all ordinary shares that they beneficially own, subject to applicable community property laws.

As of June 30, 2023 we had 15 holders of record in the United States, which represented approximately 0.85% of our ordinary shares outstanding. The percentage ownership of each listed person before this offering is based upon 143,465,521 ordinary shares outstanding at June 30, 2023. The percentage ownership of each listed person after the offering is based upon ordinary shares outstanding immediately after the closing of this offering, including the ordinary shares identified in the immediately preceding sentence plus the ordinary shares to be sold by us in this offering, assuming no exercise of outstanding options issued under our Performance Rights and Options Plan, and no exercise by the underwriters of their option to purchase additional ADSs.

In computing the number of ordinary shares beneficially owned by a person and the percentage ownership of that person, we deemed outstanding ordinary shares subject to options held by that person that are currently exercisable or exercisable within 60 days of June 30, 2023. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

The underwriters have an option for a period of thirty (30) days from the date of this prospectus to purchase up to an additional ADSs from us at the initial public offering price less the underwriting discounts and commissions.

Unless otherwise indicated, the principal address of each of the shareholders below is c/o CardieX Limited, 55 Lime Street, Suite 301, Sydney, NSW, 2000, Australia.

Name	Shares beneficially owned before offering		Shares beneficially owned after offering	
	Number	Percentage	Number	Percentage(1)
<b>5% or Greater Shareholders:</b>				
C2 Ventures Pty Limited(2)	26,674,394	18.4%		
Mr. Darryl Patterson & Mrs. Margaret Stewart Patterson(3)	9,383,142	6.5%		
<b>Directors:</b>				
Craig Cooper(4)	27,274,394	18.9%		
Niall Cairns(5)	27,284,394	19.2%		
R. King Nelson(6)	165,385	*		
Jarrold White(7)	1,290,324	*		
Lesla Musatto(8)	150,000	*		
<b>Senior Management:</b>				
Steven Kesten(9)	333,333	*		
Mark Gorelick(10)	318,761			
Ahmad Qasem(11)	374,700			
Toni Hoffine(12)	83,333			
Catherine Liao(13)	166,667			
Josh Stevens(14)	83,333			
<b>All directors and executive officers as a group (11 persons)</b>	<b>31,350,230</b>	<b>21.4%</b>		

\* Less than 1% of the outstanding ordinary shares.

- (1) Assumes that the underwriters will not exercise the over-allotment option to purchase additional ADSs.
- (2) Consists of 25,524,394 ordinary shares and 1,150,000 options to purchase ordinary shares exercisable within 60 days of June 30, 2023. For the sake of clarity, beneficial ownership amounts exclude any ordinary shares that may be issued upon the conversion of convertible notes that may be purchased by C2 Ventures Pty Limited in the convertible note offering that we commenced in June 2023. See "Related Party Transactions" for more information regarding the June 2023 convertible note offering to related parties.
- (3) Consists of 9,133,142 ordinary shares and 250,000 options to purchase ordinary shares exercisable within 60 days of June 30, 2023.
- (4) Consists of (i) 600,000 ordinary shares held by Craig Cooper, (ii) 25,524,394 ordinary shares held by C2 Ventures Pty Limited and (iii) 1,150,000 options to purchase ordinary shares held by C2 Ventures Pty Limited and exercisable within 60 days of June 30, 2023. Each of Mr. Cooper and Mr. Cairns is a director of C2 Ventures Pty Limited and as such share voting and investment control over the shares held by such entity.
- (5) Consists of (i) 510,000 ordinary shares held by Carnethy Evergreen Pty Ltd, (ii) 600,000 ordinary shares held by Carnethy Investments Pty Ltd, (iii) 25,524,394 ordinary shares held by C2 Ventures Pty Limited and (iv) 1,150,000 options to purchase ordinary shares held by C2 Ventures Pty Limited and exercisable within 60 days of June 30, 2023. Mr. Cairns is the sole shareholder and director of each of Carnethy Evergreen Pty Ltd and Carnethy Investments Pty Ltd and as such has voting and investment control over the shares held by each such entity. Each of Mr. Cooper and Mr. Cairns is a director of C2 Ventures Pty Limited and as such share voting and investment control over the shares held by such entity.
- (6) Consists of 15,385 ordinary shares held by Randall King Nelson and Pam Nelson and 150,000 options to purchase ordinary shares exercisable within 60 days of June 30, 2023.
- (7) Consists of 1,028,880 ordinary shares held by Traverse Accountants Pty Ltd and 261,444 options to purchase ordinary shares exercisable within 60 days of June 30, 2023. Mr. White is the founding director of Traverse Accountants Pty Ltd and as such has voting and investment control over the shares held by Traverse Accountants Pty Ltd. For the sake of clarity, beneficial ownership amounts exclude any ordinary shares that may be issued upon the conversion of convertible notes that may be purchased by Jarrold White (or his nominees) in the convertible note offering that we commenced in June 2023. See "Related Party Transactions" for more information regarding the June 2023 convertible note offering to related parties.
- (8) Consists of nil ordinary shares and 150,000 options to purchase ordinary shares exercisable within 60 days of June 30, 2023.
- (9) Consists of nil ordinary shares and 333,333 options to purchase ordinary shares exercisable within 60 days of June 30, 2023.
- (10) Consists of 110,428 ordinary shares and 208,333 options to purchase ordinary shares exercisable within 60 days of June 30, 2023.
- (11) Consists of 24,700 ordinary shares and 350,000 options to purchase ordinary shares exercisable within 60 days of June 30, 2023.
- (12) Consists of nil ordinary shares and 83,333 options to purchase ordinary shares exercisable within 60 days of June 30, 2023.
- (13) Consists of nil ordinary shares and 166,667 options to purchase ordinary shares exercisable within 60 days of June 30, 2023.
- (14) Consists of nil ordinary shares and 83,333 options to purchase ordinary shares exercisable within 60 days of June 30, 2023.

The table below summarizes significant change in the percentage ownership held by major shareholders of the Company during the past three years.

<u>Date of change</u>	<u>Shareholder</u>	<u>Number of shares held before the change(1)</u>	<u>Voting power before the change</u>	<u>Number of shares held after the change(1)</u>	<u>Voting power after the change</u>	<u>Reason for the change</u>
<b>2020</b>						
01/30/2020	Paul Cozzi	6,730,358	9.68%	9,761,540	12.96%	On-market purchase.
05/07/2020	Paul Cozzi	9,761,540	12.96%	10,951,540	14.54%	On-market purchase.
						On-market purchase.
						<i>Note: voting power decreased despite the purchase, due to dilution from a placement to third parties undertaken by CardieX.</i>
07/31/2020	Paul Cozzi	10,951,540	14.54%	11,908,206	14.22%	
<b>2021</b>						
						Conversion of convertible notes.
						<i>Note: voting power decreased due to dilution from a Share Purchase Plan undertaken by CardieX.</i>
01/12/2021	C2 Ventures Pty Limited	15,896,020	21.10%	17,724,201	20.60%	Option exercise, vesting of performance rights, off-market purchase, conversion of convertible notes.
11/30/2021	C2 Ventures Pty Limited	17,724,201	20.60%	24,159,394	21.98%	
<b>2022</b>						
						Participation in placement.
						<i>Note: voting power decreased despite the purchase, due to dilution from third party participation in the placement.</i>
12/16/2022	C2 Ventures Pty Limited	24,159,394	21.98%	27,234,394	20.95%	

(1) In February 2022, the Company undertook a 10:1 share consolidation. Figures are shown on a post-consolidation basis for consistency of presentation. Actual pre-consolidation figures may differ slightly due to rounding.

## RELATED PARTY TRANSACTIONS

*Other than compensation arrangements which are described under “Management—Remuneration” or as disclosed below, from July 1, 2019 through the date of this prospectus we did not enter into any transactions or loans with any: (i) enterprises that directly or indirectly, through one or more intermediaries, control, are controlled by or are under common control with us; (ii) associates; (iii) individuals owning, directly or indirectly, an interest in our voting power that gives them significant influence over us, and close members of any such individual’s family; (iv) key management personnel and close members of such individuals’ families; or (v) enterprises in which a substantial interest in our voting power is owned, directly or indirectly, by any person described in (iii) or (iv) or over which such person is able to exercise significant influence.*

### Related Person Transactions

We comply with Australian law (including the Corporations Act) and the ASX Listing Rules regarding approval of transactions with related parties. Our Audit & Risk Committee is responsible for reviewing and monitoring the propriety of related party transactions, as set out in the Audit & Risk Committee Charter.

#### *C2 Ventures Pty Limited*

In December 2020, C2 Ventures Pty Ltd participated in a capital placement and subscribed to 17,681,818 shares (pre-consolidation) in CardieX at A\$0.0275 per share, representing a A\$486,250 contribution of working capital to CardieX.

On December 21, 2020, we issued 1,768,182 ordinary shares at A\$0.275 per share for an aggregate offering price of A\$468,250, together with 4,420,455 options at an exercise price of \$0.05 per share, to C2 Ventures Pty Limited approved at the Annual General Meeting of shareholders held on December 11, 2020.

In January 2021, C2 Ventures Pty Ltd participated in a Share Purchase Plan (SPP), and subscribed to 600,000 shares (pre-consolidation) in CardieX at A\$0.05 per share, representing a A\$30,000 contribution of working capital to CardieX.

In October and November 2021, C2 Ventures Pty Ltd exercised 2,420,455 listed options (pre-consolidation) and 37,500,000 unlisted options (pre-consolidation) at A\$0.05 per share, representing a A\$1,996,023 contribution of working capital to CardieX.

On November 30, 2021, we issued 783,147 ordinary shares, at a deemed issue price of \$0.30 per share, to C2 Ventures Pty Limited pursuant to the exercise of 234,944 convertible notes approved at the General Meeting of shareholders held on February 26, 2019.

In September 2022, C2 Ventures Pty Ltd participated in a SPP, and subscribed to 25,000 shares (post-consolidation) in CardieX at A\$0.30 per share, representing a A\$7,500 contribution of working capital to CardieX.

On December 16, 2022, we issued 3,000,000 ordinary shares at A\$0.30 per share for an aggregate offering price of A\$900,000, together with 1,000,000 options at an exercise price of A\$0.45 per share, to C2 Ventures Pty Limited approved at the Annual General Meeting of shareholders held on November 30, 2022.

In December 2022, C2 Ventures Pty Ltd participated in a capital placement and subscribed to 3,000,000 shares (post-consolidation) in CardieX at A\$0.30 per share, representing a A\$900,000 contribution of working capital to CardieX. 1,000,000 free attaching options (post-consolidation) were received as part of the placement, which attract an exercise price of A\$0.45 per share, and expire on December 16, 2023.

C2 Ventures Pty Ltd is proposing to participate in CardieX’s convertible note facility, by subscribing for up to 750,000 convertible notes (post-consolidation) in CardieX at A\$1.00 per convertible note, representing a maximum \$750,000 contribution of working capital to CardieX. Up to 1,500,000 free-attaching options (post-consolidation) will be issued as part of the convertible note facility, which attract an exercise price of A\$0.45, and expire on August 31, 2026. The issue of convertible notes and options to C2 Ventures Pty Ltd is subject to shareholder approval, which is to be sought at the next general meeting of shareholders.

### ***Carnethy Evergreen Pty Ltd***

In January 2021, Carnethy Evergreen Pty Ltd, an entity controlled by Niall Cairns, participated in a SPP, and subscribed to 600,000 shares (pre-consolidation) in CardieX at A\$0.05 per share, representing a A\$30,000 contribution of working capital to CardieX.

In September 2022, Carnethy Evergreen Pty Ltd, participated in a SPP, and subscribed to 50,000 shares (post-consolidation) in CardieX at A\$0.30 per share, representing a A\$15,000 contribution of working capital to CardieX.

Carnethy Evergreen Pty Ltd is proposing to participate in CardieX's convertible note facility, by subscribing for up to 100,000 convertible notes (post-consolidation) in CardieX at A\$1.00 per convertible note, representing a maximum \$100,000 contribution of working capital to CardieX. Up to 200,000 free-attaching options (post-consolidation) will be issued as part of the convertible note facility, which attract an exercise price of A\$0.45, and expire on August 31, 2026. The issue of convertible notes and options to Carnethy Evergreen Pty Ltd is subject to shareholder approval, which is to be sought at the next general meeting of shareholders.

### ***Traverse Accountants Pty Ltd***

On December 21, 2020, we issued 100,000 ordinary shares, at a deemed issue price of \$0.30 per share, to Traverse Accountants Pty Ltd. in lieu of a cash payment of A\$30,000 for services approved at the Annual General Meeting of shareholders held on December 11, 2020.

In January 2021, Traverse Accountants Pty Ltd, an entity controlled by Jarrod White, participated in a SPP, and subscribed to 600,000 shares (pre-consolidation) in CardieX at A\$0.05 per share, representing a A\$30,000 contribution of working capital to CardieX.

In December 2022, Traverse Accountants Pty Ltd participated in a capital placement and subscribed to 334,331 shares (post-consolidation) in CardieX at A\$0.30 per share, representing a A\$100,299 contribution of working capital to CardieX. 111,444 free attaching options (post-consolidation) were received as part of the placement, which attract an exercise price of A\$0.45, and expire in December 16, 2023.

Traverse Accountants also provide arms' length services to CardieX, including CFO, company secretarial, tax, general accounting and advisory services.

On January 13, 2022, we issued 51,021 ordinary shares, at a deemed issue price of \$0.686 per share, to Traverse Accountants Pty Ltd in lieu of a cash payment of A\$35,000 for services approved at the Annual General Meeting of shareholders held on December 16, 2021.

On December 16, 2022, we issued 117,998 ordinary shares, at a deemed issue price of A\$0.30 per share, to Traverse Accountants Pty Ltd in lieu of a cash payment of A\$35,000 for services approved at the Annual General Meeting of shareholders held on November 30, 2022.

On December 16, 2022, we issued 334,331 ordinary shares at A\$0.30 per share for an aggregate offering price of A\$100,299.30, together with 111,444 options at an exercise price of A\$0.45 per share, to Traverse Accountants Pty Ltd approved at the Annual General Meeting of shareholders held on November 30, 2022.

### ***Jarrod White***

Jarrod White (or his nominee) is proposing to participate in CardieX's convertible note facility, by subscribing for up to 250,000 convertible notes (post-consolidation) in CardieX at A\$1.00 per convertible note, representing a maximum \$250,000 contribution of working capital to CardieX. Up to 500,000 free-attaching options (post-consolidation) will be issued as part of the convertible note facility, which attract an exercise price of A\$0.45, and expire on August 31, 2026. The issue of convertible notes and options to Jarrod White (or his nominee) is subject to shareholder approval, which is to be sought at the next general meeting of shareholders.

### ***Indemnification Obligations***

*Constitution.* Our Constitution provides, to the maximum extent permitted by the law, for the indemnification of every person who is or has been an officer or a director of CardieX (or a subsidiary of CardieX) against liability incurred by that person acting as an officer or director. The indemnity excludes a liability: (i) owed to CardieX or a related body corporate, (ii) for a pecuniary penalty or compensation order under certain provision of the Corporations Act, or (iii) that did not arise out of conduct in good faith. The indemnity also applies to the extent permitted by law to costs and expenses incurred by the person in defending proceedings, whether civil or criminal, in which the courts grant relief to the person under the Corporations Act.

Our Constitution also permits, to the maximum extent permitted by law, us to maintain insurance insuring a person who is or has been a director or an officer against a liability incurred by that person in that capacity (including for legal costs), unless the liability arises out of conduct on the part of the person which involves a willful breach of duty in relation to the company or arises out of a breach of directors' duties owed under the Corporations Act.

*Indemnification Agreements.* We have entered into a deed of access and indemnity with each member of our board of directors and each of our officers. These agreements provide for the indemnification of our directors and officers for certain expenses and liabilities incurred in connection with any action, suit, proceeding or alternative dispute resolution mechanism or hearing, inquiry or investigation that may lead to the foregoing, to which they are a party, or are threatened to be made a party, by reason of the fact that they are or were a director, officer, employee, agent or fiduciary of our company, or any of our subsidiaries, by reason of any action or inaction by them while serving as an officer, director, agent or fiduciary, or by reason of the fact that they were serving at our request as a director, officer, employee, agent or fiduciary of another entity. In the case of an action or proceeding by or in the right of our company or any of our subsidiaries, no indemnification will be provided for any claim where a court determines that the indemnified party is prohibited from receiving indemnification. We believe that these deeds of access and indemnity are necessary to attract and retain qualified persons as directors and officers. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

## DESCRIPTION OF SHARE CAPITAL

### General

The following description summarizes certain terms of our capital stock and certain provisions of our Constitution. This summary does not purport to be complete and is qualified in its entirety by the provisions of our Constitution, a copy of which are filed with the SEC as an exhibit to the Registration Statement on Form F-1 of which this prospectus forms a part, and to the applicable provisions of Australian law.

We are a public company limited by shares registered under the Corporations Act by the Australian Securities & Investments Commission, or ASIC. Our corporate affairs are principally governed by our Constitution, the Corporations Act and the ASX Listing Rules. Our ordinary shares trade on the ASX, and we are applying to list the ADSs on the Nasdaq Capital Market.

The Australian law applicable to our Constitution is not significantly different than a U.S. company's charter documents except we do not have the concept of or a limit on our authorized share capital, the concept of par value is not recognized under Australian law and as further discussed under "—Our Constitution."

Subject to restrictions on the issue of securities in our Constitution, the Corporations Act and the ASX Listing Rules and any other applicable law, we may at any time issue shares and grant options or warrants on any terms, with the rights and restrictions and for the consideration that our board of directors determine.

The rights and restrictions attaching to ordinary shares are derived through a combination of our Constitution, the common law applicable to Australia, the ASX Listing Rules, the Corporations Act and other applicable law. A general summary of some of the rights and restrictions attaching to our ordinary shares is set forth below. Each shareholder is entitled to receive notice of, and to be present, vote and speak at, general meetings.

### Changes to Our Share Capital

As of June 30, 2022, we had (i) 110,003,700 fully paid ordinary shares outstanding, (ii) outstanding options to purchase an aggregate of 1,530,000 ordinary shares expiring on January 15, 2024 at a weighted exercise price of A\$0.50, (iii) outstanding options to purchase an aggregate of 300,000 ordinary shares expiring on February 26, 2024 at a weighted exercise price of A\$0.50, (iv) outstanding options to purchase an aggregate of 400,000 ordinary shares expiring on February 15, 2026 at a weighted exercise price of A\$0.50, (v) outstanding options to purchase an aggregate of 2,925,000 ordinary shares expiring on February 15, 2026 at a weighted exercise price of A\$0.80, (vi) outstanding options to purchase an aggregate of 125,000 ordinary shares expiring on June 11, 2026 at a weighted exercise price of A\$0.80, (vii) outstanding options to purchase an aggregate of 1,300,000 ordinary shares expiring on June 30, 2027 at a weighted exercise price of A\$0.80, and (viii) outstanding performance rights to acquire an aggregate of 16,050,000 ordinary shares.

In February 2022, we completed a consolidation of all of our issued securities on a 1 for 10 basis. At the time of such consolidation, the directors proposed the consolidation for the following reasons:

- the number of shares issued by us represented a relatively large number when compared to our listed peer group;
- the consolidation would assist in reducing the volatility of our share price and enable a more consistent valuation; and
- the consolidation was expected to assist in positioning us for long term growth by making an investment in our securities more attractive to institutional and other investors.



During the last three years, the following changes have been made to our ordinary share capital:

During FY2022, we issued the following securities:

<b>Date</b>	<b>Details</b>	<b>No.</b>	<b>Issue Price A\$</b>	<b>Total Value A\$</b>
June 30, 2022	Share issue – to an employee in lieu of cash payment for services	50,000	0.31	15,500
January 13, 2022	Share issue – to director Traverse Accountants Pty Ltd (an entity controlled by Jarrod White) in lieu of cash payment for services	51,206	0.686	35,000
November 30, 2021	Share issue – conversion of convertible notes by C2 Ventures Pty Limited	783,147	0.30	234,944.01
November 30, 2021	Share issue – conversion of 6,000,000 performance rights by Carnethy Investments Pty Ltd (an entity controlled by Niall Cairns), and conversion of 6,000,000 performance rights by Craig Cooper	1,200,000	-	-
September 20, 2021 to November 30 2021	Share issue – multiple conversions of free-attaching options expiring November 30, 2021	15,204,862	0.50	7,602,431
September 20, 2021	Share issue – to an employee in lieu of cash payment for services	110,428	0.62	68,465
<b>Total FY2022 Movement</b>		<b>17,399,643</b>		<b>7,956,340</b>

During FY2021, we issued the following securities:

<b>Date</b>	<b>Details</b>	<b>No.</b>	<b>Issue Price A\$</b>	<b>Total Value A\$</b>
December 21, 2020 to June 18, 2021	Share issue – multiple conversions of free-attaching options expiring November 30, 2021	188,158	0.50	94,078
January 22, 2021	Share issue –conversion of free-attaching options expiring November 30, 2021	250,000	0.375	93,750
January 12, 2021	Share issue – to Australian and New Zealand shareholders under a share purchase plan	6,414,000	0.50	3,207,000
December 21, 2020	Share issue – conversion of employee option	13,333	0.33	4,400
December 21, 2020	Share issue – placement to C2 Ventures Pty Limited	1,768,182	0.275	486,250
December 21, 2020	Share issue – to an employee in lieu of cash payment for services	100,000	0.50	50,000
December 21, 2020	Share issue – to Traverse Accountants Pty Ltd (an entity controlled by director Jarrod White) in lieu of cash payment for services	100,000	0.30	30,000
August 3, 2020	Share issue - placement to sophisticated and professional investors	8,333,334	0.30	2,500,000
July 2, 2020	Share issue – to an employee in lieu of cash payment for services	115,881	0.23	26,652
<b>Total FY2021 Movement</b>		<b>17,282,888</b>		<b>6,492,130</b>

During FY2020, we issued the following securities:

<b>Date</b>	<b>Details</b>	<b>No.</b>	<b>Issue Price A\$</b>	<b>Total Value A\$</b>
November 21, 2019	Share issue – issue to C2 Ventures Pty Limited on conversion of 640,303 convertible notes	2,134,343	0.30	640,303
December 30, 2019	Share issue – placement to institutional investors	3,636,364	0.275	1,000,000
<b>Total FY2020 Movement</b>		<b>5,770,707</b>		<b>1,640,303</b>

## **Our Constitution**

Our Constitution is similar in nature to the bylaws of a U.S. corporation. It does not provide for or prescribe any specific objectives or purposes of CardieX. Our Constitution is subject to the terms of the ASX Listing Rules and the Corporations Act. It may be modified or repealed and replaced by special resolution passed at a meeting of shareholders, which is a resolution passed by at least 75% of the votes cast by shareholders entitled to vote on the resolution who vote at the relevant meeting, in person, by proxy, by attorney or by representative.

Under Australian law, a company has the legal capacity and powers of an individual both within and outside Australia. The material provisions of our Constitution are summarized below. This summary is not intended to be complete nor to constitute a definitive statement of the rights and liabilities of our shareholders. Our Constitution is filed as an exhibit to the registration statement, of which this prospectus forms a part.

## **Directors**

### ***Interested Directors***

Except as permitted by the Corporations Act and the ASX Listing Rules, a director (or that director's alternate) must not vote in respect of any contract or arrangement in which the director has any direct or indirect material personal interest. Such director must not be counted in a quorum, must not vote on the matter and must not be present at the meeting while the matter is being considered (unless the other directors, not having a material personal interest, resolve to the contrary, or if they are so entitled under a declaration or order made by ASIC in accordance with the Corporations Act).

Provided that a director makes disclosure as required by our Constitution and the Corporations Act, the director may execute or otherwise act in respect of a contract or arrangement with us notwithstanding any material personal interest and is not liable to account to us for any profit arising from that contract or arrangement by reason only of the director holding that office or of the director's fiduciary relationship with CardieX.

Unless a relevant exception applies, the Corporations Act requires our directors to provide disclosure of certain interests and prohibits directors of companies listed on the ASX from voting on matters in which they have a material personal interest and from being present at the meeting while the matter is being considered. In addition, unless a relevant exception applies, the Corporations Act and the ASX Listing Rules require shareholder approval of any provision of financial benefits (including the issue by us of shares and other securities) to our directors, including entities controlled by them and certain members of their families.

### ***Directors' Compensation***

Our directors are paid remuneration for their services as directors. The maximum aggregate amount of fees that can be paid to non-executive directors is subject to approval by shareholders at a general meeting of shareholders. The aggregate fixed sum for directors' remuneration is divided among the directors in such proportion as the directors themselves agree and in accordance with our Constitution. The aggregate fixed sum remuneration for non-executive directors may not be increased except at a general meeting of shareholders and the particulars of the proposed increase are required to have been provided to shareholders in the notice convening the meeting.

A managing director or an executive director may be provided with remuneration as determined by our board of directors from time to time and, subject to the ASX Listing Rules, including as a salary, commission on or participation in profits and/or by the issue of shares, options to acquire shares or performance rights or other incentives (or a combination of any of these methods of remuneration), but must not be by commission on, or a percentage of, operating revenue.

In addition to other remuneration provided in our Constitution, all of our directors are entitled to be paid by us for all other out-of-pocket travel, accommodation and other expenses incurred by the directors in attending company meetings, board meetings, committee meetings or while engaged in our business.

We may also pay a premium in respect of a contract insuring a person who is or has been a director against liability incurred by the person as a director, except in circumstances prohibited by the Corporations Act or other applicable laws.

In addition, a director may be paid a retirement benefit as determined by our board of directors, subject to the limits set out in the Corporations Act and the ASX Listing Rules which broadly restrict our ability to pay our officers a termination benefit in the event of a change of control of CardieX or of our subsidiaries as well as impose requirements for shareholder approval to be obtained to pay certain retirement benefits to our officers. See “Management—Remuneration— Non-Executive Director Compensation.”

#### ***Borrowing Powers Exercisable by Directors***

Pursuant to our Constitution, our business is managed by our board of directors. Our board of directors has the power to raise or borrow money, and charge any of our property or business or any uncalled capital, and may issue debentures or give any other security for any of our debts, liabilities, contracts or obligations or of any other person, in each case, in the manner and on terms it deems fit.

#### ***Retirement of Directors***

In accordance with our Constitution and the ASX Listing Rules, a director (other than the Managing Director) must not hold office without re-election past the third annual general meeting following the director’s appointment or three years, whichever is longer. However, a director (other than the Managing Director) who is appointed during the year by the other directors only holds office until the next annual general meeting at which time the director may stand for election by shareholders at that meeting.

While CardieX is admitted to the official list of ASX, at least one director must stand for election or re-election at each annual general meeting. If no director is standing for election or re-election or is required to retire at an annual general meeting, then the director who has been longest in office since that director’s last election must retire from office at that annual general meeting. The retiring directors are eligible for re-election to our board of directors.

In addition, provisions of the Corporations Act apply where at least 25% of the votes cast on a resolution to adopt our remuneration report (which resolution must be proposed each year at our annual general meeting) are against the adoption of the report at two successive annual general meetings. Where these provisions apply, a resolution must be put to a vote at the second annual general meeting to the effect that a further meeting, or a spill meeting, take place within 90 days. At the spill meeting, the directors in office when the remuneration report was considered at the second annual general meeting (other than the Managing Director) cease to hold office and resolutions to appoint directors (which may involve re-appointing the former directors) are put to a vote.

Voting restrictions apply in relation to the resolutions to adopt our remuneration report and to propose a spill meeting. These restrictions apply to our key management personnel and their closely related parties. See “—Voting Rights” below.

Pursuant to our Constitution, no person is eligible to be elected as a director unless a notice of the director’s candidature is given to us at least 35 business days (30 business days for a meeting shareholders have requested directors to call) before the meeting. This restriction does not apply to a retiring director or to the election of a director previously appointed by the directors during the year.

### ***Share Qualifications***

There are currently no requirements for directors to own our ordinary shares in order to qualify as directors.

### **Rights and Restrictions on Classes of Shares**

Subject to the Corporations Act and the ASX Listing Rules, the rights attaching to our ordinary shares are detailed in our Constitution. Our Constitution provides that any of our ordinary shares may be issued with preferred, deferred or other special rights, whether in relation to dividends, voting, return of share capital, payment of calls or otherwise as our board of directors may determine from time to time. Subject to the Corporations Act and the ASX Listing Rules, any rights and restrictions attached to a class of shares, we may issue further shares on such terms and conditions as our board of directors resolve. Currently, our outstanding share capital consists of only one class of ordinary shares.

### ***Dividend Rights***

Subject to the Corporations Act, our board of directors may from time to time determine to pay dividends or other distributions to shareholders. Except as otherwise provided by law, all dividends unclaimed for one year after having been determined may be invested or otherwise made use of by our board of directors for our benefit in accordance with our Constitution and any applicable law.

### ***Voting Rights***

Under our Constitution, and subject to the ASX Listing Rules and the rights or restrictions on voting attaching to a class of shares, each shareholder has one vote determined by a show of hands at a meeting of the shareholders unless a poll is demanded under the Constitution or the Corporations Act. On a poll vote, each such shareholder shall have one vote for each fully paid share and a fractional vote for each share that is not fully paid, such fraction being equivalent to the proportion of the amount that has been paid to such date on that share. Shareholders may vote by proxy, attorney or representative or via a direct vote. Under Australian law, shareholders of a public listed company are not permitted to approve corporate matters by written consent. Our Constitution does not provide for cumulative voting.

Note that ADS holders may not directly vote at a meeting of the shareholders but may instruct the depository to vote the number of deposited ordinary shares their ADSs represent.

There are a number of circumstances where the Corporations Act or the ASX Listing Rules prohibit or restrict certain shareholders or certain classes of shareholders from voting. For example, key management personnel details of whose remuneration are included in our annual remuneration report and their closely related parties are prohibited from voting on the resolution that must be proposed at each annual general meeting to adopt our remuneration report, as well as any resolution to propose a spill meeting. An exception applies to exercising a directed proxy which indicates how the proxy is to vote on the proposed resolution on behalf of someone other than the key management personnel or their closely related parties; or that person is chair of the meeting and votes an undirected proxy where the shareholder expressly authorizes the chair to exercise that power. Key management personnel and their closely related parties are also prohibited from voting undirected proxies on remuneration related resolutions. A similar exception to that described above applies if the proxy is the chair of the meeting.

### ***Right to Share in Our Profits***

Subject to the Corporations Act and pursuant to our Constitution, prior to our liquidation, our shareholders are entitled to participate in our profits only by payment of dividends.

### ***Rights to Share in the Surplus in the Event of Liquidation***

Our Constitution provides for the right of shareholders to participate in a surplus in the event of our liquidation, subject to the rights attaching to a class of shares and any amounts unpaid on the share.

### ***Redemption Provisions***

There are no redemption provisions in our Constitution in relation to ordinary shares. Under our Constitution and subject to the Corporations Act, any preference shares may be issued on the terms that they are, or may at our option or at the option of the holder be, liable to be redeemed.

### ***Sinking Fund Provisions***

Our Constitution allows our directors to, at their discretion, set aside any sums they think proper out of our profits as reserves, which may be applied for any proper purpose.

### ***Liability for Further Capital Calls***

According to our Constitution, our board of directors may make any calls from time to time upon shareholders in respect of all monies unpaid on partly paid shares respectively held by them, subject to the terms upon which any of the partly paid shares have been issued. Each shareholder is liable to pay the amount of each call in the manner, at the time and at the place specified by our board of directors. Calls may be made payable by installment.

### ***Provisions Discriminating Against Holders of a Substantial Number of Shares***

There are no provisions under our Constitution discriminating against any existing or prospective holders of a substantial number of our ordinary shares.

### **Variation or Cancellation of Share Rights**

Subject to the Corporations Act and the ASX Listing Rules, the rights attached to shares in a class of shares (unless otherwise provide by the terms of issue of the shares in that class) may only be varied or cancelled by either:

- a special resolution (being a resolution passed by at least 75% of the votes cast by shareholders entitled to vote on the resolution) passed at a meeting of shareholders holding shares in that class; or
- the written consent of shareholders with at least 75% of the votes in the class.

### **General Meetings of Shareholders**

General meetings of shareholders may be called by our board of directors or, under the Corporations Act, by a single director. Except as permitted under the Corporations Act, shareholders may not convene a meeting. Under the Corporations Act, shareholders with at least 5% of the votes that may be cast at a general meeting may call and arrange to hold a general meeting. The Corporations Act also requires the directors to call and arrange to hold a general meeting on the request of shareholders with at least 5% of the votes that may be cast at a general meeting. Notice of the proposed meeting of our shareholders is required at least 28 days prior to such meeting under the Corporations Act. We must hold an annual general meeting at least once in each calendar year, and within five months after the end of each fiscal year.

### **Foreign Ownership Regulation**

There are no limitations on the rights to own securities imposed by our Constitution. However, acquisitions and proposed acquisitions of securities in Australian companies may be subject to review and approval by the Australian Federal Treasurer under the Foreign Acquisitions and Takeovers Act 1975 (as amended) (the "FATA"), which generally applies to acquisitions or proposed acquisitions:

- by a foreign person (as defined in the FATA) or associated foreign persons that would result in such persons having an interest in 20% or more of the issued shares of, or control of 20% or more of the voting power in, an Australian company; and
- by non-associated foreign persons that would result in such foreign person having an aggregate interest in 40% or more of the issued shares of, or control of 40% or more of the voting power in, an Australian company, where the Australian company is valued above the monetary thresholds prescribed by FATA.

However, in respect of non-sensitive businesses, no such review or approval under the FATA is required if the foreign acquirer is a private U.S. entity (or an entity from certain other countries) and the value of the Australian company is less than A\$1,250 million.

The Australian Federal Treasurer may prevent a proposed acquisition in the above categories or impose conditions on such acquisition if the Treasurer is satisfied that the acquisition would be contrary to the national interest. If a foreign person acquires shares or an interest in shares in an Australian company in contravention of the FATA, the Australian Federal Treasurer may order the divestiture of such person's shares or interest in shares in that Australian company.

In addition, under FATA, all foreign government investors must notify the Australian Government and get prior approval before making a direct investment in Australia, regardless of the value of the investment. What constitutes a foreign government investor is defined broadly in FATA.

#### **Ownership Threshold**

There are no provisions in our Constitution that require a shareholder to disclose ownership above a certain threshold. The Corporations Act, however, requires a substantial shareholder to notify us and the ASX once a 5% or greater interest in our ordinary shares is obtained. Further, once a shareholder has (alone or together with associates) a 5% or greater interest in us, such shareholder must notify us and the ASX of any increase or decrease of 1% or more in its interest in our ordinary shares, and must also notify us and the ASX on its ceasing to be a substantial shareholder. In most cases, such notice must be given to us and the ASX within two business days after the relevant shareholder becomes aware of the information. Upon becoming a U.S. listed public company, our shareholders will also be subject to disclosure requirements under U.S. securities laws.

#### ***Shareholder Approval of Securities Offerings***

Under the ASX Listing Rules, a company must not, subject to specified exceptions, without the approval of its shareholders, issue or agree to issue, during any 12 month period, any equity securities, or other securities with rights to convert into equity, if the number of those securities exceeds 15% of the number of shares on issue at the commencement of that 12 month period ("Placement Capacity"), plus an additional 10% of such shares in certain circumstances.

New securities to be issued in connection with this offering do not fall within any of the specified exceptions and there is currently insufficient headroom in our Placement Capacity for us to issue all of the new securities proposed to be issued in connection with this offering. Accordingly, we intend to seek the approval of our shareholders voting at an extraordinary general meeting of shareholders to issue the new securities proposed to be issued in connection with this offering for the purposes of the ASX Listing Rules. We will need to receive this approval from our shareholders prior to the completion of this offering.

#### ***Issues of Shares and Change in Capital***

Subject to our Constitution, the Corporations Act, the ASX Listing Rules and any other applicable law, we may at any time issue shares and grant options, performance rights, or warrants on any terms, with preferred, deferred or other special rights and restrictions and for the consideration and other terms that the directors determine. Our power to issue shares includes the power to issue bonus shares (for which no consideration is payable to CardieX), preference shares and partly paid shares.

Subject to the requirements of our Constitution, the Corporations Act, the ASX Listing Rules and any other applicable law, including relevant shareholder approvals, we may consolidate or divide our share capital into a smaller or larger number by resolution, reduce our share capital (provided that the reduction is fair and reasonable to our shareholders as a whole and does not materially prejudice our ability to pay creditors) or buy back our ordinary shares including under an equal access buy-back or on a selective basis.

### *Change of Control*

Takeovers of listed Australian public companies, such as CardieX, are regulated by the Corporations Act, which prohibits the acquisition of a “relevant interest” in issued voting shares in a listed company if the acquisition will lead to that person’s or someone else’s voting power in CardieX increasing from 20% or below to more than 20% or increasing from a starting point that is above 20% and below 90%, subject to a range of exceptions.

Generally, a person will have a relevant interest in securities if the person:

- is the holder of the securities;
- has power to exercise, or control the exercise of, a right to vote attached to the securities; or
- has the power to dispose of, or control the exercise of a power to dispose of, the securities,

including any indirect or direct power or control (such as through interposed entities).

If, at a particular time, a person has a relevant interest in issued securities and the person (whether before or after acquiring the relevant interest):

- has entered or enters into an agreement with another person with respect to the securities;
- has given or gives another person an enforceable right, or has been or is given an enforceable right by another person, in relation to the securities (whether the right is enforceable presently or in the future and whether or not on the fulfillment of a condition); or
- has granted or grants an option to, or has been or is granted an option by, another person with respect to the securities,

and the other person would have a relevant interest in the securities if the agreement were performed, the right enforced or the option exercised, then the other person is taken to already have a relevant interest in the securities.

There are a number of exceptions to the above prohibition on acquiring a relevant interest in issued voting shares above 20%. In general terms, some of the more significant exceptions include:

- the acquisition by a bidder resulting from the acceptance of an offer under a formal takeover bid that complies with the Corporations Act;
- when the acquisition is conducted on market by or on behalf of the bidder under a takeover bid that complies with the Corporations Act, the acquisition occurs during the bid period, the bid is for all the voting shares in CardieX, and the bid is unconditional or only conditioned on prescribed matters set out in the Corporations Act;
- when shareholders of CardieX (other than the parties to the acquisition and their associates) approve an acquisition that would otherwise breach the prohibition, by resolution passed at general meeting;

- an acquisition by a person if, throughout the six months before the acquisition, that person or any other relevant person has had voting power in CardieX of at least 19% and, as a result of the acquisition, none of the relevant persons would have voting power in CardieX more than three percentage points higher than they had six months before the acquisition;
- as a result of a shareholder taking up its entitlement in a pro rata rights issue;
- as a result of dividend reinvestment schemes;
- as a result of certain underwriting arrangements;
- through operation of law (for example, under a will);
- an acquisition that arises through the acquisition of a relevant interest in another company listed on the ASX, certain other Australian financial markets or a foreign stock exchange approved in writing by ASIC;
- arising from an auction of forfeited shares conducted on-market; or
- arising through a compromise, arrangement, liquidation or buy-back.

Breaches of the takeovers provisions of the Corporations Act are criminal offenses. In addition, Australian courts and the Australian Takeover Panel have a wide range of powers relating to breaches of takeover provisions, including the ability to make orders canceling contracts, freezing transfers of, and rights (including voting rights) attached to, securities, and forcing a party to dispose of securities including by vesting the securities in ASIC for sale. There are certain defenses to breaches of the takeover provisions provided in the Corporations Act.

#### **Access to and Inspection of Documents**

Inspection of our records is governed by the Corporations Act. Any member of the public has the right to inspect or obtain copies of our registers on the payment of a prescribed fee (provided that the purpose to obtain copies is not a “prescribed purpose” for the purposes of the Corporations Act). Shareholders are not required to pay a fee for inspection of our registers or minute books of the meetings of shareholders. Other corporate records, including minutes of directors’ meetings, financial records and other documents, are not open for inspection by shareholders. Where a shareholder is acting in good faith and an inspection is deemed to be made for a proper purpose, a shareholder may apply to the court to make an order for inspection of our books.

#### **Exemptions from Certain Nasdaq Capital Market Corporate Governance Rules**

The Nasdaq Listing Rules allow for a foreign private issuer, such as CardieX, to follow its home country practices in lieu of certain of the Nasdaq Capital Market’s corporate governance standards. In connection with our Nasdaq Listing Application, we expect to rely on exemptions from certain corporate governance standards that are contrary to the laws, rules, regulations or generally accepted business practices in the United States. These exemptions being sought are described below:

- We expect to rely on an exemption from the independence requirements for a majority of our board of directors as prescribed by Nasdaq Listing Rules. The ASX Listing Rules do not require us to have a majority of independent directors although ASX Corporate Governance Principles and Recommendations (4<sup>th</sup> edition) do recommend a majority of independent directors, including having a Chair who is an independent director. During FY2022, 2 of our 5 directors were “independent” as defined in our Board Charter, which sets out independence criteria that are based on (but not exactly the same as) the recommended independence criteria in the ASX Corporate Governance Principles and Recommendations. Our Chair, Niall Cairns, was not considered to be an independent director. The “independence” criteria in our Board Charter (as well as the guidance in the ASX Corporate Governance Principles and Recommendations) differ from Nasdaq Capital Market’s definition of “independent.” Accordingly, because Australian law, ASX guidance and generally accepted business practices in Australia regarding director independence differ from the independence requirements under Nasdaq Listing Rules, we seek to claim this exemption.
- We expect to rely on an exemption from the requirement that our independent directors meet regularly in executive sessions under Nasdaq Listing Rules. The ASX Listing Rules and the Corporations Act do not require the independent directors of an Australian company to have such executive sessions and, accordingly, we seek to claim this exemption.
- We expect to rely on an exemption from the quorum requirements applicable to meetings of shareholders under Nasdaq Listing Rules. Consistent with Australian law, our Constitution provides that three shareholders present (whether in person or by proxy, attorney or a representative) at a meeting and entitled to vote at the meeting shall constitute a quorum for the general meeting, regardless of the number of percentage of shares they hold. Nasdaq Listing Rules require that an issuer provide for a quorum as specified in its bylaws for any meeting of the holders of ordinary shares, which quorum may not be less than 33-1/3% of the outstanding shares of an issuer’s voting ordinary shares. Accordingly, because applicable Australian law and rules governing quorums at shareholder meetings differ from Nasdaq Capital Market’s quorum requirements, we seek to claim this exemption.
- We expect to rely on an exemption from the requirement prescribed by Nasdaq Listing Rules that issuers obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions, private placements of securities, or the establishment or amendment of certain equity option, purchase or other compensation plans. Applicable Australian law and the ASX Listing Rules differ from Nasdaq Capital Market requirements, with the ASX Listing Rules providing generally for prior shareholder approval in numerous circumstances, including (i) issuance of equity securities exceeding 15% (potentially with an additional 10% capacity to issue shares for cash during the following 12 month period if shareholder approval by special resolution is sought at CardieX’s annual general meeting) of our issued share capital in any 12-month period (but, in determining the available limit, securities issued under an exception to the rule or with shareholder approval are not counted), (ii) issuance of equity securities to related parties (as defined in the ASX Listing Rules) and certain substantial shareholders who hold, or at any time in the prior six months held, at least a 10% shareholding, or to their respective associates, and (iii) issuance of equity securities to directors or their associates under an employee incentive plan. Due to differences between Australian law and ASX Listing Rules and the Nasdaq Capital Market shareholder approval requirements, we seek to claim this exemption.



## DESCRIPTION OF AMERICAN DEPOSITARY SHARES

### American Depositary Receipts

JPMorgan Chase Bank, N.A., as depositary, will issue the ADSs which you will be entitled to receive in this offering. Each ADS will represent an ownership interest in ordinary shares which we will deposit with the custodian, as agent of the depositary, under the deposit agreement among ourselves, the depositary, yourself as an ADR holder and all other ADR holders, and all beneficial owners of an interest in the ADSs evidenced by ADRs from time to time.

The depositary's office is located at 383 Madison Avenue, Floor 11, New York, NY 10179.

The ADS to share ratio is subject to amendment as provided in the form of ADR (which may give rise to fees contemplated by the form of ADR). In the future, each ADS will also represent any securities, cash or other property deposited with the depositary but which they have not distributed directly to you.

A beneficial owner is any person or entity having a beneficial ownership interest in ADSs. A beneficial owner need not be the holder of the ADR evidencing such ADS. If a beneficial owner of ADSs is not an ADR holder, it must rely on the holder of the ADR(s) evidencing such ADSs in order to assert any rights or receive any benefits under the deposit agreement. A beneficial owner shall only be able to exercise any right or receive any benefit under the deposit agreement solely through the holder of the ADR(s) evidencing the ADSs owned by such beneficial owner. The arrangements between a beneficial owner of ADSs and the holder of the corresponding ADRs may affect the beneficial owner's ability to exercise any rights it may have.

An ADR holder shall be deemed to have all requisite authority to act on behalf of any and all beneficial owners of the ADSs evidenced by the ADRs registered in such ADR holder's name for all purposes under the deposit agreement and ADRs. The depositary's only notification obligations under the deposit agreement and the ADRs is to registered ADR holders. Notice to an ADR holder shall be deemed, for all purposes of the deposit agreement and the ADRs, to constitute notice to any and all beneficial owners of the ADSs evidenced by such ADR holder's ADRs.

Unless certificated ADRs are specifically requested, all ADSs will be issued on the books of our depositary in book-entry form and periodic statements will be mailed to you which reflect your ownership interest in such ADSs. In our description, references to American depositary receipts or ADRs shall include the statements you will receive which reflect your ownership of ADSs.

You may hold ADSs either directly or indirectly through your broker or other financial institution. If you hold ADSs directly, by having an ADS registered in your name on the books of the depositary, you are an ADR holder. This description assumes you hold your ADSs directly. If you hold the ADSs through your broker or financial institution nominee, you must rely on the procedures of such broker or financial institution to assert the rights of an ADR holder described in this section. You should consult with your broker or financial institution to find out what those procedures are.

As an ADR holder or beneficial owner, we will not treat you as a shareholder of ours and you will not have any shareholder rights. Australian law governs shareholder rights. Because the depositary or its nominee will be the shareholder of record for the ordinary shares represented by all outstanding ADSs, shareholder rights rest with such record holder. Your rights are those of an ADR holder or of a beneficial owner. Such rights derive from the terms of the deposit agreement to be entered into among us, the depositary and all holders and beneficial owners from time to time of ADRs issued under the deposit agreement and, in the case of a beneficial owner, from the arrangements between the beneficial owner and the holder of the corresponding ADRs. The obligations of the depositary and its agents are also set out in the deposit agreement. Because the depositary or its nominee will actually be the registered owner of the ordinary shares, you must rely on it to exercise the rights of a shareholder on your behalf. The deposit agreement, the ADRs and the ADSs are governed by the internal laws of the State of New York without giving effect to the application of the conflict of law principles thereof. Under the deposit agreement, as an ADR holder or a beneficial owner of ADSs, you agree that any legal suit, action or proceeding against or involving us or the depositary, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated thereby, may only be instituted in the United States District Court for the Southern District of New York (or, in certain cases, the state courts of New York County, New York), and you irrevocably waive any objection which you may have to the laying of venue of any such proceeding and irrevocably submit to the exclusive jurisdiction of such courts in any such suit, action or proceeding.

The following is a summary of what we believe to be the material terms of the deposit agreement. Notwithstanding this, because it is a summary, it may not contain all the information that you may otherwise deem important. For more complete information, you should read the entire deposit agreement and the form of ADR which contains the terms of your ADSs. You can read a copy of the deposit agreement which is filed as an exhibit to the registration statement (or amendment thereto) filed with the U.S. Securities and Exchange Commission (the "SEC") of which this prospectus forms a part. You may also obtain a copy of the deposit agreement at the SEC's Public Reference Room which is currently located at 100 F Street, NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-732-0330. You may also find the registration statement and the attached deposit agreement through the EDGAR system on the SEC's internet website at <http://www.sec.gov>.

### **Ordinary Share Dividends and Other Distributions**

#### ***How will I receive dividends and other distributions on the ordinary shares underlying my ADSs?***

We may make various types of distributions with respect to our securities. The depositary has agreed that, to the extent practicable, it will pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities, after converting any cash received into U.S. dollars (if it determines such conversion may be made on a reasonable basis) and, in all cases, making any necessary deductions provided for in the deposit agreement. The depositary may utilize a division, branch or affiliate of JPMorgan Chase Bank, N.A. to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement. Such division, branch and/or affiliate may charge the depositary a fee in connection with such sales, which fee is considered an expense of the depositary. You will receive these distributions in proportion to the number of underlying securities that your ADSs represent.

Except as stated below, the depositary will deliver such distributions to ADR holders in proportion to their interests in the following manner:

- *Cash.* The depositary will distribute any U.S. dollars available to it resulting from a cash dividend or other cash distribution or the net proceeds of sales of any other distribution or portion thereof (to the extent applicable), on an averaged or other practicable basis, subject to (i) appropriate adjustments for taxes withheld, (ii) such distribution being impermissible or impracticable with respect to certain registered ADR holders, and (iii) deduction of the depositary's and/or its agents' expenses in (1) converting any foreign currency to U.S. dollars to the extent that it determines that such conversion may be made on a reasonable basis, (2) transferring foreign currency or U.S. dollars to the United States by such means as the depositary may determine to the extent that it determines that such transfer may be made on a reasonable basis, (3) obtaining any approval or license of any governmental authority required for such conversion or transfer, which is obtainable at a reasonable cost and within a reasonable time and (4) making any sale by public or private means in any commercially reasonable manner. *If exchange rates fluctuate during a time when the depositary cannot convert a foreign currency, you may lose some or all of the value of the distribution.*
- *Ordinary Shares.* In the case of a distribution in ordinary shares, the depositary will issue additional ADRs to evidence the number of ADSs representing such ordinary shares. Only whole ADSs will be issued. Any ordinary shares which would result in fractional ADSs will be sold and the net proceeds will be distributed in the same manner as cash to the ADR holders entitled thereto.

- *Rights to receive additional ordinary shares.* In the case of a distribution of rights to subscribe for additional ordinary shares or other rights, if we timely provide evidence satisfactory to the depositary that it may lawfully distribute such rights, the depositary will distribute warrants or other instruments in the discretion of the depositary representing such rights. However, if we do not timely furnish such evidence, the depositary may:

(i) sell such rights if practicable and distribute the net proceeds in the same manner as cash to the ADR holders entitled thereto; or

(ii) if it is not practicable to sell such rights by reason of the non-transferability of the rights, limited markets therefor, their short duration or otherwise, do nothing and allow such rights to lapse, in which case ADR holders will receive nothing and the rights may lapse. We have no obligation to file a registration statement under the U.S. Securities Act of 1933, as amended (the "Securities Act"), in order to make any rights available to ADR holders.

- *Other Distributions.* In the case of a distribution of securities or property other than those described above, the depositary may either (i) distribute such securities or property in any manner it deems equitable and practicable or (ii) to the extent the depositary deems distribution of such securities or property not to be equitable and practicable, sell such securities or property and distribute any net proceeds in the same way it distributes cash.
- *Elective Distributions.* In the case of a dividend payable at the election of our shareholders in cash or in additional ordinary shares, we will notify the depositary at least 30 days prior to the proposed distribution stating whether or not we wish such elective distribution to be made available to ADR holders. The depositary shall make such elective distribution available to ADR holders only if (i) we shall have timely requested that the elective distribution is available to ADR holders, (ii) the depositary shall have determined that such distribution is reasonably practicable and (iii) the depositary shall have received satisfactory documentation within the terms of the deposit agreement including any legal opinions of counsel that the depositary in its reasonable discretion may request. If the above conditions are not satisfied, the depositary shall, to the extent permitted by law, distribute to the ADR holders, on the basis of the same determination as is made in the local market in respect of the ordinary shares for which no election is made, either (x) cash or (y) additional ADSs representing such additional ordinary shares. If the above conditions are satisfied, the depositary shall establish procedures to enable ADR holders to elect the receipt of the proposed dividend in cash or in additional ADSs. There can be no assurance that ADR holders or beneficial owners of ADSs generally, or any ADR holder or beneficial owner of ADSs in particular, will be given the opportunity to receive elective distributions on the same terms and conditions as the holders of ordinary shares.

If the depositary determines in its discretion that any distribution described above is not practicable with respect to any specific registered ADR holder, the depositary may (after consultation with us, if practicable, in the case where the depositary believes such distribution is not practicable with respect to all ADR holders) choose any method of distribution that it deems practicable for such ADR holder, including the distribution of foreign currency, securities or property, or it may retain such items, without paying interest on or investing them, on behalf of the ADR holder as deposited securities, in which case the ADSs will also represent the retained items.

Any U.S. dollars will be distributed by checks drawn on a bank in the United States for whole dollars and cents. Fractional cents will be withheld without liability and dealt with by the depositary in accordance with its then current practices.

*The depositary is not responsible if it fails to determine that any distribution or action is lawful or reasonably practicable.*

*There can be no assurance that the depositary will be able to convert any currency at a specified exchange rate or sell any property, rights, ordinary shares or other securities at a specified price, nor that any of such transactions can be completed within a specified time period. All purchases and sales of securities will be handled by the depositary in accordance with its then current policies, which are currently set forth on the "Disclosures" page (or successor page) of [www.adr.com](http://www.adr.com) (as updated by the depositary from time to time, "ADR.com").*

#### **Deposit, Withdrawal and Cancellation**

##### ***How does the depositary issue ADSs?***

The depositary will issue ADSs if you or your broker deposit ordinary shares or evidence of rights to receive ordinary shares with the custodian and pay the fees and expenses owing to the depositary in connection with such issuance. In the case of the ADSs to be issued under this prospectus, we will arrange with the underwriters named herein to deposit such ordinary shares.

Ordinary shares deposited in the future with the custodian must be accompanied by certain delivery documentation and shall, at the time of such deposit, be registered in the name of JPMorgan Chase Bank, N.A., as depositary for the benefit of holders of ADRs or in such other name as the depositary shall direct.

The custodian will hold all deposited ordinary shares (including those being deposited by or on our behalf in connection with the offering to which this prospectus relates) for the account and to the order of the depositary, in each case for the benefit of ADR holders, to the extent not prohibited by law. ADR holders and beneficial owners thus have no direct ownership interest in the ordinary shares and only have such rights as are contained in the deposit agreement. The custodian will also hold any additional securities, property and cash received on or in substitution for the deposited ordinary shares. The deposited ordinary shares and any such additional items are referred to as "deposited securities".

Deposited securities are not intended to, and shall not, constitute proprietary assets of the depositary, the custodian or their nominees. Beneficial ownership in deposited securities is intended to be, and shall at all times during the term of the deposit agreement continue to be, vested in the beneficial owners of the ADSs representing such deposited securities. Notwithstanding anything else contained herein, in the deposit agreement, in the form of ADR and/or in any outstanding ADSs, the depositary, the custodian and their respective nominees are intended to be, and shall at all times during the term of the deposit agreement be, the record holder(s) only of the deposited securities represented by the ADSs for the benefit of the ADR holders. The depositary, on its own behalf and on behalf of the custodian and their respective nominees, disclaims any beneficial ownership interest in the deposited securities held on behalf of the ADR holders.

Upon each deposit of ordinary shares, receipt of related delivery documentation and compliance with the other provisions of the deposit agreement, including the payment of the fees and charges of the depositary and any taxes or other fees or charges owing, the depositary will issue an ADR or ADRs in the name or upon the order of the person entitled thereto evidencing the number of ADSs to which such person is entitled. All of the ADSs issued will, unless specifically requested to the contrary, be part of the depositary's direct registration system, and a registered holder will receive periodic statements from the depositary which will show the number of ADSs registered in such holder's name. An ADR holder can request that the ADSs not be held through the depositary's direct registration system and that a certificated ADR be issued.

### ***How do ADR holders cancel an ADS and obtain deposited securities?***

When you turn in your ADR certificate at the depositary's office, or when you provide proper instructions and documentation in the case of direct registration ADSs, the depositary will, upon payment of certain applicable fees, charges and taxes, deliver the underlying ordinary shares to you or upon your written order. Delivery of deposited securities in certificated form will be made at the custodian's office. At your risk, expense and request, the depositary may deliver deposited securities at such other place as you may request.

The depositary may only restrict the withdrawal of deposited securities in connection with:

- temporary delays caused by closing our transfer books or those of the depositary or the deposit of ordinary shares in connection with voting at a shareholders' meeting, or the payment of dividends;
- the payment of fees, taxes and similar charges; or
- compliance with any U.S. or foreign laws or governmental regulations relating to the ADRs or to the withdrawal of deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

### **Record Dates**

The depositary may, after consultation with us if practicable, fix record dates (which, to the extent applicable, shall be as near as practicable to any corresponding record dates set by us) for the determination of the registered ADR holders who will be entitled (or obligated, as the case may be):

- to receive any distribution on or in respect of deposited securities,
- to give instructions for the exercise of voting rights at a meeting of holders of ordinary shares,
- to pay any fees, expenses or charges assessed by, or owing to, the depositary for administration of the ADR program as provided for in the ADR, or
- to receive any notice or to act in respect of other matters,

all subject to the provisions of the deposit agreement.

### **Voting Rights**

#### ***How do I vote?***

If you are an ADR holder and the depositary asks you to provide it with voting instructions, you may instruct the depositary how to exercise the voting rights for the ordinary shares which underlie your ADSs. As soon as practicable after receipt from us of notice of any meeting at which the holders of ordinary shares are entitled to vote, or of our solicitation of consents or proxies from holders of ordinary shares, the depositary shall fix the ADS record date in accordance with the provisions of the deposit agreement, provided that if the depositary receives a written request from us in a timely manner and at least 30 days prior to the date of such vote or meeting, the depositary shall, at our expense, distribute to the registered ADR holders a "voting notice" stating (i) final information particular to such vote and meeting and any solicitation materials, (ii) that each ADR holder on the record date set by the depositary will, subject to any applicable provisions of Australian law, be entitled to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the deposited securities represented by the ADSs evidenced by such ADR holder's ADRs and (iii) the manner in which such instructions may be given, including instructions for giving a discretionary proxy to a person designated by us. Each ADR holder shall be solely responsible for the forwarding of voting notices to the beneficial owners of ADSs registered in such ADR holder's name. There is no guarantee that ADR holders and beneficial owners generally or any holder or beneficial owner in particular will receive the notice described above with sufficient time to enable such ADR holder or beneficial owner to return any voting instructions to the depositary in a timely manner.

Following actual receipt by the ADR department responsible for proxies and voting of ADR holders' instructions (including, without limitation, instructions of any entity or entities acting on behalf of the nominee for DTC), the depositary shall, in the manner and on or before the time established by the depositary for such purpose, endeavor to vote or cause to be voted the deposited securities represented by the ADSs evidenced by such ADR holders' ADRs in accordance with such instructions insofar as practicable and permitted under the provisions of or governing deposited securities.

ADR holders are strongly encouraged to forward their voting instructions to the depositary as soon as possible. For instructions to be valid, the ADR department of the depositary that is responsible for proxies and voting must receive them in the manner and on or before the time specified, notwithstanding that such instructions may have been physically received by the depositary prior to such time. The depositary will not itself exercise any voting discretion in respect of deposited securities. The depositary and its agents will not be responsible for any failure to carry out any instructions to vote any of the deposited securities, for the manner in which any voting instructions are given, including instructions to give a discretionary proxy to a person designated by us, for the manner in which any vote is cast, including, without limitation, any vote cast by a person to whom the depositary is instructed to grant a discretionary proxy, or for the effect of any such vote. Notwithstanding anything contained in the deposit agreement or any ADR, the depositary may, to the extent not prohibited by any law, rule, or regulation, or by the rules, regulations or requirements of any stock exchange on which the ADSs are listed, in lieu of distribution of the materials provided to the depositary in connection with any meeting of or solicitation of consents or proxies from holders of deposited securities, distribute to the registered holders of ADRs a notice that provides such ADR holders with or otherwise publicizes to such ADR holders instructions on how to retrieve such materials or receive such materials upon request (*i.e.*, by reference to a website containing the materials for retrieval or a contact for requesting copies of the materials).

We have advised the depositary that under Australian law and our Constitution, each as in effect as of the date of the deposit agreement, voting at any meeting of our shareholders is by way of a show of hands, unless a poll is demanded on the relevant resolution by the chair of the meeting, or by at least 5 holders of ordinary shares, or by holders of ordinary shares who collectively hold at least 5% of the ordinary shares issued and outstanding. We have further advised that current best practice in Australia is for all substantive resolutions to be voted on by way of a poll instead of a show of hands, and for this procedure to be specified in the notice of meeting. In the event that voting on any resolution or matter is conducted on a show of hands basis in accordance with Australian law or our Constitution, the depositary will refrain from voting and the voting instructions received by the depositary from ADS holders shall lapse. The depositary will not demand a poll or join in demanding a poll, whether or not requested to do so by holders of ADSs.

There is no guarantee that you will receive voting materials in time to instruct the depositary to vote and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.

#### **Reports and Other Communications**

##### ***Will ADR holders be able to view our reports?***

The depositary will make available for inspection by ADR holders at the offices of the depositary and the custodian the deposit agreement, the provisions of or governing deposited securities, and any written communications from us which are both received by the custodian or its nominee as a holder of deposited securities and made generally available to the holders of deposited securities.

Additionally, if we make any written communications generally available to holders of our ordinary shares, and we furnish copies thereof (or English translations or summaries) to the depositary, it will distribute the same to registered ADR holders.

#### **Fees and Expenses**

##### ***What fees and expenses will I be responsible for paying?***

The depositary may charge each person to whom ADSs are issued, including, without limitation, issuances against deposits of ordinary shares, issuances in respect of ordinary share distributions, rights and other distributions, issuances pursuant to a stock dividend or stock split declared by us or issuances pursuant to a merger, exchange of securities or any other transaction or event affecting the ADSs or deposited securities, and each person surrendering ADSs for withdrawal of deposited securities or whose ADRs are cancelled or reduced for any other reason, US\$5.00 for each 100 ADSs (or any portion thereof) issued, delivered, reduced, cancelled or surrendered, or upon which a share distribution or elective distribution is made or offered, as the case may be. The depositary may sell (by public or private sale) sufficient securities and property received in respect of an ordinary share distribution, rights and/or other distribution prior to such deposit to pay such charge.

The following additional fees, charges and expenses shall also be incurred by the ADR holders, the beneficial owners, by any party depositing or withdrawing ordinary shares or by any party surrendering ADSs and/or to whom ADSs are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by us or an exchange of stock regarding the ADSs or the deposited securities or a distribution of ADSs), whichever is applicable:

- a fee of US\$0.05 or less per ADS held for any cash distribution made, or for any elective cash/stock dividend offered, pursuant to the deposit agreement;
- an aggregate fee of US\$0.05 or less per ADS per calendar year (or portion thereof) for services performed by the depositary in administering the ADRs (which fee may be charged on a periodic basis during each calendar year and shall be assessed against holders of ADRs as of the record date or record dates set by the depositary during each calendar year and shall be payable in the manner described in the next succeeding provision);
- an amount for the reimbursement of such charges and expenses as are incurred by the depositary and/or any of its agents (including, without limitation, the custodian and charges and expenses incurred on behalf of ADR holders in connection with compliance with foreign exchange control regulations or any law or regulation relating to foreign investment) in connection with the servicing of the ordinary shares or other deposited securities, the sale of securities (including, without limitation, deposited securities), the delivery of deposited securities or otherwise in connection with the depositary's or its custodian's compliance with applicable law, rule or regulation (which charges and expenses may be assessed on a proportionate basis against ADR holders as of the record date or dates set by the depositary and shall be payable at the sole discretion of the depositary by billing such ADR holders or by deducting such charge or expense from one or more cash dividends or other cash distributions);
- a fee for the distribution of securities (or the sale of securities in connection with a distribution), such fee being in an amount equal to the US\$0.05 per ADS issuance fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities (treating all such securities as if they were ordinary shares) but which securities or the net cash proceeds from the sale thereof are instead distributed by the depositary to those ADR holders entitled thereto;
- stock transfer or other taxes and other governmental charges;
- a transaction fee per cancellation request (including through SWIFT, telex and facsimile transmission) as disclosed on the "Disclosures" page (or successor page) of ADR.com and any applicable delivery expenses (which are payable by such persons or holders);
- transfer or registration fees for the registration of transfer of deposited securities on any applicable register in connection with the deposit or withdrawal of deposited securities; and
- fees of any division, branch or affiliate of the depositary utilized by the depositary to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement.

To facilitate the administration of various depositary receipt transactions, including disbursement of dividends or other cash distributions and other corporate actions, the depositary may engage the foreign exchange desk within JPMorgan Chase Bank, N.A. (the "**Bank**") and/or its affiliates in order to enter into spot foreign exchange transactions to convert foreign currency into U.S. dollars. For certain currencies, foreign exchange transactions are entered into with the Bank or an affiliate, as the case may be, acting in a principal capacity. For other currencies, foreign exchange transactions are routed directly to and managed by an unaffiliated local custodian (or other third party local liquidity provider), and neither the Bank nor any of its affiliates is a party to such foreign exchange transactions.

The foreign exchange rate applied to a foreign exchange transaction will be either (a) a published benchmark rate, or (b) a rate determined by a third party local liquidity provider, in each case plus or minus a spread, as applicable. The depository will disclose which foreign exchange rate and spread, if any, apply to such currency on the "Disclosures" page (or successor page) of ADR.com. Such applicable foreign exchange rate and spread may (and neither the depository, the Bank nor any of their affiliates is under any obligation to ensure that such rate does not) differ from rates and spreads at which comparable transactions are entered into with other customers or the range of foreign exchange rates and spreads at which the Bank or any of its affiliates enters into foreign exchange transactions in the relevant currency pair on the date of the foreign exchange transaction. Additionally, the timing of execution of a foreign exchange transaction varies according to local market dynamics, which may include regulatory requirements, market hours and liquidity in the foreign exchange market or other factors. Furthermore, the Bank and its affiliates may manage the associated risks of their position in the market in a manner they deem appropriate without regard to the impact of such activities on the depository, us, holders or beneficial owners. *The spread applied does not reflect any gains or losses that may be earned or incurred by the Bank and its affiliates as a result of risk management or other hedging related activity.*

Notwithstanding the foregoing, to the extent we provide U.S. dollars to the depository, neither the Bank nor any of its affiliates will execute a foreign exchange transaction as set forth herein. In such case, the depository will distribute the U.S. dollars received from us.

*Further details relating to the applicable foreign exchange rate, the applicable spread and the execution of foreign exchange transactions will be provided by the depository on ADR.com. Each holder and beneficial owner by holding or owning an ADR or ADS or an interest therein, and we, each acknowledge and agree that the terms applicable to foreign exchange transactions disclosed from time to time on ADR.com will apply to any foreign exchange transaction executed pursuant to the deposit agreement.*

We will pay all other fees, charges and expenses of the depository and any agent of the depository (except the custodian) pursuant to agreements from time to time between us and the depository.

The right of the depository to receive payment of fees, charges and expenses survives the termination of the deposit agreement, and shall extend for those fees, charges and expenses incurred prior to the effectiveness of any resignation or removal of the depository.

The fees and charges described above may be amended from time to time by agreement between us and the depository.

The depository may make available to us a set amount or a portion of the depository fees charged in respect of the ADR program or otherwise upon such terms and conditions as we and the depository may agree from time to time. The depository collects its fees for issuance and cancellation of ADSs directly from investors depositing ordinary shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depository collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depository may collect its annual fee for depository services by deduction from cash distributions, or by directly billing investors, or by charging the book-entry system accounts of participants acting for them. The depository will generally set off the amounts owing from distributions made to holders of ADSs. If, however, no distribution exists and payment owing is not timely received by the depository, the depository may refuse to provide any further services to ADR holders that have not paid those fees and expenses owing until such fees and expenses have been paid. At the discretion of the depository, all fees and charges owing under the deposit agreement are due in advance and/or when declared owing by the depository.

#### **Payment of Taxes**

ADR holders or beneficial owners must pay any tax or other governmental charge payable by the custodian or the depository on any ADS or ADR, deposited security or distribution. If any taxes or other governmental charges (including any penalties and/or interest) shall become payable by or on behalf of the custodian or the depository with respect to any ADR, any deposited securities represented by the ADSs evidenced thereby or any distribution thereon, such tax or other governmental charge shall be paid by the ADR holder thereof to the depository and by holding or owning, or having held or owned, an ADR or any ADSs evidenced thereby, the ADR holder and all beneficial owners thereof, and all prior ADR holders and beneficial owners thereof, jointly and severally, agree to indemnify, defend and save harmless each of the depository and its agents in respect of such tax or governmental charge.



Neither the depositary, nor any of its agents, shall be liable to holders or beneficial owners of the ADSs and ADRs for failure of any of them to comply with applicable tax laws, rules and/or regulations. Notwithstanding the depositary's right to seek payment from current and former beneficial owners of ADSs and ADRs, ADR holders (and all prior ADR holders) acknowledge and agree that the depositary has no obligation to seek payment of amounts owing for tax and other governmental charges from any current or former beneficial owner of ADSs and ADRs. If an ADR holder owes any tax or other governmental charge, the depositary may (i) deduct the amount thereof from any cash distributions, or (ii) sell deposited securities (by public or private sale after attempting by reasonable means to notify the ADR holder prior to such sale) and deduct the amount owing from the net proceeds of such sale. In either case the ADR holder remains liable for any shortfall. If any tax or governmental charge is unpaid, the depositary may also refuse to effect any registration, registration of transfer, split-up or combination of deposited securities or withdrawal of deposited securities until such payment is made. If any tax or governmental charge is required to be withheld on any cash distribution, the depositary may deduct the amount required to be withheld from any cash distribution or, in the case of a non-cash distribution, sell the distributed property or securities (by public or private sale) in such amounts and in such manner as the depositary deems necessary and practicable to pay such taxes and distribute any remaining net proceeds or the balance of any such property after deduction of such taxes to the ADR holders entitled thereto.

As an ADR holder or beneficial owner, you will be agreeing to indemnify us, the depositary, its custodian and any of our or their respective officers, directors, employees, agents and affiliates against, and hold each of them harmless from, any claims by any governmental authority with respect to taxes, additions to tax, penalties or interest arising out of any refund of taxes, reduced rate of withholding at source or other tax benefit obtained.

#### **Reclassifications, Recapitalizations and Mergers**

If we take certain actions that affect the deposited securities, including (i) any change in par value, split-up, consolidation, cancellation or other reclassification of deposited securities or (ii) any distributions of ordinary shares or other property not made to holders of ADRs or (iii) any recapitalization, reorganization, merger, consolidation, liquidation, receivership, bankruptcy or sale of all or substantially all of our assets, then the depositary may choose to, and shall if reasonably requested by us:

- amend the form of ADR;
- distribute additional or amended ADRs;
- distribute cash, securities or other property it has received in connection with such actions;
- sell any securities or property received and distribute the proceeds as cash; or
- none of the above.

If the depositary does not choose any of the above options, any of the cash, securities or other property it receives will constitute part of the deposited securities and each ADS will then represent a proportionate interest in such property.

## **Amendment and Termination**

### ***How may the deposit agreement be amended?***

We may agree with the depository to amend the deposit agreement and the ADSs without your consent for any reason. ADR holders must be given at least 30 days' notice of any amendment that imposes or increases any fees, charges or expenses (other than stock transfer or other taxes and other governmental charges, transfer or registration fees, a transaction fee per cancellation request (including through SWIFT, telex or facsimile transmission), applicable delivery expenses or other such fees, charges or expenses), or otherwise prejudices any substantial existing right of ADR holders or beneficial owners. Such notice need not describe in detail the specific amendments effectuated thereby, but must identify to ADR holders and beneficial owners a means to access the text of such amendment. If an ADR holder continues to hold an ADR or ADRs after being so notified, such ADR holder and any beneficial owner are deemed to agree to such amendment and to be bound by the deposit agreement as so amended. No amendment, however, will impair your right to surrender your ADSs and receive the underlying securities, except in order to comply with mandatory provisions of applicable law.

Any amendments or supplements which (i) are reasonably necessary (as agreed by us and the depository) in order for (a) the ADSs to be registered on Form F-6 under the Securities Act or (b) the ADSs or ordinary shares to be traded solely in electronic book-entry form and (ii) do not in either such case impose or increase any fees or charges to be borne by ADR holders, shall be deemed not to prejudice any substantial rights of ADR holders or beneficial owners. Notwithstanding the foregoing, if any governmental body or regulatory body should adopt new laws, rules or regulations which would require amendment or supplement of the deposit agreement or the form of ADR to ensure compliance therewith, we and the depository may amend or supplement the deposit agreement and the ADR at any time in accordance with such changed laws, rules or regulations. Such amendment or supplement to the deposit agreement in such circumstances may become effective before a notice of such amendment or supplement is given to ADR holders or within any other period of time as required for compliance.

Notice of any amendment to the deposit agreement or form of ADRs shall not need to describe in detail the specific amendments effectuated thereby, and failure to describe the specific amendments in any such notice shall not render such notice invalid, provided, however, that, in each such case, the notice given to the ADR holders identifies a means for ADR holders and beneficial owners to retrieve or receive the text of such amendment (*i.e.*, upon retrieval from the SEC's, the depository's or our website or upon request from the depository).

### ***How may the deposit agreement be terminated?***

The depository may, and shall at our written direction, terminate the deposit agreement and the ADRs by mailing notice of such termination to the registered holders of ADRs at least 30 days prior to the date fixed in such notice for such termination; provided, however, if the depository shall have (i) resigned as depository under the deposit agreement, notice of such termination by the depository shall not be provided to registered ADR holders unless a successor depository shall not be operating under the deposit agreement within 60 days of the date of such resignation, and (ii) been removed as depository under the deposit agreement, notice of such termination by the depository shall not be provided to registered holders of ADRs unless a successor depository shall not be operating under the deposit agreement on the 60<sup>th</sup> day after our notice of removal was first provided to the depository. Notwithstanding anything to the contrary herein, the depository may terminate the deposit agreement (a) without notifying us, but subject to giving 30 days' notice to the ADR holders, under the following circumstances: (i) in the event of our bankruptcy or insolvency, (ii) if the ordinary shares cease to be listed on an internationally recognized stock exchange, (iii) if we effect (or will effect) a redemption of all or substantially all of the deposited securities, or a cash or share distribution representing a return of all or substantially all of the value of the deposited securities, or (iv) there occurs a merger, consolidation, sale of assets or other transaction as a result of which securities or other property are delivered in exchange for or in lieu of deposited securities, and (b) immediately without prior notice to us, any holder or beneficial owner or any other person if required by any law, rule or regulation or any governmental authority or body, or the depository would be subject to liability under or pursuant to any law, rule or regulation or by any governmental authority or body, in each case as determined by the depository in its reasonable discretion.

After the date fixed for termination, then instead of the provisions in the prior paragraph, after the date so fixed for termination, the depositary and its agents will perform no further acts under the deposit agreement or the ADRs, except to receive and hold (or sell) distributions on ordinary shares and/or deposited securities and deliver ordinary shares and/or deposited securities being withdrawn. As soon as practicable after the date so fixed for termination, the depositary has agreed to use its reasonable efforts to sell the ordinary shares and/or deposited securities and shall thereafter (as long as it may lawfully do so) hold in an account (which may be a segregated or unsegregated account) the net proceeds of such sales, together with any other cash then held by it under the deposit agreement, without liability for interest, in trust for the pro rata benefit of the registered ADR holders not theretofore surrendered. After making such sale, the depositary shall be discharged from all obligations in respect of the deposit agreement and the ADRs, except to account for such net proceeds and other cash. After the date so fixed for termination, we shall be discharged from all obligations under the deposit agreement except for our obligations to the depositary and its agents.

#### **Limitations on Obligations and Liability to ADR holders**

##### *Limits on our obligations and the obligations of the depositary; limits on liability to ADR holders and holders of ADSs*

Prior to the issue, registration, registration of transfer, split-up, combination, or cancellation of any ADRs, or the delivery of any distribution in respect thereof, and from time to time in the case of the production of proofs as described below, we or the depositary or its custodian may require:

- payment with respect thereto of (i) any stock transfer or other tax or other governmental charge, (ii) any stock transfer or registration fees in effect for the registration of transfers of ordinary shares or other deposited securities upon any applicable register and (iii) any applicable fees and expenses described in the deposit agreement;
- the production of proof satisfactory to it of (i) the identity of any signatory and genuineness of any signature and (ii) such other information, including without limitation, information as to citizenship, residence, exchange control approval, beneficial or other ownership of, or interest in, any securities, compliance with applicable law, regulations, provisions of or governing deposited securities and terms of the deposit agreement and the ADRs, as it may deem necessary or proper; and
- compliance with such regulations as the depositary may establish consistent with the deposit agreement.

The issuance of ADRs, the acceptance of deposits of ordinary shares, the registration, registration of transfer, split-up or combination of ADRs or the withdrawal of ordinary shares, may be suspended, generally or in particular instances, when the ADR register or any register for deposited securities is closed or when any such action is deemed advisable by the depositary; provided that the ability to withdraw ordinary shares may only be limited under the following circumstances: (i) temporary delays caused by closing transfer books of the depositary or our transfer books or the deposit of ordinary shares in connection with voting at a shareholders' meeting, or the payment of dividends, (ii) the payment of fees, taxes, and similar charges, and (iii) compliance with any laws or governmental regulations relating to ADRs or to the withdrawal of deposited securities.

The deposit agreement expressly limits the obligations and liability of the depositary, the depositary's custodian or ourselves and each of our and their respective agents, provided, however, that no provision of the deposit agreement is intended to constitute a waiver or limitation of any rights which ADR holders or beneficial owners of ADSs may have under the Securities Act of 1933 or the Securities Exchange Act of 1934, to the extent applicable. The deposit agreement provides that each of us, the depositary and our respective agents will:

- incur or assume no liability (including, without limitation, to holders or beneficial owners) if any present or future law, rule, regulation, fiat, order or decree of Australia, the United States or any other country or jurisdiction, or of any governmental or regulatory authority or securities exchange or market or automated quotation system, the provisions of or governing any deposited securities, any present or future provision of our Constitution, any act of God, war, terrorism, epidemic, pandemic, naturalization, expropriation, currency restrictions, extraordinary market conditions, work stoppage, strike, civil unrest, revolutions, rebellions, explosions, cyber, ransomware or malware attack, computer failure or circumstance beyond our, the depositary's or our respective agents' direct and immediate control shall prevent or delay, or shall cause any of them to be subject to any civil or criminal penalty in connection with, any act which the deposit agreement or the ADRs provide shall be done or performed by us, the depositary or our respective agents (including, without limitation, voting);
- incur or assume no liability (including, without limitation, to holders or beneficial owners) by reason of any non-performance or delay, caused as aforesaid, in the performance of any act or things which by the terms of the deposit agreement it is provided shall or may be done or performed or any exercise or failure to exercise discretion under the deposit agreement or the ADRs including, without limitation, any failure to determine that any distribution or action may be lawful or reasonably practicable;
- incur or assume no liability (including, without limitation, to holders or beneficial owners) if it performs its obligations under the deposit agreement and ADRs without gross negligence or willful misconduct;
- in the case of the depositary and its agents, be under no obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities the ADSs or the ADRs;
- in the case of us and our agents, be under no obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities the ADSs or the ADRs, which in our or our agents' opinion, as the case may be, may involve it in expense or liability, unless indemnity satisfactory to us or our agent, as the case may be against all expense (including fees and disbursements of counsel) and liability be furnished as often as may be requested;
- not be liable (including, without limitation, to holders or beneficial owners) for any action or inaction by it in reliance upon the advice of or information from any legal counsel, any accountant, any person presenting ordinary shares for deposit, any registered holder of ADRs, or any other person believed by it to be competent to give such advice or information and/or, in the case of the depositary, us; or
- may rely and shall be protected in acting upon any written notice, request, direction, instruction or document believed by it to be genuine and to have been signed, presented or given by the proper party or parties.

Neither the depository nor its agents have any obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities, the ADSs or the ADRs. We and our agents shall only be obligated to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities, the ADSs or the ADRs, which in our opinion may involve us in expense or liability, if indemnity satisfactory to us against all expense (including fees and disbursements of counsel) and liability is furnished as often as may be required. The depository and its agents may fully respond to any and all demands or requests for information maintained by or on its behalf in connection with the deposit agreement, any registered holder or holders of ADRs, any ADRs or otherwise related to the deposit agreement or ADRs to the extent such information is requested or required by or pursuant to any lawful authority, including without limitation laws, rules, regulations, administrative or judicial process, banking, securities or other regulators. The depository shall not be liable for the acts or omissions made by, or the insolvency of, any securities depository, clearing agency or settlement system. Furthermore, the depository shall not be responsible for, and shall incur no liability in connection with or arising from, the insolvency of any custodian that is not a branch or affiliate of JPMorgan Chase Bank, N.A. Notwithstanding anything to the contrary contained in the deposit agreement or any ADRs, the depository shall not be responsible for, and shall incur no liability in connection with or arising from, any act or omission to act on the part of the custodian except to the extent that any registered ADR holder has incurred liability directly as a result of the custodian having (i) committed fraud or willful misconduct in the provision of custodial services to the depository or (ii) failed to use reasonable care in the provision of custodial services to the depository as determined in accordance with the standards prevailing in the jurisdiction in which the custodian is located. The depository and the custodian(s) may use third party delivery services and providers of information regarding matters such as, but not limited to, pricing, proxy voting, corporate actions, class action litigation and other services in connection with the ADRs and the deposit agreement, and use local agents to provide services such as, but not limited to, attendance at any meetings of security holders of issuers. Although the depository and the custodian will use reasonable care (and cause their agents to use reasonable care) in the selection and retention of such third party providers and local agents, they will not be responsible for any errors or omissions made by them in providing the relevant information or services. The depository shall not have any liability for the price received in connection with any sale of securities, the timing thereof or any delay in action or omission to act nor shall it be responsible for any error or delay in action, omission to act, default or negligence on the part of the party so retained in connection with any such sale or proposed sale.

The depository has no obligation to inform ADR holders or beneficial owners about the requirements of the laws, rules or regulations or any changes therein or thereto of Australia, the United States or any other country or jurisdiction or of any governmental or regulatory authority or any securities exchange or market or automated quotation system.

Additionally, none of the depository, the custodian or us, or any of their or our respective directors, officers, employees, agents or affiliates shall be liable for the failure by any registered holder of ADRs or beneficial owner therein to obtain the benefits of credits or refunds of non-U.S. tax paid against such ADR holder's or beneficial owner's income tax liability. The depository is under no obligation to provide the ADR holders and beneficial owners, or any of them, with any information about our tax status. Neither the depository or us shall incur any liability for any tax or tax consequences that may be incurred by registered ADR holders or beneficial owners on account of their ownership or disposition of ADRs or ADSs.

Neither the depository nor its agents will be responsible for any failure to carry out any instructions to vote any of the deposited securities, for the manner in which any voting instructions are given, including instructions to give a discretionary proxy to a person designated by us, for the manner in which any vote is cast, including, without limitation, any vote cast by a person to whom the depository is instructed to grant a discretionary proxy, or for the effect of any such vote. The depository may rely upon instructions from us or our counsel in respect of any approval or license required for any currency conversion, transfer or distribution. The depository shall not incur any liability for the content of any information submitted to it by us or on our behalf for distribution to ADR holders or for any inaccuracy of any translation thereof, for any investment risk associated with acquiring an interest in the deposited securities, for the validity or worth of the deposited securities, for the credit-worthiness of any third party, for allowing any rights to lapse upon the terms of the deposit agreement or for the failure or timeliness of any notice from us. The depository shall not be liable for any acts or omissions made by a successor depository whether in connection with a previous act or omission of the depository or in connection with any matter arising wholly after the removal or resignation of the depository. Neither the depository nor us, nor any of our or their respective agents shall be liable to the other for any indirect, special, punitive or consequential damages (excluding reasonable fees and expenses of counsel) or lost profits, in each case of any form (collectively, "Special Damages") incurred by any of them, or liable to any other person or entity (including, without limitation, holders or beneficial owners of ADRs and ADSs) for any Special Damages, or any fees or expenses of counsel in connection therewith, whether or not foreseeable and regardless of the type of action in which such a claim may be brought; provided, however, that (i) notwithstanding the foregoing, the depository and its agents shall be entitled to legal fees and expenses in defending against any claim for Special Damages and (ii) to the extent Special Damages arise from or out of a claim brought by a third party (including, without limitation, holders and beneficial owners of ADRs and ADSs) against the depository or any of its agents, the depository and its agents shall be entitled to full indemnification from us for all such Special Damages, and reasonable fees and expenses of counsel in connection therewith, unless such Special Damages are found to have been a direct result of the gross negligence or willful misconduct of the depository.

In the deposit agreement each party thereto (including, for avoidance of doubt, each ADR holder and beneficial owner) irrevocably waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in any suit, action or proceeding against the depository and/or us directly or indirectly arising out of or relating to the ordinary shares or other deposited securities, the ADSs or the ADRs, the deposit agreement or any transaction contemplated therein, or the breach thereof (whether based on contract, tort, common law or any other theory). No provision of the deposit agreement or the ADRs is intended to constitute a waiver or limitation of any rights which an ADR holder or any beneficial owner may have under the Securities Act or the Securities Exchange Act of 1934, to the extent applicable.

The depositary and its agents may own and deal in any class of securities of our company and our affiliates and in ADRs.

#### **Disclosure of Interest in ADSs**

To the extent that the provisions of or governing any deposited securities, or an applicable law or the order or requirement of any relevant regulatory or government body or agency (such as ASIC, ASX, or the Australian Takeovers Panel), may require disclosure of or impose limits on beneficial or other ownership of, or interest in, deposited securities, other ordinary shares and other securities and may provide for blocking transfer, voting or other rights, or for sale, transfer or divestiture of such deposited securities, ordinary shares or other securities, to enforce such disclosure or limits, you as ADR holders or beneficial owners agree to comply with (and authorize the depositary and custodian to comply with) all such requirements and ownership limitations and to comply with any reasonable instructions we may provide in respect thereof.

#### **Books of Depositary**

The depositary or its agent will maintain a register for the registration, registration of transfer, combination and split-up of ADRs, which register shall include the depositary's direct registration system. Registered holders of ADRs may inspect such records at the depositary's office at all reasonable times, but solely for the purpose of communicating with other ADR holders in the interest of the business of our company or a matter relating to the deposit agreement. Such register (and/or any portion thereof) may be closed at any time or from time to time, when deemed expedient by the depositary.

The depositary will maintain facilities for the delivery and receipt of ADRs.

#### **Appointment**

In the deposit agreement, each registered holder of ADRs and each beneficial owner, upon acceptance of any ADSs or ADRs (or any interest in any of them) issued in accordance with the terms and conditions of the deposit agreement will be deemed for all purposes to:

- be a party to and bound by the terms of the deposit agreement and the applicable ADR or ADRs,
- appoint the depositary its attorney-in-fact, with full power to delegate, to act on its behalf and to take any and all actions contemplated in the deposit agreement and the applicable ADR or ADRs, to adopt any and all procedures necessary to comply with applicable laws and to take such action as the depositary in its sole discretion may deem necessary or appropriate to carry out the purposes of the deposit agreement and the applicable ADR and ADRs, the taking of such actions to be the conclusive determinant of the necessity and appropriateness thereof; and
- acknowledge and agree that (i) nothing in the deposit agreement or any ADR shall give rise to a partnership or joint venture among the parties thereto, nor establish a fiduciary or similar relationship among such parties, (ii) the depositary, its divisions, branches and affiliates, and their respective agents, may from time to time be in the possession of non-public information about us, ADR holders, beneficial owners and/or their respective affiliates, (iii) the depositary and its divisions, branches and affiliates may at any time have multiple banking relationships with us, ADR holders, beneficial owners and/or the affiliates of any of them, (iv) the depositary and its divisions, branches and affiliates may, from time to time, be engaged in transactions in which parties adverse to us or ADR holders or beneficial owners and/or their respective affiliates may have interests, (v) nothing contained in the deposit agreement or any ADR(s) shall (A) preclude the depositary or any of its divisions, branches or affiliates from engaging in any such transactions or establishing or maintaining any such relationships, or (B) obligate the depositary or any of its divisions, branches or affiliates to disclose any such transactions or relationships or to account for any profit made or payment received in any such transactions or relationships, (vi) the depositary shall not be deemed to have knowledge of any information held by any branch, division or affiliate of the depositary and (vii) notice to an ADR holder shall be deemed, for all purposes of the deposit agreement and the ADRs, to constitute notice to any and all beneficial owners of the ADSs evidenced by such ADR holder's ADRs. For all purposes under the deposit agreement and the ADRs, the ADR holders thereof shall be deemed to have all requisite authority to act on behalf of any and all beneficial owners of the ADSs evidenced by such ADRs.

### **Governing Law**

The deposit agreement, the ADSs and the ADRs are governed by and construed in accordance with the internal laws of the State of New York without giving effect to the application of the conflict of law principles thereof. In the deposit agreement, we have submitted to the non-exclusive jurisdiction of the courts of the State of New York and appointed an agent for service of process on our behalf. Any action based on the deposit agreement, the ADSs, the ADRs or the transactions contemplated therein or thereby may also be instituted by the depository against us in any competent court in Australia, the United States and/or any other court of competent jurisdiction.

Under the deposit agreement, by holding or owning an ADR or ADS or an interest therein, ADR holders and beneficial owners each irrevocably agree that any legal suit, action or proceeding against or involving ADR holders or beneficial owners brought by us or the depository, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated thereby, may be instituted in a state or federal court in New York, New York, irrevocably waive any objection which you may have to the laying of venue of any such proceeding, and irrevocably submit to the non-exclusive jurisdiction of such courts in any such suit, action or proceeding. We and, by holding or owning an ADR or ADS or an interest therein, ADR holders and beneficial owners each also irrevocably agree that any legal suit, action or proceeding against or involving the depository and/or us brought by ADR holders or beneficial owners, arising out of or based upon the deposit agreement, the ADSs, the ADRs or the transactions contemplated thereby, including, without limitation, claims under the Securities Act of 1933 and Exchange Act, may only be instituted in the United States District Court for the Southern District of New York (or except for claims under the Exchange Act, in the state courts of New York County in New York if either (i) the United States District Court for the Southern District of New York lacks subject matter jurisdiction over a particular dispute or (ii) the designation of the United States District Court for the Southern District of New York as the exclusive forum for any particular dispute is, or becomes, invalid, illegal or unenforceable).

### **Jury Trial Waiver**

In the deposit agreement, each party thereto (including, for the avoidance of doubt, each holder and beneficial owner of, and/or holder of interests in, ADSs or ADRs) irrevocably waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in any suit, action or proceeding against the depository and/or us directly or indirectly arising out of, based on or relating in any way to the ordinary shares or other deposited securities, the ADSs or the ADRs, the deposit agreement or any transaction contemplated therein, or the breach thereof (whether based on contract, tort, common law or any other theory), including any claim under the U.S. federal securities laws.

If we or the depository were to oppose a jury trial demand based on such waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable state and federal law, including whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. The waiver to right to a jury trial in the deposit agreement is not intended to be deemed a waiver by any holder or beneficial owner of ADSs of our or the depository's compliance with the U.S. federal securities laws and the rules and regulations promulgated thereunder.

## SHARES ELIGIBLE FOR FUTURE SALE

Upon completion of this offering, we will have outstanding \_\_\_\_\_ ADSs representing approximately \_\_\_\_\_ % of our ordinary shares in issue. In addition, we will have outstanding \_\_\_\_\_ ordinary shares not represented by ADSs. All of the ADSs sold in this offering will be freely transferable by persons other than our “affiliates” without restriction or further registration under the Securities Act. Sales of substantial amounts of our ADSs in the public market could have a material adverse effect on the prevailing market prices of our ADSs.

Our ordinary shares have been trading on the ASX since November 2005. While application has been made for the ADSs to be listed on the Nasdaq Capital Market, we cannot assure you that an active trading market for our ADSs will develop.

### Lock-up agreements

#### Rule 144

In general, under Rule 144 as currently in effect, beginning 90 days after the date of this prospectus a person who has beneficially owned our “restricted securities” within the meaning of Rule 144 for at least six months is entitled to sell the restricted securities without registration under the Securities Act, subject to certain restrictions. Persons who are our affiliates may sell within any three-month period a number of restricted securities that does not exceed the greater of the following:

- 1% of the number of our ordinary shares then outstanding, in the form of ADSs or otherwise, which will equal approximately shares immediately after this offering, or approximately shares if the underwriters exercise their option to purchase additional ADSs in full; and
- The average weekly trading volume of our ADSs on the during the four calendar weeks preceding the date on which notice of the sale is filed with the SEC.

Sales under Rule 144 by persons who are deemed our affiliates are subject to manner-of-sale provisions, notice requirements and the availability of current public information about us. Persons who are not our affiliates and have beneficially owned our restricted securities for more than six months but not more than one year may sell the restricted securities without registration under the Securities Act, subject to the availability of current public information about us. Persons who are not our affiliates and have beneficially owned our restricted securities for more than one year may freely sell the restricted securities without registration under the Securities Act.

In addition, in each case, these shares would remain subject to lock-up arrangements and would only become eligible for sale when the lock-up period expires.



**Rule 701**

Beginning 90 days after the date of the prospectus, persons other than our affiliates who purchased ordinary shares under a written compensatory plan or contract may be entitled to sell such shares in the United States in reliance on Rule 701. Rule 701 permits affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. Rule 701 further provides that non-affiliates may sell these shares in reliance on Rule 144 subject only to its manner-of-sale requirements.

**Share options**

Shortly after the completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register all ordinary shares issuable under our equity-based compensation plan. See “Management—Remuneration—Non- Executive Remuneration” for a description of such plan.

This Form S-8 registration statement is expected to become effective immediately upon filing, and ordinary shares covered by that registration statement will then be eligible for sale in the public markets, subject to:

- The Rule 144 limitations applicable to affiliates;
- The expiration of the lock-up period; and
- Vesting restrictions imposed by us.

As of June 30, 2023, there were employee options outstanding to purchase 9,405,000 ordinary shares.

## TAXATION

*The following summary of the material Australian and U.S. federal income tax consequences of an investment in our ADSs or ordinary shares (collectively “Offered Securities”) is based upon laws and relevant interpretations thereof in effect as of the date of this prospectus, all of which are subject to change, possibly with retroactive effect. This summary does not deal with all possible tax consequences relating to an investment in our Offered Securities, such as the tax consequences under U.S. state, local and other tax laws other than Australian and U.S. federal income tax laws. To the extent that the discussion relates to matters of Australian tax law, it represents the opinion of Hamilton Locke, our Australian counsel. To the extent that the discussion states definitive legal conclusions under U.S. federal income tax law as to the material U.S. federal income tax consequences of an investment in our Offered Securities, and subject to the qualifications, assumptions and limitations set forth herein (including those set forth in the discussion below regarding the applicability of the passive foreign investment company, or PFIC, rules), it represents the opinion of Wilson, Sonsini, Goodrich & Rosati, Professional Corporation, our special U.S. tax counsel.*

### Material U.S. Federal Income Tax Considerations

The following summary describes the material U.S. federal income tax consequences of the ownership and disposition of our Offered Securities as of the date hereof. Except where noted, this summary deals only with Offered Securities acquired in the initial offering and held as capital assets within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended, or the Code. This section does not discuss the tax consequences to any particular holder, nor any tax considerations that may apply to holders subject to special tax rules, such as:

- banks, insurance companies, regulated investment companies and real estate investment trusts;
- financial institutions;
- individual retirement and other tax-deferred accounts;
- regulated investment companies;
- real estate investment trusts;
- certain former U.S. citizens or long-term residents or U.S. expatriates;
- brokers or dealers in securities or currencies;
- traders that elect to use a mark-to-market method of accounting;
- partnerships and other entities treated as partnership or pass-through entities for U.S. federal income tax purposes, and partners or investors in such entities;
- tax-exempt organizations (including private foundations);
- persons subject to the alternative minimum tax;
- persons that hold or dispose of Offered Securities as a position in a straddle or as part of a hedging, constructive sale, conversion or other integrated transaction, as “qualified small business stock” within the meaning of Section 1202 of the Code, or as Section 1244 stock for purposes of the Code;
- persons that have a functional currency other than the U.S. dollar;

- persons who acquired their Offered Securities pursuant to any employee stock option or otherwise as compensation;
- persons that own (directly, indirectly or constructively) 10% or more of our equity (by vote or value); or
- persons that are not U.S. holders (as defined below), except where specifically discussed below.

In this section, a “U.S. holder” means a beneficial owner of Offered Securities, other than a partnership or other entity treated as a partnership for U.S. federal income tax purposes, that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States (for U.S. federal income tax purposes);
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States or any state thereof or the District of Columbia;
- an estate the income of which is includable in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust (i) the administration of which is subject to the primary supervision of a court in the United States and for which one or more U.S. persons have the authority to control all substantial decisions or (ii) that has an election in effect under applicable income tax regulations to be treated as a U.S. person.

The discussion below is based upon the provisions of the Code, and the U.S. Treasury Regulations, rulings and judicial decisions thereunder as of the date hereof, and such authorities may be replaced, revoked or modified, possibly with retroactive effect, so as to result in U.S. federal income tax consequences different from those discussed below. In addition, this summary is based, in part, upon representations made by the depository to us and assumes that the deposit agreement, and all other related agreements, will be performed in accordance with their terms.

If a partnership or an entity or arrangement treated as a partnership for U.S. federal income tax purposes acquires, owns or disposes of Offered Securities, the U.S. federal income tax treatment of a partner of such partnership generally will depend on the status of the partner and the activities of the partnership. Partners of partnerships that acquire, own or dispose of Offered Securities should consult their tax advisors.

***You are urged to consult your own tax advisor with respect to the U.S. federal, as well as state, local and non-U.S., tax consequences to you of acquiring, owning and disposing of Offered Securities in light of your particular circumstances, including the possible effects of changes in U.S. federal income and other tax laws.***

***Tax Treatment of ADSs***

If you hold ADSs you generally will be treated, for U.S. federal income tax purposes, as the owner of the underlying ordinary shares that are represented by such ADSs. Accordingly, deposits or withdrawals of ordinary shares for ADSs will not be subject to U.S. federal income tax.

## *Taxation of ADSs and Ordinary Shares to U.S. Holders*

### *Distributions*

Subject to the passive foreign investment company, or PFIC, rules discussed below, U.S. holders generally will include as dividend income the U.S. dollar value of the gross amount of any distributions of cash or property (without deduction for any withholding tax), other than certain pro rata distributions of ordinary shares, with respect to ordinary shares or ADSs to the extent the distributions are made from our current or accumulated earnings and profits, as determined for U.S. federal income tax purposes. A U.S. holder will include the dividend income on the day actually or constructively received: (i) by the holder, in the case of ordinary shares, or (ii) by the depository, in the case of ADSs. To the extent, if any, that the amount of any distribution by us exceeds our current and accumulated earnings and profits, as so determined, the excess will be treated first as a tax-free return of the U.S. holder's tax basis in the ordinary shares or ADSs and thereafter as capital gain. Notwithstanding the foregoing, we do not intend to determine our earnings and profits on the basis of U.S. federal income tax principles. Consequently, any distributions generally will be reported as dividend income for U.S. information reporting purposes. See "—Backup Withholding Tax and Information Reporting Requirements" below. Dividends paid by us will not be eligible for the dividends-received deduction generally allowed to U.S. corporate shareholders.

The U.S. dollar amount of dividends received by an individual, trust or estate with respect to the ordinary shares or ADSs will be subject to taxation at a maximum rate of 20% if the dividends are "qualified dividends." Dividends paid on ordinary shares or ADSs will be treated as qualified dividends if (i)(a) we are eligible for the benefits of a comprehensive income tax treaty with the United States that the Secretary of the Treasury of the United States determines is satisfactory for this purpose and includes an exchange of information program or (b) the dividends are with respect to ordinary shares (or ADSs in respect of such shares) which are readily tradable on a U.S. securities market; (ii) certain holding period requirements are met; and (iii) we are not classified as a PFIC for the taxable year in which the dividend is paid or for the preceding taxable year. The Agreement between the Government of the United States of America and the Government of Australia for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income, or the Treaty, has been approved for the purposes of the qualified dividend rules, and we expect to qualify for benefits under the Treaty. We have applied to list the ADSs on The Nasdaq Capital Market. Provided that the listing is approved, U.S. Treasury Department guidance indicates that the ADSs will be readily tradable on an established U.S. securities market. Thus, we believe that as long as we are not a PFIC and certain holding requirements are met, dividends we pay on ADSs or ordinary shares generally should be eligible for the reduced income tax rate on qualified dividends. However, the determination of whether a dividend qualifies for the preferential tax rates must be made at the time the dividend is paid. U.S. holders should consult their own tax advisors.

Includible distributions paid in Australian dollars, including any Australian withholding taxes, will be included in the gross income of a U.S. holder in a U.S. dollar amount calculated by reference to the spot exchange rate in effect on the date of actual or constructive receipt, regardless of whether the Australian dollars are converted into U.S. dollars at that time. If Australian dollars are converted into U.S. dollars on the date of actual or constructive receipt, the tax basis of the U.S. holder in those Australian dollars will be equal to their U.S. dollar value on that date and, as a result, a U.S. holder generally should not be required to recognize any foreign currency exchange gain or loss. If Australian dollars so received are not converted into U.S. dollars on the date of receipt, the U.S. holder will have a basis in the Australian dollars equal to their U.S. dollar value on the date of receipt. Any foreign currency exchange gain or loss on a subsequent conversion or other disposition of the Australian dollars generally will be treated as ordinary income or loss to such U.S. holder and generally will be income or loss from sources within the United States for foreign tax credit limitation purposes.

Dividends received by a U.S. holder with respect to ordinary shares (or ADSs in respect of such shares) will be treated as foreign source income, which may be relevant in calculating the holder's foreign tax credit limitation. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends distributed by us with respect to ADSs or ordinary shares will generally constitute "passive category income" but could, in the case of certain U.S. holders, constitute "general category income."

Subject to certain complex limitations, including the PFIC rules discussed below, a U.S. holder generally will be entitled, at its option, to claim either a credit against its U.S. federal income tax liability or a deduction in computing its U.S. federal taxable income in respect of any Australian taxes withheld. If a U.S. holder elects to claim a deduction, rather than a foreign tax credit, for Australian taxes withheld for a particular taxable year, the election will apply to all foreign taxes paid or accrued by or on behalf of the U.S. holder in the particular taxable year.

The availability of the foreign tax credit and the application of the limitations on its availability are fact specific and are subject to complex rules. You are urged to consult your own tax advisor as to the consequences of Australian withholding taxes and the availability of a foreign tax credit or deduction. See "—Australian Tax Considerations — Taxation of Dividends."

### *Sale, Exchange or Other Disposition of Ordinary Shares or ADSs*

Subject to the PFIC rules discussed below, a U.S. holder generally will, for U.S. federal income tax purposes, recognize capital gain or loss, if any, on a sale, exchange or other disposition of ordinary shares or ADSs equal to the difference between the amount realized on the disposition and the U.S. holder's tax basis (in U.S. dollars) in the ordinary shares or ADSs. This recognized gain or loss will generally be long-term capital gain or loss if the U.S. holder has held the ordinary shares or ADSs for more than one year. Generally, for U.S. holders who are individuals (as well as certain trusts and estates), long-term capital gains are subject to U.S. federal income tax at preferential rates. For foreign tax credit limitation purposes, gain or loss recognized upon a disposition generally will be treated as from sources within the United States. The deductibility of capital losses is subject to limitations for U.S. federal income tax purposes.

You should consult your own tax advisor regarding the tax consequences if a foreign tax is imposed on a disposition of ADSs or ordinary shares, including availability of a foreign tax credit or deduction in respect of any Australian tax imposed on a sale or other disposition of ordinary shares or ADSs. See “—Australian Tax Considerations — Tax on Sales or Other Dispositions of Shares—Capital Gains Tax.”

*Passive Foreign Investment Company*

As a non-U.S. corporation, we will be a PFIC for any taxable year if either: (i) 75% or more of our gross income for the taxable year is passive income (such as certain dividends, interest, rents or royalties) and certain gains from the sale of shares and securities or commodities transactions, including amounts derived by reason of the temporary investment of funds raised in offerings of our ordinary shares or ADSs; or (ii) the average percentage value of our gross assets during the taxable year that produce passive income or are held for the production of passive income is at least 50% of the value of our total assets. For purposes of the PFIC asset test, passive assets generally include any cash, cash equivalents and cash invested in short-term, interest bearing debt instruments or bank deposits that is readily convertible into cash. If we own at least 25% (by value) of the stock of another corporation, we will be treated, for purposes of the PFIC income and asset tests, as owning our proportionate share of the other corporation’s assets and receiving our proportionate share of the other corporation’s income.

We believe we were not a PFIC for the taxable year ending June 30, 2022 and we do not expect to be a PFIC for the taxable year ending June 30, 2023 or the foreseeable future. Our expectation is based on our business projections and the anticipated composition of our income and assets for the current and future taxable years. If our actual business results do not match our projections, it is possible that we may become a PFIC in the current or a future taxable year. The value of our assets for purposes of the PFIC asset test will generally be determined by reference to our market capitalization, which may fluctuate. The composition of our income and assets will also be affected by how, and how quickly, we spend the cash raised in this offering. Since a separate factual determination as to whether we are or have become a PFIC must be made each year (after the close of such year), we cannot assure you that we will not be or become a PFIC in the current year or any future taxable year. Under circumstances where revenues from activities that produce passive income significantly increase relative to our revenues from activities that produce non-passive income or where we decide not to deploy significant amounts of cash for active purposes, our risk of becoming classified as a PFIC may substantially increase. Despite our expectation, there can be no assurance that we will not be a PFIC for any taxable year, as PFIC status is determined each year and depends on the composition of our income and assets and the value of our assets in such year. Our special U.S. tax counsel expresses no opinion with respect to our expectations contained in this paragraph.

### *Default PFIC Rules*

If we are a PFIC for any taxable year during which you own our ordinary shares or ADSs, unless you make the mark-to-market election or the Qualified Electing Fund election described below, you will generally be (and remain) subject to additional taxes and interest charges, regardless of whether we remain a PFIC in any subsequent taxable year, on (i) certain “excess” distributions we may make and (ii) any gain realized on the disposition or deemed disposition of your ordinary shares or ADSs. Distributions in respect of your ordinary shares (or ADSs in respect of such shares) during the taxable year will generally constitute “excess” distributions if, in the aggregate, they exceed 125% of the average amount of distributions in respect of your ordinary shares (or ADSs) over the three preceding taxable years or, if shorter, the portion of your holding period before such taxable year.

To compute the tax on “excess” distributions or any gain: (i) the “excess” distribution or the gain will be allocated ratably to each day in your holding period for the ADSs or the ordinary shares; (ii) the amount allocated to the current taxable year and any taxable year before we became a PFIC will be taxed as ordinary income in the current year; (iii) the amount allocated to other taxable years will be taxable at the highest applicable marginal rate in effect for that year; and (iv) an interest charge at the rate for underpayment of taxes will be imposed with respect to any portion of the “excess” distribution or gain described under (iii) above that is allocated to such other taxable years. In addition, if we are a PFIC or, with respect to a particular U.S. holder, we are treated as a PFIC for the taxable year in which the distribution was paid or the prior taxable year, no distribution that you receive from us will qualify for taxation at the preferential rate for non-corporate holders discussed in “—Distributions” above. You should consult with your own tax advisor regarding the application of the default PFIC rules based on your particular circumstances.

If we are a PFIC for any taxable year during which a U.S. holder holds our ADSs or ordinary shares and any of our non-U.S. subsidiaries is also a PFIC (i.e., a lower-tier PFIC), such a U.S. holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC and would be subject to the rules described above on certain distributions by the lower-tier PFIC and our disposition of shares of the lower-tier PFIC, even though such U.S. holder would not receive the proceeds of those distributions or dispositions. You should consult with your own tax advisor regarding the application of the PFIC rules to any of our subsidiaries if we are a PFIC.

### *Mark-to-Market Election*

If we are a PFIC for any taxable year during which you own our ADSs or ordinary shares, you will be able to avoid the rules applicable to “excess” distributions or gains described above if the ordinary shares or ADSs are “marketable” and you make a timely “mark-to-market” election with respect to your ordinary shares or ADSs. The ordinary shares or ADSs will be “marketable” stock as long as they remain regularly traded on a national securities exchange, such as The Nasdaq Capital Market, or a foreign securities exchange regulated by a governmental authority of the country in which the market is located and which meets certain requirements, including that the rules of the exchange effectively promote active trading of listed stocks. If such stock is traded on such a qualified exchange or other market, such stock generally will be “regularly traded” for any calendar year during which such stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter, but no assurances can be given in this regard. Our ordinary shares are traded on the ASX, which may qualify as an eligible foreign securities exchange for this purpose. We have applied to list the ADSs on The Nasdaq Capital Market; provided that the listing is approved, the ADSs will be traded on a national securities market.

If you are eligible to make a “mark-to-market” election with respect to our ordinary shares or ADSs and you make this election in a timely fashion, you will generally recognize as ordinary income or ordinary loss the difference between the fair market value of your ordinary shares or ADSs on the last day of any taxable year and your adjusted tax basis in the ordinary shares or ADSs. Any ordinary income resulting from this election will generally be taxed at ordinary income rates. Any ordinary losses will be deductible only to the extent of the net amount of previously included income as a result of the mark-to-market election, if any. Your adjusted tax basis in the ordinary shares or ADSs will be adjusted to reflect any such income or loss. Any gain recognized on the sale or other disposition of your ordinary shares or ADSs in a year when we are a PFIC will be treated as ordinary income, and any loss will be treated as an ordinary loss (but only to the extent of the net amount previously included as ordinary income as a result of the mark-to-market election).

Because a mark-to-market election cannot be made for any lower-tier PFICs that we may own, a U.S. holder may continue to be subject to the PFIC rules with respect to its indirect interest in any investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes, including shares in any of our subsidiaries that are treated as PFICs.

You should consult with your own tax advisor regarding the applicability and potential advantages and disadvantages to you of making a “mark-to-market” election with respect to your ordinary shares or ADSs if we are or become a PFIC, including the tax issues raised by lower-tier PFICs that we may own and the procedures for making such an election.

### *QEF Election*

Alternative rules to those set forth in “—Default PFIC Rules” above apply if an election is made to treat us as a “Qualified Electing Fund,” or QEF, under Section 1295 of the Code. A QEF election is available with respect to the ADSs or ordinary shares only if the U.S. holder receives an annual information statement from the PFIC setting forth its ordinary earnings and net capital gains, as calculated for U.S. federal income tax purposes.

Upon request from a U.S. holder, we will endeavor to provide to the U.S. holder no later than 90 days after the request an annual information statement, in order to enable the U.S. holder to make and maintain a QEF election for us or for any of our subsidiaries that is or becomes a PFIC. However, there is no assurance that we will have timely knowledge of our or our subsidiaries’ status as a PFIC in the future or of the required information to be provided. You should consult your own tax advisor regarding the availability and tax consequences of a QEF election with respect to the ordinary shares or ADSs or with respect to any lower-tier PFIC that we may own under your particular circumstances.

### *Information Reporting*

If we are a PFIC for any taxable year during which you own our ordinary shares or ADSs, as a U.S. holder, you will generally be required to file IRS Form 8621 on an annual basis, and other reporting requirements may apply. The PFIC rules are complex and you should consult with your own tax advisor regarding whether we or any of our subsidiaries are a PFIC, the tax consequences of any elections that may be available to you, and how the PFIC rules may affect the U.S. federal income tax consequences of the receipt, ownership, and disposition of our ordinary shares or ADSs.

### *Tax on Net Investment Income*

Certain non-corporate U.S. holders will be subject to a 3.8% tax on the lesser of (i) the U.S. holder’s “net investment income” for the relevant taxable year and (ii) the excess of the U.S. holder’s modified adjusted gross income for the taxable year over a certain threshold. A U.S. holder’s net investment income will generally include dividends received on the ordinary shares or ADSs and net gains from the disposition of ordinary shares or ADSs, unless such dividend income or net gains are derived in the ordinary course of the conduct of a trade or business (other than a trade or business that consists of certain passive or trading activities). A U.S. holder that is an individual, estate or trust should consult the holder’s tax advisor regarding the applicability of the tax on net investment income to the holder’s dividend income and gains in respect of the holder’s investment in the ordinary shares or ADSs.

### *Taxation of ADSs and Ordinary Shares to Non-U.S. Holders*

The following applies to non-U.S. holders of our own ordinary shares or ADSs. For purposes of this discussion, a non-U.S. holder means a beneficial owner (other than a partnership or an entity or arrangement so characterized for U.S. federal income tax purposes) of ordinary shares or ADSs that is not a U.S. holder, including:

- a nonresident alien individual, other than certain former citizens and residents of the United States;
- a foreign corporation; or
- a foreign estate or trust.

Any (i) distributions of cash or property paid to a non-U.S. holder in respect of ordinary shares or ADSs or (ii) gain realized upon the sale or other taxable disposition of ordinary shares or ADSs generally will not be subject to U.S. federal income taxation unless:

- the gain or distribution is effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the non-U.S. holder maintains a permanent establishment in the United States to which such gain is attributable); or
- in the case of any gain, the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met.

Gain or distributions described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates. A non-U.S. holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by U.S. source capital losses of the non-U.S. holder (even though the individual is not considered a resident of the United States), provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

Non-U.S. holders should consult their own tax advisors regarding potentially applicable income tax treaties that may provide for different rules.



### ***Backup Withholding Tax and Information Reporting Requirements***

U.S. backup withholding tax and information reporting requirements generally apply to payments to non-corporate holders of Offered Securities. Information reporting will apply to payments of dividends on ordinary shares or ADSs and to proceeds from the disposition of ordinary shares or ADSs by a paying agent within the United States to a U.S. holder, other than U.S. holders that are exempt from information reporting and properly certify their exemption. A paying agent within the United States will be required to withhold at the applicable statutory rate, in respect of any payments of dividends on ordinary shares or ADSs and the proceeds from the disposition of ordinary shares or ADSs within the United States to a U.S. holder (other than U.S. holders that are exempt from backup withholding and properly certify their exemption) if the holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with applicable backup withholding requirements. U.S. holders who are required to establish their exempt status generally must provide a properly completed IRS Form W-9.

Information returns may be filed with the IRS in connection with, and non-U.S. holders may be subject to backup withholding on amounts received in respect of, a non-U.S. holder's ordinary shares or ADSs, unless the non-U.S. holder furnishes to the applicable withholding agent the required certification as to its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, as applicable, or the non-U.S. holder otherwise establishes an exemption. Distributions paid with respect to ordinary shares or ADSs and proceeds from the sale or other disposition of ordinary shares or ADSs received in the United States by a non-U.S.-related financial intermediaries may be subject to information reporting and backup withholding unless such non-U.S. holder provides proof of an applicable exemption or complies with certain certification procedures described above, and otherwise complies with the applicable requirements of the backup withholding rules.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against the taxpayer's U.S. federal income tax liability. The taxpayer generally may obtain a refund of any amounts withheld under the backup withholding rules in excess of such holder's U.S. federal income tax liability by filing the appropriate claim for refund with the IRS in a timely manner and furnishing any required information.

Certain U.S. holders may also be required to report information with respect to such holder's interest in "specified foreign financial assets" (as defined in Section 6038D of the Code), including stock of a non-U.S. corporation that is not held in an account maintained by a U.S. "financial institution." Persons who are required to report specified foreign financial assets and fail to do so may be subject to substantial penalties. U.S. holders are urged to consult their own tax advisors regarding foreign financial asset reporting obligations and their possible application to the holding of ordinary shares or ADSs.

#### **Australian tax considerations**

In this section, we discuss the material Australian income tax, stamp duty and goods and services tax considerations related to the acquisition, ownership and disposal by the absolute beneficial owners of the ordinary shares or ADSs. This discussion represents the opinion of Hamilton Locke, our Australian counsel. It is based upon existing Australian tax law as of the date of this registration statement, which is subject to change, possibly retrospectively. This discussion does not address all aspects of Australian tax law which may be important to particular investors in light of their individual investment circumstances, such as shares held by investors subject to special tax rules (for example, financial institutions, insurance companies or tax exempt organizations). In addition, this summary does not discuss any foreign or state tax considerations, other than stamp duty and goods and services tax. Prospective investors are urged to consult their tax advisors regarding the Australian and foreign income and other tax considerations of the acquisition, ownership and disposition of the shares. This summary is based upon the premise that the holder is not an Australian tax resident and is not carrying on business in Australia through a permanent establishment.

#### ***Australian Income Tax***

##### ***Nature of ADSs for Australian Taxation Purposes***

Ordinary shares represented by ADSs held by a U.S. holder will be treated for Australian taxation purposes as held under a "bare trust" for such holder. Consequently, the underlying ordinary shares will be regarded as owned by the ADS holder for Australian income tax and capital gains tax purposes. Dividends paid on the underlying ordinary shares will also be treated as dividends paid to the ADS holder, as the person beneficially entitled to those dividends. Therefore, in the following analysis we discuss the tax consequences to non-Australian resident holders of ordinary shares which, for Australian taxation purposes, will be the same as to U.S. holders of ADSs.

##### ***Taxation of Dividends***

Australia operates a dividend imputation system under which dividends may be declared to be "franked" to the extent of tax paid on company profits. Fully franked dividends are not subject to dividend withholding tax. Dividends payable to non-Australian resident shareholders that are not operating from an Australian permanent establishment, or Foreign Shareholders, will be subject to dividend withholding tax, to the extent the dividends are not foreign (i.e. non Australian) sourced and declared to be conduit foreign income, or CFI, and are unfranked. Dividend withholding tax will be imposed at 30%, unless a shareholder is a resident of a country with which Australia has a double taxation agreement and qualifies for the benefits of the treaty. Under the provisions of the current Double Taxation Convention between Australia and the United States, the Australian tax withheld on unfranked dividends that are not CFI paid by us to which a resident of the United States is beneficially entitled is limited to 15%.

If a company that is a non-Australian resident shareholder directly owns a 10% or more interest, the Australian tax withheld on unfranked dividends (that are not CFI) paid by us to which a resident of the United States is beneficially entitled is limited to 5%. In limited circumstances the rate of withholding can be reduced to zero.

##### ***Tax on Sales or Other Dispositions of Shares — Capital Gains Tax***

Foreign Shareholders will not be subject to Australian capital gains tax on the gain made on a sale or other disposal of our ordinary shares, unless they, together with associates, hold 10% or more of our issued capital, at the time of disposal or for 12 months of the last 2 years prior to disposal.

Foreign Shareholders who own a 10% or more interest would be subject to Australian capital gains tax if more than 50% of our assets held directly or indirectly, determined by reference to market value, consists of Australian real property (which includes land and leasehold interests) or Australian mining, quarrying or prospecting rights (indirect real property interests). The Double Taxation Convention between the United States and Australia is unlikely to limit the amount of this taxable gain. Australian capital gains tax applies to net capital gains of Foreign Shareholders at the Australian tax rates for non-Australian residents, which start at a marginal rate of 32.5%. Net capital gains are calculated after reduction for capital losses, which may only be offset against capital gains.

The 50% capital gains tax discount is not available to non-Australian residents individuals on gains accrued after May 8, 2012. Companies are not entitled to a capital gains tax discount.

Under the 'foreign resident capital gains withholding' regime (applies from 1 July 2016), a purchaser of shares may have an obligation to withhold and pay to the ATO an amount equal to 12.5% of the purchase price for each share.

The purchaser may be required to withhold under the foreign resident capital gains withholding regime if the shares qualify as 'indirect real property interests' (see above) and the purchaser:

- knows or reasonably believes that the Shareholder is a Foreign Shareholder; or
- does not reasonably believe that the Shareholder is an Australian resident, and either:
  - the relevant Shareholder has an address outside Australia; or
  - the purchaser is authorized to provide a payable to a place outside Australia.

***Tax on Sales or Other Dispositions of Shares — Shareholders Holding Shares on Revenue Account***

Some Foreign Shareholders may hold ordinary shares on revenue account rather than on capital account for example, share traders. These shareholders may have the gains made on the sale or other disposal of the ordinary shares included in their assessable income under the ordinary income provisions of the income tax law, if the gains are sourced in Australia.

Non-Australian resident shareholders assessable under these ordinary income provisions in respect of gains made on ordinary shares held on revenue account would be assessed for such gains at the Australian tax rates for non-Australian residents, which start at a marginal rate of 32.5%. Some relief from Australian income tax may be available to such non-Australian resident shareholders under the Double Taxation Convention between the United States and Australia.

To the extent an amount would be included in a non-Australian resident shareholder's assessable income under both the capital gains tax provisions and the ordinary income provisions, the capital gain amount would generally be reduced, so that the shareholder would not be subject to double tax on any part of the income gain or capital gain.

### ***Dual Residency***

If a shareholder were a resident of both Australia and the United States under those countries' domestic taxation laws, that shareholder may be subject to tax as an Australian resident. If, however, the shareholder is determined to be a U.S. resident for the purposes of the Double Taxation Convention between the United States and Australia, the Australian tax may be subject to limitation by the Double Taxation Convention. Shareholders should obtain specialist taxation advice in these circumstances.

### ***Australian Death Duty***

Australia does not have estate or death duties. As a general rule, no capital gains tax liability is realized upon the inheritance of a deceased person's ordinary shares. The disposal of inherited ordinary shares by beneficiaries may, however, give rise to a capital gains tax liability if the gain falls within the scope of Australia's jurisdiction to tax (as discussed above).

### ***Stamp Duty***

No Australian stamp duty is payable on the issue, trading or surrender of the ADSs. Further, no Australian stamp duty is payable on the issue or trading of the underlying CardieX ordinary shares provided that all of our issued ordinary shares remain quoted on the ASX and no person commences to hold an associate inclusive interest of 90% or more in CardieX. ***The Australian stamp duty treatment of 'bare trusts' in respect of such shares for foreign residents is complex and specialist advice should be sought.***

### ***Goods and Services Tax***

The issue or transfer of ordinary shares to a non-Australian resident investor will not incur Australian goods and services tax.

***The discussion above is not intended to constitute a complete analysis of all tax considerations applicable to an investment in our ordinary shares or ADSs. You should consult with your own tax advisor concerning the tax consequences to you in your particular situation.***

## UNDERWRITING

Roth Capital Partners, LLC (the “representative”) is acting as the representative of the underwriters and the book-running manager of the offering of the securities described in this prospectus. We will enter into an underwriting agreement with the representative of the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, on a firm commitment basis, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of ADSs listed next to its name in the following table:

Name of Underwriter	Number of ADSs
Roth Capital Partners, LLC	_____
Total	_____

The underwriters are committed to purchase all the ADSs offered by us other than those covered by the option to purchase additional ADSs described below, if they purchase any such securities. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Pursuant to the underwriting agreement, the underwriters’ obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers’ certificates and legal opinions.

The underwriters are offering the ADSs subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

The underwriters propose to offer the ADSs directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at such price less a concession not in excess of US\$ \_\_\_\_\_ per ADS. After the initial offering of the ADSs to the public, if all of the ADSs are not sold at the initial public offering price, the underwriters may change the public offering price and the other selling terms.

Some of the underwriters are expected to make offers and sales both inside and outside the United States through their respective selling agents. All sales of securities in the United States will be made by broker-dealers registered with the SEC. Sales of any securities made outside of the United States may be made by affiliates of the underwriters.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended, and to contribute to payments the underwriters may be required to make in respect thereof.

### Option to purchase additional ADSs

We have granted to the underwriters an option to purchase up to \_\_\_\_\_ additional ADSs from us at the public offering price, less underwriting discounts and commissions, for a period of thirty (30) days from the date of this prospectus. If any additional ADSs are purchased, the underwriters will offer the additional ADSs on the same terms as those on which the ADSs are being offered.

### Discount

The following table shows the public offering price, underwriting discounts and commissions to be paid by us, and proceeds before expenses to us, assuming both no exercise and full exercise of the underwriters’ option to purchase additional ADSs.

	Per ADS <sup>(1)</sup>	Total Without Over- Allotment Option	Total With Full Over- Allotment Option
Public offering price	\$ _____	\$ _____	\$ _____
Underwriting discount (7.0%) <sup>(1)</sup>	\$ _____	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____	\$ _____

<sup>(1)</sup> Underwriting discounts and commissions per ADS with respect to the sale of ADSs to the public will be 7.0% and underwriting discounts and commissions per ADS with respect to the sale of ADSs to certain identified investors will be 5.0%.

We have agreed to pay for a certain amount of the representative’s accountable expenses including the reasonable and documented fees and disbursements of the underwriters’ counsel up to an amount of US\$200,000. Any advance expense deposits paid to the underwriters will be returned to the extent that offering expenses are not actually incurred in accordance with FINRA Rule 5110(g)(4)(A) in the event the offering is terminated. We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately US\$ \_\_\_\_\_.

### **Representative's Warrants**

Upon the closing of this offering, we have agreed to issue to the representative of the underwriters or its designees a five-year warrant to purchase a number of ADSs equal to 5.0% of the ADSs sold by us in this offering (the "Representative's Warrants"). The Representative's Warrants will be exercisable at a per ADS exercise price equal to US\$ (or 100% of the public offering price). The Representative's Warrants will be exercisable at any time, and from time to time, in whole or in part, during the period from the closing date of the offering to the date that is five years after the date of commencement of sales in this offering in compliance with Financial Industry Regulatory Authority, or FINRA, Rule 5110. The Representative's Warrants are also exercisable on a cashless basis. Pursuant to FINRA Rule 5110(e), the Representative's Warrants and any ADSs issued upon exercise of the Representative's Warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of reorganization of the issuer; (ii) to any FINRA member firm participating in the offering and the officers, partners, registered persons or affiliates thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the Representative or related persons does not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period; (vi) if we meet the registration requirements of Forms S-3, F-3 or F-10; or (vii) back to us in a transaction exempt from registration with the SEC. The Representative's Warrants and the ADSs issuable upon exercise thereof are registered on the registration statement of which this prospectus forms a part.

### **Discretionary Accounts**

The underwriters do not intend to confirm sales of the ADSs offered hereby to any accounts over which they have discretionary authority.

### **Lock-Up Agreements**

We have agreed for a period of days after the date of this prospectus not to sell, transfer or otherwise dispose of any of our ordinary shares, ADSs or similar securities. Furthermore, each of our directors and officers have agreed to a similar day lock-up.

### **Right of First Refusal**

We have granted the representative a right of first refusal, for a period of twelve (12) months from the closing of this offering, to act as underwriter or placement agent at the representative's discretion, for each and every future public and private equity, equity-linked offering.

### **Tail Fee**

We shall pay the representative the cash compensation and warrant compensation provided above on the gross proceeds provided to us by investors that participated in this offering or whom the representative introduced to us or had discussions on our behalf during our engagement of the representative in any public or private offering or capital-raising transaction within six (6) months following the expiration or termination of our engagement of the representative.

### **Electronic Offer, Sale and Distribution of ADSs**

A prospectus in electronic format may be made available on the websites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of ADSs to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

### **Listing**

Our ordinary shares are presently quoted on the ASX under the symbol "CDX." We have applied to have our ADSs approved for listing on the Nasdaq Capital Market under the symbol "CDEX." We will not consummate this offering unless our ADSs are approved for listing on Nasdaq Capital Market. No assurance can be given that our application will be approved.

### **Stabilization**

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling ADSs in the open market for the purpose of preventing or retarding a decline in the market price of the ADSs while this offering is in progress. These stabilizing transactions may include making short sales of ADSs, which involves the sale by the underwriters of a greater number of ADSs than they are required to purchase in this offering, and purchasing ADSs on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' option to purchase additional ADSs referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional ADSs, in whole or in part, or by purchasing ADSs in the open market. In making this determination, the underwriters will consider, among other things, the price of ADSs available for purchase in the open market compared to the price at which the underwriters may purchase ADSs through the option to purchase additional ADSs. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ADSs in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase ADSs in the open market to cover the position.

The underwriters have advised us that, in accordance with Regulation M of the Securities Act of 1933, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the ADSs, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase ADSs in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those ADSs as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the ADSs or preventing or retarding a decline in the market price of the ADSs, and, as a result, the price of the ADSs may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the Nasdaq Capital Market, in the over-the-counter market or otherwise.

#### **Pricing of the Offering**

Prior to this offering, there has been no public market for our ADSs. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters and our board of directors will approve the public offering price and other terms of this offering. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded securities of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our ADSs, or that the ADSs will trade in the public market at or above the initial public offering price.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

#### **Other Relationships**

Certain of the underwriters and their affiliates may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they may receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

## **Selling Restrictions**

No action may be taken in any jurisdiction other than the United States that would permit a public offering of the ADSs or the possession, circulation or distribution of this prospectus in any jurisdiction where action for that purpose is required. Accordingly, the ADSs may not be offered or sold, directly or indirectly, and neither the prospectus nor any other offering material or advertisements in connection with the ADSs may be distributed or published in or from any country or jurisdiction except under circumstances that will result in compliance with any applicable laws, rules and regulations of any such country or jurisdiction.

### **Australia**

This document:

- does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth), or the Corporations Act;
- has not been, and will not be, lodged with the Australian Securities & Investments Commission, or ASIC, as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors available under section 708 of the Corporations Act, or Exempt Investors.

The securities may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the securities may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any securities may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the securities, you represent and warrant to us that you are an Exempt Investor.

As any offer of securities under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 of the Corporations Act if none of the exemptions in section 708 or 708A of the Corporations Act applies to that resale. By applying for the securities you undertake to us that you will not, for a period of 12 months from the date of issue of the securities, offer, transfer, assign or otherwise alienate those securities to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

### **Canada**

The ADSs may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the ADSs must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.



Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

#### **Cayman Islands**

This prospectus does not constitute an invitation or offer to the public in the Cayman Islands of the ADSs, whether by way of sale or subscription. The underwriters have not offered or sold, and will not offer or sell, directly or indirectly, any ADSs in the Cayman Islands.

#### **Dubai International Finance Center, or DIFC**

This document relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority, or DFSA. This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this document you should consult an authorized financial advisor.

In relation to its use in the DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

#### **European Economic Area**

In relation to each Member State of the European Economic Area and the United Kingdom, or each a Relevant State, no ADSs have been offered or will be offered pursuant to this offering to the public in that Relevant State prior to the publication of a prospectus in relation to the ADSs which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of ADSs may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the underwriters; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of ADSs shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any ADSs or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and us that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any ADSs being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the ADSs acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any ADSs to the public other than their offer or resale in a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an “offer to the public” in relation to ADSs in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any ADSs to be offered so as to enable an investor to decide to purchase or subscribe for any ADSs, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

#### **Hong Kong**

The ADSs have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or the SFO, of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong), or the CO, or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the ADSs has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to ADSs which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the SFO and any rules made thereunder.

#### **Israel**

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus may be distributed only to, and is directed only at, investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds; provident funds; insurance companies; banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange Ltd., underwriters, each purchasing for their own account; venture capital funds; entities with equity in excess of NIS 50 million and “qualified individuals,” each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors. Qualified investors shall be required to submit written confirmation that they fall within the scope of the Addendum.

#### **Japan**

The ADSs have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the ADSs nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any “resident” of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

#### **Kingdom of Saudi Arabia**

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority, or CMA, pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution number 1-28-2008, as amended, or the CMA Regulations. The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorized financial adviser.

## **Korea**

The ADSs have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder, or the FSCMA, and the ADSs have been and will be offered in Korea as a private placement under the FSCMA. None of the ADSs may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder, or the FETL. The ADSs have not been listed on any of securities exchanges in the world including, without limitation, the Korea Exchange in Korea. Furthermore, the purchaser of the ADSs shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the ADSs. By the purchase of the ADSs, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the ADSs pursuant to the applicable laws and regulations of Korea.

## **Kuwait**

Unless all necessary approvals from the Kuwait Capital Markets Authority pursuant to Law No. 7 of 2010 Concerning the Establishment of the Capital Markets Authority and Regulating of Securities Activities and the implementing regulations thereto (as amended), and the various resolutions, regulations, instructions and announcements issued from time to time pursuant thereto, or in connection therewith, have been given in relation to the marketing of, and sale of, the ADSs, the ADSs may not be marketed, offered for sale, nor sold in the State of Kuwait. Neither this prospectus (including any related document), nor any of the information contained therein is intended to lead to the conclusion of any contract of whatsoever nature within Kuwait.

## **Malaysia**

No prospectus or other offering material or document in connection with the offer and sale of the ADSs has been or will be registered with the Securities Commission of Malaysia, or Commission, for the Commission's approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the ADSs may not be circulated or distributed, nor may the ADSs be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services Licence; (iii) a person who acquires the ADSs, as principal, if the offer is on terms that the ADSs may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months; (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the ADSs is made by a holder of a Capital Markets Services Licence who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

## **Mexico**

None of the ADSs or the ordinary shares have been or will be registered with the National Securities Registry (Registro Nacional de Valores) maintained by the Mexican National Banking and Securities Commission (Comision Nacional Bancaria y de Valores), or CNBV, of Mexico and, as a result, may not be offered or sold publicly in Mexico. The ADSs and the ordinary shares may only be sold to Mexican institutional and qualified investors, pursuant to the private placement exemption set forth in the Mexican Securities Market Law (Ley del Mercado de Valores). As required under the Mexican Securities Market Law, the company will give notice to the CNBV of the offering of the securities under the terms set forth herein. Such notice will be submitted to the CNBV to comply with the Mexican Securities Market Law, and for informational purposes only. The delivery to, and receipt by, the CNBV of such notice does not certify the solvency of the company, the investment quality of the securities, or that the information contained in this prospectus or in any prospectus supplement. The company has prepared this prospectus and is solely responsible for its content, and the CNBV has not reviewed or authorized such content.

## People's Republic of China

This prospectus will not be circulated or distributed in the PRC and the ADSs will not be offered or sold, and will not be offered or sold to any person for re-offering or resale directly or indirectly to any residents of the PRC except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

## Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the underwriters have not offered or sold any ADSs or caused the ADSs to be made the subject of an invitation for subscription or purchase and will not offer or sell any ADSs or cause the ADSs to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the ADSs, whether directly or indirectly, to any person in Singapore other than:

(a) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA) pursuant to Section 274 of the SFA;

(b) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA; or

(c) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the ADSs are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the ADSs pursuant to an offer made under Section 275 of the SFA except:

(i) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(ii) where no consideration is or will be given for the transfer;

(iii) where the transfer is by operation of law;

(iv) as specified in Section 276(7) of the SFA; or

(v) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

## **State of Qatar**

The ADSs described in this prospectus have not been, and will not be, offered, sold or delivered, at any time, directly or indirectly in the State of Qatar in a manner that would constitute a public offering. This prospectus has not been, and will not be, registered with or approved by the Qatar Financial Markets Authority or Qatar Central Bank and may not be publicly distributed. This prospectus is intended for the original recipient only and must not be provided to any other person. It is not for general circulation in the State of Qatar and may not be reproduced or used for any other purpose.

## **Switzerland**

The ADSs may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the ADSs or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the ADSs have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of ADSs will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of ADSs has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of ADSs.

## **Taiwan**

The ADSs have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the ADSs in Taiwan.

## **United Arab Emirates**

The ADSs have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

## **United Kingdom**

The ADSs may not be made in the United Kingdom, except that an offer to the public of any ADSs may be made in the United Kingdom at any time:

- (a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representative for any such offer; or
- (c) in any other circumstances falling within Section 86 of the Financial Services and Markets Act 2000 (as amended, the "FSMA").

provided that no such offer of ADSs shall result in the requirement for the publication by us of a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to the any ADSs in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and the ADSs to be offered so as to enable an investor to decide to purchase or subscribe for the ADSs, and the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

This prospectus is only being distributed to and is only directed at: (1) persons who are outside the United Kingdom; (2) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order"); or (3) high net worth companies, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (ed) of the Order (all such persons falling within (1)-(3) together being referred to as "relevant persons"). The ADSs are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire the ADSs will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this prospectus or any of its contents.

## EXPENSES RELATING TO THIS OFFERING

The following table sets forth the estimated costs and expenses, other than the underwriting discounts and commissions, payable by us in connection with the offering (all amounts are estimated except the SEC registration fee and the FINRA filing fee):

SEC registration fee	US\$	*
FINRA filing fee		*
Listing fee		*
Printing expenses		*
Legal fees and expenses		*
Accounting fees and expenses		*
Miscellaneous		*
Total		

\* To be provided by amendment.

## LEGAL MATTERS

Certain legal matters as to United States federal and New York law in connection with this offering will be passed upon for us by Wilson Sonsini Goodrich & Rosati, Professional Corporation. Certain legal matters as to Australian law in connection with this offering will be passed upon for us by Hamilton Locke. Wilson Sonsini Goodrich & Rosati, Professional Corporation, may rely upon Hamilton Locke with respect to matters governed by Australian law. Certain legal matters as to United States federal and New York law in connection with the offering will be passed on for the underwriters by Ellenoff Grossman & Schole LLP.

## EXPERTS

Our consolidated financial statements as of June 30, 2021 and 2022 and for each of the two years in the period ended June 30, 2022 included in this prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to our ability to continue as a going concern as described in Note 1 of the financial statements) of BDO Audit Pty Ltd, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting. The offices of BDO Audit Pty Ltd are located at Level 11, 1 Margaret Street, Sydney NSW.

## ENFORCEMENT OF CIVIL LIABILITIES

We are a public limited company incorporated under the laws of Australia. Certain of our directors are non-residents of the United States and all or substantially all of their assets are located outside the United States. As a result, it may not be possible for you to:

- effect service of process within the United States upon our non-U.S. resident directors or on us;
- enforce in U.S. courts judgments obtained against our non-U.S. resident directors or us in the U.S. courts in any action, including actions under the civil liability provisions of U.S. securities laws;
- enforce in U.S. courts judgments obtained against our non-U.S. resident directors or us in courts of jurisdictions outside the United States in any action, including actions under the civil liability provisions of U.S. securities laws; or
- bring an original action in an Australian court to enforce liabilities against our non-U.S. resident directors or us based solely upon U.S. securities laws.

You may also have difficulties enforcing in courts outside the United States judgments that are obtained in U.S. courts against any of our non-U.S. resident directors or us, including actions under the civil liability provisions of the U.S. securities laws.

With that noted, there are no treaties between Australia and the United States that would affect the recognition or enforcement of foreign judgments in Australia. We also note that investors may be able to bring an original action in an Australian court against us to enforce liabilities based in part upon U.S. federal securities laws.

We have appointed ATCOR Medical, Inc., as our agent to receive service of process with respect to any action brought against us in the U.S. District Court for the Southern District of New York under the federal securities laws of the United States or any action brought against us in the Supreme Court of the State of New York in the County of New York under the securities laws of the State of New York.

#### **WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the SEC a registration statement on Form F-1 under the Securities Act with respect to the ADSs offered in this prospectus. This prospectus, which forms a part of the registration statement, does not contain all of the information included in the registration statement. Certain information is omitted and you should refer to the registration statement and its exhibits for that information. With respect to references made in this prospectus to any contract or other document of CardieX, such references are not necessarily complete and you should refer to the exhibits attached to the registration statement for copies of the actual contract or document.

Upon the closing of this offering, we will become subject to periodic reporting and other informational requirements of the Exchange Act as applicable to foreign private issuers. Accordingly, we will be required to file reports, including annual reports on Form 20-F, periodic reports and other information, with the SEC.

We are allowed four months after the end of our fiscal year to file our annual report with the SEC, and we are not required to disclose certain detailed information regarding executive compensation that is required from U.S. domestic issuers. Also, as a foreign private issuer, we are exempt from the rules of the Exchange Act prescribing the furnishing of proxy statements to shareholders, and the members of our board of directors, our senior management and our principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

As a foreign private issuer, we are also exempt from the requirements of Regulation FD (Fair Disclosure) which, generally, are meant to ensure that select groups of investors are not privy to specific information about an issuer before other investors. We are, however, still subject to the anti-fraud and anti-manipulation rules of the SEC, such as Rule 10b-5. Since many of the disclosure obligations required of us as a foreign private issuer are different than those required of U.S. domestic reporting companies, our shareholders, potential shareholders and the investing public in general should not expect to receive information about us in the same amount, or at the same time, as information is received from, or provided by, other U.S. domestic reporting companies. We are only liable for violations of the rules and regulations of the SEC that apply to us as a foreign private issuer.

The SEC maintains a website at [www.sec.gov](http://www.sec.gov) that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. You also can inspect our registration statement, as well as any other information we file with or furnish to the SEC, on this website. This reference to the SEC's website is an inactive textual reference only and is not a hyperlink.

We expect to make our annual reports and other information filed with or furnished to the SEC available, free of charge, through our website at [www.cardiex.com](http://www.cardiex.com) as soon as reasonably practicable after those reports and other information are filed with or furnished to the SEC. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus.

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Australia

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Shareholders and Board of Directors

CardieX Limited  
55 Lime Street, Suite 301  
Sydney, NSW, 2000 Australia

### Opinion on Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of CardieX Limited and Controlled Entities (the 'Company') as of June 30, 2022 and 2021, the related consolidated statements of profit or loss and other comprehensive income, stockholders' equity, and cash flows for each of the years then ended, and the related notes and schedules (collectively referred to as the 'consolidated financial statements'). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at June 30, 2022 and 2021, and the results of its operations and its cash flows for each of the years then ended, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

### Substantial doubt about the Company's ability to continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations, has a net capital deficiency, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

### Basis for opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ('PCAOB') and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO Audit Pty Ltd

We have served as the Company's auditor since 2022.  
Sydney, Australia  
January 19, 2023

BDO Audit Pty Ltd ABN 33 134 022 870 is a member of a national association of independent entities which are all members of BDO Australia Ltd ABN 77 050 110 275, an Australian company limited by guarantee. BDO Audit Pty Ltd and BDO Australia Ltd are members of BDO International Ltd, a UK company limited by guarantee, and form part of the international BDO network of independent member firms.

**CARDIEX LIMITED AND CONTROLLED ENTITIES**  
**CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME**  
**FOR THE FISCAL YEARS ENDED 30 JUNE 2022 AND 2021**

(in thousands, except share and per share amounts)

	<u>Note</u>	<u>30 Jun 2022</u>	<u>30 Jun 2021</u>
<b>Revenue</b>	2	\$ 2,952	\$ 3,735
<b>Other income</b>	3	1,016	819
<b>Total revenue</b>		<u>3,968</u>	<u>4,554</u>
<b>Expenses</b>			
Cost of goods sold	4	(705)	(676)
Research & development	4	(2,813)	(1,310)
Sales & marketing	4	(2,279)	(998)
Management & administration	4	(4,725)	(3,482)
Stock based compensation	23(c)	(1,459)	(1,051)
Fair value loss on financial assets	24	(200)	(42)
Finance costs	4	(166)	(200)
Other expenses	4	(192)	(664)
<b>Total expenses</b>		<u>(12,539)</u>	<u>(8,423)</u>
<b>Net loss before income tax expense</b>		<u>(8,571)</u>	<u>(3,869)</u>
Income tax expense	5	-	-
<b>Net loss for the period</b>		<u>\$ (8,571)</u>	<u>\$ (3,869)</u>
Other comprehensive income for the period, net of tax – Exchange differences on translation to the presentation currency		(128)	751
<b>Total comprehensive loss for the period attributable to the members of CardieX Limited</b>		<u>\$ (8,699)</u>	<u>\$ (3,118)</u>
<b>Loss per share attributable to the members of CardieX Limited</b>			
Basic and diluted loss per share <sup>1</sup>	6	\$ (0.08)	\$ (0.04)

The above consolidated statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes.

<sup>1</sup>On 16 February 2022, there was a share consolidation of the issued capital of the Company on the basis of one (1) security for every ten (10) securities held. Where the consolidation resulted in a fraction of a Share, Performance Right or Option being held, the Company rounded that fraction up to the next whole number. The prior year weighted average number of ordinary shares has been adjusted accordingly so that the basic and diluted loss per share are comparable.

**CONSOLIDATED BALANCE SHEETS  
AS OF JUNE 30, 2022 AND 2021**

(in thousands)

	Note	30 Jun 2022	30 Jun 2021
<b>Assets</b>			
<b>Current assets</b>			
Cash and cash equivalents	7	\$ 1,003	\$ 2,756
Trade and other receivables	8	560	418
Inventories	9	685	334
Financial assets	13	-	3,712
Other current assets	10	1,079	826
<b>Total current assets</b>		<b>3,327</b>	<b>8,046</b>
<b>Non-current assets</b>			
Property, plant and equipment	11	277	158
Intangible assets	12	221	250
Financial assets	13	4,189	483
Right-of-use asset	14	460	107
Other non-current assets		53	24
<b>Total non-current assets</b>		<b>5,200</b>	<b>1,022</b>
<b>Total assets</b>		<b>\$ 8,527</b>	<b>\$ 9,068</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	15	\$ 1,532	\$ 808
Unearned revenue	16	604	323
Provisions	17	363	305
Financial liabilities	18	46	207
Lease liabilities	19	85	53
Borrowings	20	894	744
<b>Total current liabilities</b>		<b>\$ 3,524</b>	<b>\$ 2,440</b>
<b>Non-current liabilities</b>			
Provisions	17	1	-
Lease liabilities	19	448	81
<b>Total non-current liabilities</b>		<b>449</b>	<b>81</b>
<b>Total liabilities</b>		<b>\$ 3,973</b>	<b>\$ 2,521</b>
<b>Net assets</b>		<b>\$ 4,554</b>	<b>\$ 6,547</b>
<b>Equity</b>			
Contributed equity	21	\$ 46,537	\$ 44,572
Reserves	23	5,177	(1,678)
Accumulated losses		(47,160)	(36,347)
<b>Total equity</b>		<b>\$ 4,554</b>	<b>\$ 6,547</b>

The above consolidated balance sheets should be read in conjunction with the accompanying notes.

**CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY  
FOR THE FISCAL YEARS ENDED JUNE 30, 2022 AND 2021**

(in thousands)

	<u>Contributed equity</u>	<u>Reserves</u>	<u>Accumulated losses</u>	<u>Total equity</u>
<b>Balance at 1 July 2020</b>	\$ 36,462	\$ 2,417	\$ (34,844)	\$ 4,035
Loss after income tax expense for the period	-	-	(3,869)	(3,869)
Other comprehensive loss for the period, net of tax – <i>Exchange differences on translation to the presentation currency</i>	3,480	(4,869)	2,140	751
<b>Total comprehensive loss for the period</b>	<b>\$ 3,480</b>	<b>\$ (4,869)</b>	<b>\$ (1,729)</b>	<b>\$ (3,118)</b>
<i>Transactions with owners in their capacity as owners:</i>				
Issue of share capital	4,800	-	-	4,800
Costs of issuing share capital	(250)	-	-	(250)
Shares issued in lieu of payments to employees	80	-	-	80
Share-based payments	-	774	226	1,000
<b>Balance at 30 June 2021</b>	<b>\$ 44,572</b>	<b>\$ (1,678)</b>	<b>\$ (36,347)</b>	<b>\$ 6,547</b>
Loss after income tax expense for the period	-	-	(8,571)	(8,571)
Other comprehensive loss for the period, net of tax – <i>Exchange differences on translation to the presentation currency</i>	(3,730)	6,264	(2,662)	(128)
<b>Total comprehensive loss for the period</b>	<b>\$ (3,730)</b>	<b>\$ 6,264</b>	<b>\$ (11,233)</b>	<b>\$ (8,699)</b>
<i>Transactions with owners in their capacity as owners:</i>				
Costs of issuing share capital	(102)	-	-	(102)
Shares issued in lieu of payments to employees	82	-	-	82
Shares issued on vesting of performance rights	291	(291)	-	-
Shares issued on the exercise of options	5,237	-	-	5,237
Conversion of convertible notes	187	(25)	-	162
Share-based payments	-	932	395	1,327
Transfer to retained earnings	-	(25)	25	-
<b>Balance at 30 June 2022</b>	<b>\$ 46,537</b>	<b>\$ 5,177</b>	<b>\$ (47,160)</b>	<b>\$ 4,554</b>

The above consolidated statement of stockholders' equity should be read in conjunction with the accompanying notes.

**CONSOLIDATED STATEMENT OF CASH FLOWS  
FOR THE FISCAL YEARS ENDED 30 JUNE 2022 AND 2021**

(in thousands)

	Note	30 Jun 2022	30 Jun 2021
<b>Cash flows used in operating activities</b>			
Receipts from customers		\$ 3,115	\$ 3,369
Payments to suppliers and employees		(10,096)	(6,740)
Interest received		1	1
Receipt for Research and Development Tax Incentives		340	391
<b>Net cash used in operating activities</b>	7	<b>\$ (6,640)</b>	<b>\$ (2,979)</b>
<b>Cash flows used in investing activities</b>			
Payments for property, plant and equipment		(305)	(53)
Payments for intangible assets		(12)	(214)
Repayment of convertible notes		-	539
<b>Net cash (used in)/from investing activities</b>		<b>\$ (317)</b>	<b>\$ 272</b>
<b>Cash flows from financing activities</b>			
Proceeds from shares issued		5,517	4,768
Share issue costs		(108)	(249)
Borrowings received, net of transaction costs		870	10
Borrowings repaid		(766)	(344)
Finance costs		(19)	(131)
Lease principal repayments		(113)	(108)
<b>Net cash from financing activities</b>		<b>\$ 5,381</b>	<b>\$ 3,946</b>
<b>Net (decrease)/increase in cash and cash equivalents</b>		<b>(1,576)</b>	<b>1,239</b>
Cash and cash equivalents at the beginning of the fiscal period		2,756	1,415
Effects of foreign currency exchange		(177)	102
<b>Cash and cash equivalents at the end of the period</b>	7	<b>\$ 1,003</b>	<b>\$ 2,756</b>

The above consolidated statement of cash flows should be read in conjunction with the accompanying notes.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE FISCAL YEARS ENDED 30 JUNE 2022 AND 2021

### NOTE 1. SIGNIFICANT ACCOUNTING POLICIES

The financial report includes the consolidated financial statements and notes of CardieX Limited and controlled entities ('Consolidated Group' or 'Group'). The separate financial statements and notes of CardieX Limited as an individual parent entity ('Company') have not been presented within the financial report as permitted by the *Corporations Act 2001*. CardieX Limited is a for-profit entity.

#### BASIS OF PREPARATION

These financial statements have been prepared in accordance with International Financial Reporting Standards and International Accounting Standards as issued by the International Accounting Standards Board (IASB) and Interpretations (collectively IFRSs), and the *Corporations Act 2001*.

##### *Historical cost convention*

The consolidated financial statements have been prepared on a historical cost basis, except for the financial instruments which are recorded at fair value through profit or loss (refer to individual accounting policies for details).

##### *Critical accounting estimates*

The preparation of the consolidated financial statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the financial statements, are disclosed throughout the notes to the consolidated financial statements.

#### BASIS OF CONSOLIDATION

The consolidated financial statements comprise the financial statements of the Group (refer to Note 25 for the list of consolidated entities) as at the end of the reporting period. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee. Specifically, the Group controls an investee if and only if the Group has:

- Power over the investee (i.e. existing rights that give it the current ability to direct the relevant activities of the investee)
- Exposure, or rights, to variable returns from its involvement with the investee, and
- The ability to use its power over the investee to affect its returns

When the Group has less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

- The contractual arrangement with the other vote holders of the investee
- Rights arising from other contractual arrangements
- The Group's voting rights and potential voting rights

The Group re-assesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control. Consolidation of a subsidiary begins when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary. Assets, liabilities, income and expenses of a subsidiary acquired or disposed of during the year are included in the statement of profit and loss and other comprehensive income from the date the Group gains control until the date the Group ceases to control the subsidiary.

Profit or loss and each component of other comprehensive income are attributed to the equity holders of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with the Group's accounting policies. All intra-Group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

#### GOING CONCERN

The consolidated financial statements of the Group have been prepared on a Going Concern basis, which indicates the continuation of business activities and realization of assets and settlement of liabilities in the normal course of business.

At the date of issue of the consolidated financial statements, the Directors have assessed that there is substantial doubt related to going concern that may cast significant doubt over the ability of the Group to continue as a going concern given that the Group incurred a loss after tax of \$8.57 million (2021: \$3.87 million), had net cash outflows from operating activities of \$6.64 million for the year ended 30 June 2022 (2021: \$2.98 million) and had a net current liability position as at year-end of \$0.20 million (2021: net current asset position of \$5.61 million). As a result of these conditions the Group may be unable to realise its assets and discharge its liabilities in the normal course of business.

## **NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE FISCAL YEARS ENDED 30 JUNE 2022 AND 2021**

The Directors believe that there are reasonable grounds that the Group will be able to continue as a going concern, after consideration of the following factors:

- On 22 August 2022, CardiacX announced that it had completed a A\$4.33 million (~US\$3.00 million) placement, as well as the launch of a share purchase plan (SPP) where proceeds exceeded the target of A\$1.00 million (~US\$0.69 million).
- On 29 September 2022, the Company announced the results of the SPP and raised A\$1.60 million (~US\$1.10 million) – this represents a 59.3% over-subscription over the originally targeted raise of A\$1.00 million.
- On 9 December 2022, CardiacX announced a significant new clinical trial agreement with Procurement Partner, CliniChain BV. The clinical trial involves the provision of ATCOR's XCEL devices and data management services over a period of approximately 30 months. Since June 30, 2022, over US\$1 million has been received under this contract.
- On 6 January 2023, CardiacX announced that AtCor Medical Pty Ltd had entered into a short-term working capital loan facility with Mitchell Asset Management. The facility limit is A\$880,000 at a rate of 16% per annum and matures on 30 October 2023.
- The Company is the process of progressing a dual ASX/NASDAQ or NYSE listing, and if successful, this would raise significant equity funding for the Company, along with improving the Company's options with regards to equity raising.
- If required, the Group has the ability to continue to raise additional funds on a timely basis pursuant to the Corporations Act 2001. Based on the Group's track record of successful equity funding in the preceding financial years and subsequent to the reporting period end, the Directors believe that the Group will be able to continue to source equity or alternative funding if required.
- There is a term loan facility of A\$1.3 million repayable in December 2023, however this will be partially offset by R&D tax rebates expected for FY2022 and FY2023

Accordingly, the Directors believe that the Group will be able to continue as a going concern, and that it is appropriate to adopt the going concern basis in the preparation of the financial report.

Should the Group be unable to raise additional funds on a timely basis, it may be required to realise its assets and discharge its liabilities other than in the normal course of business and at amounts different to those stated in the financial statements. The financial statements do not include any adjustments to the recoverability and classification of asset carrying amounts or the amount of liabilities that might result should the Group be unable to continue as a going concern and meet its debts as and when they fall due.

### **ROUNDING OF AMOUNTS**

Amounts in this report have been rounded off to the nearest thousand United States dollars, except share and per share amounts.

### **FUNCTIONAL AND PRESENTATIONAL CURRENCY**

The functional currency of the parent entity is Australian Dollars ("AUD") as the parent company is based in Australia and the majority of transactions take place in AUD. The financial statements are presented in United States dollars ("USD"), which is the presentational currency of the Group, which management have determined that this is the most relevant currency for the users of the financial statements.

### **FOREIGN CURRENCY TRANSACTIONS**

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the date of the transaction. Foreign currency monetary items are translated at the year-end exchange rate. Non-monetary items measured at historical cost continue to be carried at the exchange rate at the date of the transaction. Non-monetary items held at fair value are reported at the exchange rate at the date when the fair values were determined. Equity balances are translated as at the balance sheet date, with the variance passed through the Foreign Currency Translation Reserve (FCTR).

Exchange differences arising on the translation of monetary items are recognized in profit or loss.

Exchange differences arising on the translation of non-monetary items are recognized directly in other comprehensive income to the extent that the underlying gain or loss is directly recognized in other comprehensive income; otherwise the exchange difference is recognized in profit or loss.

### **CURRENT AND NON-CURRENT CLASSIFICATION**

Assets and liabilities are presented in the statement of financial position based on current and non-current classification.

An asset is current when it is expected to be realized or intended to be sold or consumed in normal operating cycle; it is held primarily for the purpose of trading; it is expected to be realized within 12 months after the reporting period; or the asset is cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least 12 months after the reporting period. All other assets are classified as non-current.

A liability is current when it is expected to be settled in normal operating cycle; it is held primarily for the purpose of trading; it is due to be settled within 12 months after the reporting period; or there is no unconditional right to defer the settlement of the liability for at least 12 months after the reporting period. All other liabilities are classified as non-current.

Deferred tax assets and liabilities are always classified as non-current.

### **PARENT ENTITY INFORMATION**

In accordance with the Corporations Act 2001, these financial statements present the results of the consolidated entity only. Supplementary information about the parent entity is disclosed in Note 30.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE FISCAL YEARS ENDED 30 JUNE 2022 AND 2021**

**OPERATING SEGMENTS**

Operating segments are presented using the 'management approach', where the information presented is on the same basis as the internal reports provided to the Chief Operating Decision Makers ('CODM'). The CODM is responsible for the allocation of resources to operating segments and assessing their performance. As disclosed in Note 27, the Group has one operating segment.

**NEW, REVISED OR AMENDED ACCOUNTING STANDARDS ADOPTED**

The Group has retrospectively adopted all of the new, revised or amended Accounting Standards and Interpretations issued by the International Accounting Standards (IASB) that are relevant to its operations and effective for the year commencing 1 July 2021. There was no material impact on the group's financial statements on the adoption of these Standards and Interpretations.

Revised or amending Accounting Standards or Interpretations that are not yet mandatory for the year ended 30 June 2022 have not been early adopted.

**OTHER SIGNIFICANT ACCOUNTING POLICIES**

Other significant accounting policies for transactions and balances are disclosed throughout the notes to the consolidated financial statements.

**NOTE 2. REVENUE**

Revenue consists of the following (*in thousands*):

	<u>30 Jun 2022</u>	<u>30 Jun 2021</u>
Sale of goods revenue	\$ 1,695	\$ 1,573
Lease revenue	860	1,615
Other revenue	397	547
	<u>\$ 2,952</u>	<u>\$ 3,735</u>

***Accounting policy for revenue recognition***

The Group has disaggregated revenue recognized from contracts with customers into categories that depict how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors.

***Sale of goods revenue***

Sale of goods revenue is recognized at the point of sale, which is where the customer has taken delivery of the goods, the control is transferred to the customer and there is a valid sales contract. The transaction price is stipulated in the sales contract. Performance obligations after the transfer of control of the goods (such as after sales service) are measured and recorded separately, as detailed in *Other revenue* below. Amounts disclosed as revenue are net of sales returns and trade discounts.

***Lease revenue***

Lease income is derived from both finance and operating lease of goods and continues to recognize related income in line with IFRS 16 – Leases. The Group recognize unearned revenue for lease income received in advance where the benefit from the use of the underlying asset has not been diminished. The unearned revenue is reported in the statement of financial position. Similarly, if the Group provide benefits from the underlying asset before it receives the consideration, the group recognize either a contract lease asset or a receivable in the statement of financial position, depending on whether something other than the passage of time is required before the consideration is due. For operating leases, the lease income and interest in relation to the goods are recognized over time per the terms set in the contract with the customer. For goods sold on a finance lease, income is recognized at the point of sale, which is where the customer has taken delivery of the goods, the control is transferred to the customer and there is a valid sales contract. Any associated interest income is recognized over the life of the lease in line with the terms set in the contract with the customer. CardieX leases multiple medical devices to customers as part of pharmaceutical trials. The amounts are paid over an accelerated term per the signed contract, and then revenue is recognized on a straight-line basis based on the amount of equipment delivered. The equipment is leased to the customer for approximately three to four years which is not considered to be a major part of the economic life of the asset. The equipment is returned to CardieX at the end of the lease and the equipment can continue to be used without any major modification.

***Other revenue***

Other revenue is primarily service income, which is recognized over time in line with management's assessment of the performance obligations under each contract. Freight income is recognized when the control is transferred to the customer and there is a valid sales contract. Royalty income is recognized when entitled under royalty agreements.



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE FISCAL YEARS ENDED 30 JUNE 2022 AND 2021**

**NOTE 2. REVENUE (CONTINUED)**

*Disaggregation of revenue*

The Group derives its revenue from the transfer of goods and services at a point in time. The table above provides a breakdown of revenue by major business line. The categories above depict how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic data. As disclosed in Note 27, the Group has one operating segment.

**NOTE 3. OTHER INCOME**

Other income consists of the following (*in thousands*):

	<u>30 Jun 2022</u>	<u>30 Jun 2021</u>
Research and development tax incentive scheme	\$ 480	\$ 401
JobKeeper Covid 19 stimulus	-	47
PPP loan forgiveness	-	174
Foreign exchange gains	215	-
Interest income	314	192
Miscellaneous other income	7	5
	<u>\$ 1,016</u>	<u>\$ 819</u>

*Accounting policy for other income*

*Research and development tax incentive scheme*

Our research and development activities are eligible under an Australian government tax incentive for eligible expenditure. Management has assessed these activities and expenditure to determine which are likely to be eligible under the incentive scheme. At each period end, management estimates and recognizes the refundable tax offset available to us based on available information at the time.

The receivable for reimbursable amounts that have not been collected is reflected in trade and other receivables on our consolidated balance sheets.

*PPP loan forgiveness*

The Group received loan proceeds of US\$0.2M under the Paycheck Protection Program (“PPP”) provisions of the CARES Act. The PPP provided a mechanism for forgiveness of up to the full amount borrowed, as long as the borrower uses the loan proceeds for eligible purposes, including payroll costs, certain benefits costs, rent and utilities costs or other permitted purposes, and maintains its payroll levels, subject to certain other requirements and limitations. The amount of loan forgiveness is subject to reduction for numerous reasons, including if the borrower has recently terminated employees or reduce salaries.

The Company received full forgiveness of the first-round loan including all interest accrued during the 2021 fiscal year. This has been recognized as other income when forgiveness was received.

*Interest income*

Interest income is accrued on a time basis by reference to the principal outstanding and at the effective interest rate applicable.

**NOTE 4. EXPENSES**

	<u>30 Jun 2022</u>	<u>30 Jun 2021</u>
<b>Cost of goods sold</b>		
Cost of manufacture	\$ 558	\$ 489
Royalties	137	183
Production overhead	10	4
	<u>\$ 705</u>	<u>\$ 676</u>
<b>Research &amp; development</b>		
Personnel costs	\$ 1,218	\$ 848
Third party costs	1,197	341
Other	398	121
	<u>\$ 2,813</u>	<u>\$ 1,310</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE FISCAL YEARS ENDED 30 JUNE 2022 AND 2021**

**NOTE 4. EXPENSES (CONTINUED)**

Net loss before income tax expense includes the following specific expenses (*in thousands*):

	<b>30 Jun 2022</b>	<b>30 Jun 2021</b>
<b>Sales &amp; marketing</b>		
Personnel costs	\$ 1,161	\$ 862
Marketing expenditure	977	103
Other	141	33
	<b>\$ 2,279</b>	<b>\$ 998</b>
<b>Management &amp; administration</b>		
Personnel costs	\$ 3,252	2,189
Legal & professional fees	1,096	1,047
Other	377	246
	<b>\$ 4,725</b>	<b>\$ 3,482</b>
<b>Finance costs</b>		
Interest expenses	\$ 166	\$ 200
	<b>\$ 166</b>	<b>\$ 200</b>
<b>Other expenses</b>		
Depreciation & amortization	\$ 162	\$ 136
Foreign exchange loss	-	362
Other	30	166
	<b>\$ 192</b>	<b>\$ 664</b>

**Accounting policy for expenses**

*Research costs*

Expenditure on research activities, undertaken with the prospect of obtaining new technical knowledge and understanding, is recognized in the statement of profit or loss and other comprehensive income as an expense when it is incurred.

*Other expenses*

Other expenses are classified according to their function, as sales & marketing or management & administrative, including expenses mainly related with facilities, materials and depreciation.

**NOTE 5. INCOME TAX EXPENSE**

Income tax expense consists of the following (*in thousands*):

	<b>30 Jun 2022</b>	<b>30 Jun 2021</b>
Deferred tax expense	\$ -	\$ -
Current tax expense	-	-
<b>Aggregate income tax expense</b>	<b>\$ -</b>	<b>\$ -</b>

**Effective tax rate reconciliation (*in thousands*):**

	<b>30 Jun 2022</b>	<b>30 Jun 2021</b>
Loss before income tax expense	\$ (8,571)	\$ (3,869)
Tax at the statutory tax rate of 25% (2021: 26%)	(2,413)	(1,006)
Tax effect amounts which are not deductible/(taxable) in calculating taxable income:		
Other non-allowable items	795	488
Items not assessable for taxation	(120)	(220)
Items deductible for taxation but not accounting	(196)	(87)
Differences in overseas tax rates	92	(3)
Benefit of tax losses and temporary differences not recognized	1,842	828
<b>Income tax expense</b>	<b>\$ -</b>	<b>\$ -</b>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE FISCAL YEARS ENDED 30 JUNE 2022 AND 2021**

**NOTE 5. INCOME TAX EXPENSE (CONTINUED)**

The Group has carried forward tax losses, calculated according to Australian income tax legislation of \$35.15 million (2021: \$29.05 million) which will be deductible from future assessable income provided that income is derived, and:

- a) The Company and its controlled entities carry on a business of, or a business that includes software development in Australia; and
- b) No change in tax legislation adversely affects the Group and its controlled entities in realising the benefit from the deduction for the losses.

The benefit of these losses will only be recognised where it is probable that future taxable profit will be available against which the benefits of the deferred tax asset can be utilised. Deferred tax assets are estimated but not recognised at \$8.79 million at 30 June 2022 (2021: \$7.56 million) so as to enable the Board to determine more reliably the probability of utilising these tax assets in the foreseeable future.

As at the date of this report the entities in the tax consolidation group had not entered into a tax sharing agreement. No compensation has been received or paid for any current tax payable or deferred tax assets relating to tax losses assumed by the parent entity since implementation of the tax consolidation regime.

***Accounting policy for income tax***

The income tax expense for the year comprises current income tax expenses and deferred tax expenses.

Current income tax expense charged to the profit or loss in the tax payable on taxable income for the current period. Current tax liabilities are measured as the amounts expected to be paid to the relevant tax authority using the tax rates and tax laws that have been enacted or substantively enacted by the end of the reporting period.

CardieX Limited and its wholly owned Australian controlled entities have implemented the tax consolidation legislation as of July 1, 2005.

The head entity, CardieX Limited, and the controlled entities in the tax consolidated group account for their own current and deferred tax amounts. These amounts are measured as if each entity in the tax consolidated group continues to be a standalone taxpayer in its own right.

Deferred income tax expense reflects movements in deferred tax asset and deferred tax liability balances during the year as well as unused tax losses.

Deferred tax assets and liabilities are calculated at the tax rates that are expected to apply to the period when the asset is realized, or the liability is settled, and their measurement also reflects the manner in which management expects to recover or settle the carrying amount of the related asset or liability.

Deferred tax assets relating to temporary differences and unused tax losses are only recognized to the extent that it is probably that future taxable profit will be available against which the benefits of the deferred tax asset can be utilized.

Deferred tax assets and liabilities are offset only where there is a legally enforceable right to offset current tax assets against current tax liabilities and deferred tax assets against deferred tax liabilities; and they relate to the same taxable authority on either the same taxable entity or different taxable entities which intend to settle simultaneously.

***Critical accounting judgements, estimates and assumptions***

The Group is subject to income taxes in the jurisdictions in which it operates. Significant judgement is required in determining the provision for income tax. There are many transactions and calculations undertaken during the ordinary course of business for which the ultimate tax determination is uncertain. The Group recognizes liabilities for anticipated tax audit issues based on the Group's current understanding of the tax law. Where the final tax outcome of these matters is different from the carrying amounts, such differences will impact the current and deferred tax provisions in the period in which such determination is made.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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**NOTE 6. LOSS PER SHARE**

The calculation of the basic and diluted loss per share is based on the following information (*in thousands, except share and per share amounts*):

	<b>30 Jun 2022</b>	<b>30 Jun 2021</b>
<b>Reconciliation of earnings used in calculating earnings per share</b>		
Loss attributable to ordinary equity holders of CardieX Limited	\$ (8,571)	\$ (3,869)
	<b>No. of shares</b>	<b>No. of shares</b>
<b>Weighted average number of ordinary shares<sup>1</sup></b>	<b>103,005,388</b>	<b>87,278,943</b>
<b>Basic and diluted loss per share</b>	<b>\$ (0.08)</b>	<b>\$ (0.04)</b>

Performance rights and options to acquire shares that would be dilutive if the Group was generating a profit have been excluded from the weighted average number of issued ordinary shares as the Group is generating a loss. Refer to Note 23 for additional details in relation to the performance rights.

<sup>1</sup>On 16 February 2022, there was a share consolidation of the issued capital of the Company on the basis of one (1) security for every ten (10) securities held. Where the consolidation resulted in a fraction of a Share, Performance Right or Option being held, the Company rounded that fraction up to the next whole number. The prior year weighted average number of ordinary shares has been adjusted accordingly so that the basic and diluted loss per share are comparable.

**NOTE 7. CASH AND CASH EQUIVALENTS**

Cash and cash equivalents consisted of the following (*in thousands*):

	<b>30 Jun 2022</b>	<b>30 Jun 2021</b>
Cash at bank	\$ 1,003	\$ 2,756
	<b>\$ 1,003</b>	<b>\$ 2,756</b>

There are no restrictions or limitations on the use of cash and cash equivalents.

**Accounting policy for cash and cash equivalents**

Cash and cash equivalents include cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less or that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

**Reconciliation of Cash Flow from Operations with net loss for the period (*in thousands*):**

	<b>30 Jun 2022</b>	<b>30 Jun 2021</b>
<b>Net loss for the year</b>	<b>\$ (8,571)</b>	<b>\$ (3,869)</b>
Depreciation and amortization expense	162	136
Stock based compensation	1,459	1,051
Interest income on convertible notes	(314)	(192)
Unrealized foreign exchange difference	(179)	423
Interest expense	177	119
<b>Change in operating assets and liabilities</b>		
Increase in trade and other receivables	(178)	(20)
Increase in inventories - net	(380)	(139)
Increase in trade and other payables	792	273
Increase/(decrease) in unearned revenue	308	(823)
Increase in provisions	84	62
<b>Net cash outflow used in operating activities</b>	<b>\$ (6,640)</b>	<b>\$ (2,979)</b>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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**NOTE 8. TRADE AND OTHER RECEIVABLES**

Trade and other receivables consisted of the following (*in thousands*):

	<b>30 Jun 2022</b>	<b>30 Jun 2021</b>
Trade receivables	\$ 593	\$ 454
Less: Provision for impairment	(33)	(36)
	<b>\$ 560</b>	<b>\$ 418</b>

Provision for impairment (*in thousands*):

	<b>30 Jun 2022</b>	<b>30 Jun 2021</b>
Balance as on beginning of period	\$ 36	\$ 51
Provision for doubtful debts recognized during the year	-	31
Reversal of provision upon receipt of payment	(3)	-
Receivables written off during the year as uncollectible	-	(46)
Balance as on end of period	<b>\$ 33</b>	<b>\$ 36</b>

**Accounting policy for trade and other receivables**

Trade receivables are initially recognized at fair value and subsequently measured at amortized cost using the effective interest method, less any provision for impairment. Trade and other receivables are non-interest bearing and are generally on 30 to 60 day terms.

Collectability of trade receivables is reviewed on an ongoing basis in accordance with the expected credit loss (“ECL”) model. Credit losses are measured at the present value of all cash shortfalls (i.e. the difference between the cash flows due to the Group in accordance with the contract and the cash flows that the Group expects to receive). ECLs are discounted at the effective interest rate of the financial asset.

The ECL assessment completed by the Group as at year end has resulted in an immaterial credit loss and no impairment allowance has been recognized by the Group (2021: \$Nil). A specific provision of \$0.03M (2021: \$0.04M) was recognized at each financial year end.

**Critical accounting judgements, estimates and assumptions**

The provision for impairment of receivables and the ECL calculation assessment requires a degree of estimation and judgment. The level of provision is assessed by taking into account the recent sales experience, the ageing of receivables, historical collection rates and specific knowledge of the individual debtor’s financial position.

**NOTE 9. INVENTORIES**

Inventories consisted of the following (*in thousands*):

	<b>30 Jun 2022</b>	<b>30 Jun 2021</b>
Raw materials	\$ 356	\$ 214
Finished goods	329	120
<b>Inventories</b>	<b>\$ 685</b>	<b>\$ 334</b>

**Accounting policy for inventories**

Inventories are stated at the lower of cost and net realizable value. Cost includes all expenses directly attributable to the manufacturing process as well as suitable portions of related production overheads, based on normal operating capacity. Costs are assigned using the first in, first out cost formula. Net realizable value is the estimated selling price in the ordinary course of business less any applicable selling expenses.

**Critical accounting judgements, estimates and assumptions**

The provision for impairment of inventories assessment requires a degree of estimation and judgement. The level of the provision is assessed by taking into account the recent sales experience, the ageing of inventories and other factors that affect inventory obsolescence.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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**NOTE 10. OTHER CURRENT ASSETS**

Other current assets consisted of the following (*in thousands*):

	<b>30 Jun 2022</b>	<b>30 Jun 2021</b>
Prepaid expenses	\$ 562	\$ 335
Contract assets	9	63
Research and development tax incentive receivable (Note 3)	507	408
Deposits	-	19
Other	1	1
	<b>\$ 1,079</b>	<b>\$ 826</b>

**NOTE 11. PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment consisted of the following (*in thousands*):

	<b>30 Jun 2022</b>	<b>30 Jun 2021</b>
Plant & equipment - at cost	\$ 593	\$ 432
Less: Accumulated depreciation	(372)	(377)
<b>Plant &amp; equipment</b>	<b>\$ 221</b>	<b>\$ 55</b>
Devices leased to customers	\$ 207	\$ 174
Less: Accumulated depreciation	(151)	(71)
<b>Devices leased to customers</b>	<b>\$ 56</b>	<b>\$ 103</b>
<b>Property, plant and equipment</b>	<b>\$ 277</b>	<b>\$ 158</b>

Movements (*in thousands*):

	<b>Plant &amp; equipment</b>	<b>Devices leased to customers</b>	<b>Total</b>
<b>Balance as of 1 July 2020</b>	<b>\$ 82</b>	<b>\$ 126</b>	<b>\$ 208</b>
Additions	16	38	54
Foreign exchange differences	2	4	6
Disposals	-	-	-
Depreciation expense	(45)	(65)	(110)
<b>Balance at 30 June 2021</b>	<b>\$ 55</b>	<b>\$ 103</b>	<b>\$ 158</b>
Additions	210	19	229
Foreign exchange differences	(9)	5	(4)
Disposals	-	-	-
Depreciation expense	(35)	(71)	(106)
<b>Balance at 30 June 2022</b>	<b>\$ 221</b>	<b>\$ 56</b>	<b>\$ 277</b>

**Accounting policy for property, plant and equipment**

Plant and equipment are stated at cost less accumulated depreciation and any accumulated impairment losses. Cost includes expenditure that is directly attributable to the acquisition of the items. Subsequent costs are included in the assets carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably.

Plant and equipment are depreciated over their estimated useful lives using the straight-line method.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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**NOTE 11. PROPERTY, PLANT AND EQUIPMENT (CONTINUED)**

The expected useful lives of the assets are as follows:

Plant & equipment	3-10 years
Devices leased to customers	3-4 years

The residual values and useful lives are reviewed, and adjusted if appropriate, at each statement of financial position date or when there is an indication that they have changed.

A carrying amount is written down immediately to its recoverable amount if the carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposals are determined by comparing proceeds with carrying amount. These are included in the statement of profit or loss and other comprehensive income.

**Critical accounting judgements, estimates and assumptions**

*Estimation of useful lives of assets*

The Group determines the estimated useful lives and related depreciation and amortization charges for its property, plant and equipment and finite life intangible assets. The useful lives could change significantly as a result of technical innovations or some other event. The depreciation and amortization charge will increase where the useful lives are less than previously estimated lives, or technically obsolete or non-strategic assets that have been abandoned or sold will be written off or written down.

**NOTE 12. INTANGIBLE ASSETS**

Intangible assets consisted of the following (*in thousands*):

	<b>30 Jun 2022</b>	<b>30 Jun 2021</b>	
Capitalized development costs - at cost	\$ 265	\$ 289	
Less: Accumulated amortization of capitalized development costs	(63)	(68)	
Website costs	49	49	
Less: Accumulated amortization of website costs	(30)	(20)	
<b>Capitalized development costs</b>	<b>\$ 221</b>	<b>\$ 250</b>	
	<b>Capitalized</b>		
	<b>development costs</b>	<b>Website costs</b>	<b>Total</b>
<b>Balance at 1 July 2020</b>	<b>\$ -</b>	<b>\$ 39</b>	<b>\$ 39</b>
Additions	221	-	221
Foreign exchange differences	-	-	-
Disposals	-	-	-
Amortization expense	-	(10)	(10)
<b>Balance at 30 June 2021</b>	<b>\$ 221</b>	<b>\$ 29</b>	<b>\$ 250</b>
Additions	-	-	-
Foreign exchange differences	(19)	-	(19)
Disposals	-	-	-
Amortization expense	-	(10)	(10)
<b>Balance at 30 June 2022</b>	<b>\$ 202</b>	<b>\$ 19</b>	<b>\$ 221</b>

**Accounting policy for capitalized development costs**

Development costs on an individual project are recognized as an intangible asset when the Group can demonstrate:

- The technical feasibility of completing the intangible asset so that the asset will be available for use or sale.
- Its intention to complete and its ability and intention to use or sell the asset.
- How the asset will generate future economic benefits.
- The availability of resources to complete the asset.

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**NOTE 12. INTANGIBLE ASSETS (CONTINUED)**

The costs that are eligible for capitalization of development costs are the following:

- Engineers' compensation for time directly attributable to developing the project.
- An allocated amount of direct costs, such as overhead related to the project and the facilities they occupy.
- Costs associated with testing of the product for market.
- Patents acquisition and registration costs (patents, application fees, and legal fees).
- Other direct developing costs that are incurred to bring the product to market.

Following initial recognition of the development expenditure as an asset, the asset is carried at cost less any accumulated amortization and accumulated impairment losses. Amortization of the asset begins when development is complete, and the asset is available for use. Development costs are amortized on a straight-line basis over the period of expected future sales from the related project which is 5 years. Amortization is recorded in profit or loss.

*accounting judgements, estimates and assumptions*

*Capitalized development costs*

The Group capitalizes development costs for a project in accordance with the above accounting policy. Initial capitalization of cost is based on management's judgement that technological and economic feasibility is confirmed. In determining the amounts to be capitalized, management makes assumptions regarding the expected future cash generation of the project, discount rates to be applied and the expected period of the benefits.

*Impairment of intangible assets*

The Group assesses impairment of intangible assets other than goodwill at each reporting date by evaluating conditions specific to the Group and to the particular asset that may lead to impairment. If an impairment trigger exists, the recoverable amount of the asset is determined. This involves fair value less costs of disposal or value-in-use calculations, which incorporate several key estimates and assumptions.

**NOTE 13. FINANCIAL ASSETS**

Financial assets consisted of the following (*in thousands*):

	<u>30 Jun 2022</u>	<u>30 Jun 2021</u>
<b>Current</b>		
inHealth Medical Services convertible note (b)	\$ -	\$ 3,712
	<u>-</u>	<u>3,712</u>
<b>Non-current</b>		
Blumio Inc convertible note (a)	-	-
inHealth Medical Services investment (b)	447	483
inHealth Medical Services convertible note (b)	3,742	-
	<u>\$ 4,189</u>	<u>\$ 483</u>
<b>Total financial assets</b>	<u>\$ 4,189</u>	<u>\$ 4,195</u>

*(a) Blumio Inc convertible note*

- In March 2018, the Company entered into a convertible note purchase agreement for the acquisition of a Convertible Note (the "Blumio Note") issued by Blumio Inc ("Blumio"), payable in two instalments. The full principal balance of \$600,000 payable under the Blumio Note agreement was met on 14 March 2019.
- Both the debt and derivative components of the Blumio Note are measured as a single instrument at fair value through profit and loss (FVTPL). It is measured at FVTPL as there is an embedded conversion feature. It is measured at FVTPL as a single instrument to significantly reduce any measurement or recognition inconsistencies that would arise from other methods. The term of the Blumio Convertible Note continues until a fundraising event of more than \$8,000,000 occurs at which point the investment will convert into shares in Blumio at a 20% discount to the price of the fundraising.
- As part of a detailed review of all financial assets in the Group as at 30 June 2022, management determined that the fair value of the Blumio Note should be written down to nil as at 30 June 2021. This is due to the fact the Company obtained financial statements from Blumio which indicated that Blumio was in a net liabilities position as at 30 June 2020, 30 June 2021 and 30 June 2022. No equity funding has been received by Blumio in over five years, and only minor convertible note debt funding had been received in the past three years with no conversions to equity to date. The financial statements also indicated that Blumio has not generated any income to date, other than research grants.
- As at 30 June 2022, the face value of the Blumio Note was \$600,000 and in \$118,750 in interest had accrued.



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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**NOTE 13. FINANCIAL ASSETS (CONTINUED)**

- On 16 November 2022, CardieX announced the acquisition of the core assets from Blumio, Inc. The purchase price of the asset was US \$15,100 payable on execution of the asset purchase agreement, followed by US \$150,000 in CardieX ordinary shares, payable in two equal tranches on 15 June 2023 and 15 March 2024 subject to service-based performance criteria. The acquisition negotiations commenced after CardieX released its FY2022 annual report on the ASX on 30 September 2022. The face value and accrued interest owing to CardieX was extinguished as result of the acquisition. There was no deemed control over Blumio or any of its assets prior to this time. Although the Blumio convertible note asset was written down to nil in FY2021 in line with the interpretation of accounting standards, CardieX management firmly believed there was a strategic gain in acquiring Blumio assets, particularly due to Blumio's capabilities in wearable sensor development, signal processing, and big data analytics, as well as the wealth of experience and technical knowledge from Blumio's team members that are joining CardieX as a result of the acquisition.

**(b) inHealth Medical Services investment & convertible note**

- On 31 January 2019, the Company exercised in full its option under the agreement to purchase \$3,000,000 of inHealth Medical Services "Tranche 2" (T2) Convertible Note (the "inHealth Note") securities.
- Both the debt and derivative components of the inHealth Note are measured as a single instrument at FVTPL as there is an embedded conversion feature. It is measured at FVTPL as a single instrument to significantly reduce any measurement or recognition inconsistencies that would arise from other methods.
- By 31 December 2019, the Company had paid the full \$3,000,000 to inHealth under the Agreement for the T2 Notes.
- In July 2020, the Company and inHealth had signed an agreement to restructure the partnership. Key changes were reducing the outstanding convertible note to \$2,500,000 by repayment of \$500,000, extending the maturity date to 1 July 2021, and exchanging the option to move to 50.5% for the issuance of 1% of the fully diluted equity of inHealth.
- In July 2021 it was agreed to further extend the maturity date of the convertible note to 31 December 2021, and further agreed between the parties to forgive accrued interest up until 30 June 2020 totaling A\$338,373 in return for a further 1% of fully diluted equity of inHealth to CardieX.
- In March 2022, the inHealth Note was extended a further term to November 2023, incorporating all interest for the period 1 July 2021 to 28 February 2022 to the principal value of the inHealth Note totaling \$2,875,317.
- As at 30 June 2022, the face value of the inHealth Note was \$2,875,317 and \$57,191 in interest had accrued.
- As at 30 June 2022, the total convertible note asset was fair valued at \$3.74M (2021:\$3.71M).
- As at 30 June 2022, the Company holds 8.35% equity in inHealth Medical Services, Inc, currently valued at \$0.4M (2021: \$0.5M).

**Critical estimates and judgements**

*Valuation of inHealth Medical Services Convertible Notes – key assumptions used in assessment*

The valuation used to support the carrying amounts of the convertible notes are, by nature, uncertain. The valuation was performed by an external independent professional valuer. The nature and basis of the key assumptions used to estimate the valuation of the convertible notes are set out below:

- The inHealth Medical Services Convertible Notes were valued with reference to the underlying note agreement.
- Control Premium – a control premium of 15% has been used in the valuation of the convertible notes. Given that conversion of the convertible notes in inHealth would give CardieX a controlling interest in the company, a premium has been calculated. This was calculated with reference to 122 deals from the overall market for latest quarter of 2022, which were noted to have an average premium of 37.6% and a median premium of 26.5%. It was also calculated with reference to other factors affecting control premiums including, but not limited to, the performance of the entity, the number of potential buyers and the size of the business.
- Discount Rate – a discount rate of 14.75% has been used in the valuation of the convertible notes. This discount rate represents the market yield of the healthcare sector as of the valuation date.
- Time until Events – is the expected amount of time that the convertible notes will be held by CardieX prior to being converted into shares of inHealth. It has been assumed that the time until events (years) is 1.419, which represents management's best estimate of when the convertibles notes will be converted.

**NOTE 14. RIGHT-OF-USE-ASSET**

Right of use asset consisted of the following (*in thousands*):

	<b>30 Jun 2022</b>	<b>30 Jun 2021</b>
Right-of-use-asset - at cost	\$ 614	\$ 315
Less: Accumulated depreciation	(154)	(208)
<b>Right-of-use-asset</b>	<b>\$ 460</b>	<b>\$ 107</b>
	<b>Right-of-use-asset</b>	
<b>Balance at 1 July 2020</b>	<b>\$ 180</b>	
Foreign exchange differences	8	
Depreciation expense	(81)	
<b>Balance at 30 June 2021</b>	<b>\$ 107</b>	
Additions	492	
Foreign exchange differences	(22)	
Disposals - net	-	
Depreciation expense	(117)	
<b>Balance at 30 June 2022</b>	<b>\$ 460</b>	

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**NOTE 14. RIGHT-OF-USE-ASSET (CONTINUED)**

*Accounting policy for right-of-use-asset*

The right-of-use asset is initially measured at cost, which comprised the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and an estimate of costs to dismantle and remove the underlying asset or to restore the underlying or the site on which it is located, less any lease incentives received.

The Group assesses whether a contract is or contains a lease, at inception of the contract. The Group recognizes a right-of-use asset and a corresponding lease liability with respect to all lease arrangements in which it is the lessee, except for short-term leases (defined as leases with a lease term of 12 months or less) and leases of low value assets. For these leases, the Group recognizes the lease payments as an operating expense on a straight-line basis over the term of the lease unless another systematic basis is more representative of the time pattern in which economic benefits from the leased assets are consumed.

The right-of-use asset is subsequently depreciated using the straight-line method from the commencement date to the earlier of the end of the useful life of the right-of-use asset or the end of the lease term. The estimated useful lives of right-of-use assets are determined on the same basis as those of property and equipment. In addition, the right-of-use asset is periodically reduced by impairment losses, if any, and adjusted for certain remeasurements of the lease liability.

**NOTE 15. TRADE AND OTHER PAYABLES**

Trade and other payables consisted of the following (*in thousands*):

	<u>30 Jun 2022</u>	<u>30 Jun 2021</u>
Trade payables	\$ 1,336	\$ 584
Other payables	196	224
	<u>\$ 1,532</u>	<u>\$ 808</u>

*Accounting policy for trade and other payables*

These amounts represent liabilities for goods and services provided to the Group prior to the end of the fiscal year and which are unpaid. Due to their short-term nature they are measured at amortized cost and are not discounted. The amounts are unsecured and are usually paid within 30 days of recognition.

**NOTE 16. UNEARNED REVENUE**

Unearned revenue consisted of the following (*in thousands*):

	<u>2 Jan 2022</u>	<u>3 Jan 2021</u>
Unearned revenue	\$ 604	\$ 323
	<u>\$ 604</u>	<u>\$ 323</u>

*Accounting policy for unearned revenue*

The above unearned revenue relates to contracts where payments have been received, but revenue has not yet been recognized due to the fact revenue recognition criteria under IFRS 15 has not yet been met as goods and services have not yet been provided to the customers.

**NOTE 17. PROVISIONS**

Provisions consisted of the following (*in thousands*):

	<u>30 Jun 2022</u>	<u>30 Jun 2021</u>
<b>Current</b>		
Employee benefits	\$ 363	\$ 305
	<u>363</u>	<u>305</u>
<b>Non-current</b>		
Employee benefits	1	-
	<u>\$ 1</u>	<u>\$ -</u>
<b>Total provisions</b>	<u>\$ 364</u>	<u>\$ 305</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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**NOTE 17. PROVISIONS (CONTINUED)**

*Accounting policy for employee benefits*

Short-term employee benefits are benefits, other than termination benefits, that are expected to be settled wholly within 12 months after the end of the period in which the employees render the related service. Examples of such benefits include wages and salaries, non-monetary benefits and accumulating sick leave. Short-term employee benefits are measured at the undiscounted amounts expected to be paid when the liabilities are settled.

The Group's liabilities for annual leave and long service leave are included in other long term benefits as they are not expected to be settled wholly within 12 months after the end of the period in which the employees render the related service. They are measured at the present value of the expected future payments to be made to employees. The expected future payments incorporate anticipated future wage and salary levels, experience of employee departures and periods of service, and are discounted at rates determined by reference to market yields at the end of the reporting period on high quality corporate bonds that have maturity dates that approximate the timing of the estimated future cash outflows. Any re-measurements arising from experience adjustments and changes in assumptions are recognized in profit or loss in the periods in which the changes occur. The Group presents employee benefit obligations as current liabilities in the statement of financial position if the Group does not have an unconditional right to defer settlement for at least 12 months after the reporting period, irrespective of when the actual settlement is expected to take place.

**NOTE 18. FINANCIAL LIABILITIES**

Financial liabilities consisted of the following (*in thousands*):

	<u>30 Jun 2022</u>	<u>30 Jun 2021</u>
Convertible note liabilities	\$ 46	\$ 207
	<u>\$ 46</u>	<u>\$ 207</u>

In January 2019, C2 Ventures Pty Ltd applied to the Company for 2,500,000 convertible notes at A\$1 per note.

On 6 March 2019, 1,638,503 notes were converted to shares and a further 640,303 notes were converted to shares on 21 November 2019. The remaining 221,194 notes were approved in the 2021 AGM and subsequently converted on 7 December 2021. The balance of \$0.04M reflects unpaid interest.

*Accounting policy for financial liabilities*

Financial liabilities are initially measured at fair value, and, where applicable, adjusted for transaction costs unless the Group designated a financial liability at fair value through profit or loss. Subsequently, financial liabilities are measured at amortized cost using the effective interest method except for derivatives and financial liabilities designated at FVTPL, which are carried subsequently at fair value with gains or losses recognized in profit or loss (other than derivative financial instruments that are designated and effective as hedging instruments).

The convertible note liabilities recorded in FY2021 and FY2022 were measured at FVTPL as there is an embedded conversion feature. It is measured at FVTPL as a single instrument to significantly reduce any measurement or recognition inconsistencies that would arise from other methods.

**NOTE 19. LEASE LIABILITIES**

Lease liabilities consisted of the following (*in thousands*):

	<u>30 Jun 2022</u>	<u>30 Jun 2021</u>
Current	\$ 85	\$ 53
Non-current	448	81
	<u>\$ 533</u>	<u>\$ 134</u>

Net present value of lease liabilities (*in thousands*):

	<u>Less than 6 months</u>	<u>6 to 12 months</u>	<u>Between 1 and 5 years</u>	<u>5+ years</u>	<u>Total</u>
Lease payments	\$ 71	\$ 74	\$ 542	\$ 22	\$ 709
Finance charges	(32)	(28)	(116)	-	(176)
	<u>\$ 39</u>	<u>\$ 46</u>	<u>\$ 426</u>	<u>\$ 22</u>	<u>\$ 533</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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**NOTE 19. LEASE LIABILITIES (CONTINUED)**

*Accounting policy for lease liabilities*

Where a lease is identified at inception, the Group recognizes a right-of-use asset and a lease liability at the lease commencement date. The right-of-use asset is initially measured at cost, which comprises the ignition amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and an estimate of costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is location, less any leased incentives received.

The Group assesses whether a contract is or contains a lease, at inception of the contract. The Group recognizes a right-of-use asset and a corresponding lease liability with respect to all lease arrangements in which it is the lessee, except for short-term leases (defined at leases with a lease term of 12 months or less) and leases of low value assets. For these leases, the Group recognizes the lease payments as an operating expense on a straight-line basis over the term of the lease unless another systematic basis is more representative of the time pattern in which economic benefits from the leased assets are consumed.

**NOTE 20. BORROWINGS**

Borrowings includes the following liabilities carried at amortized cost (*in thousands*):

	<u>30 Jun 2022</u>	<u>30 Jun 2021</u>
Term loan facility	\$ 894	\$ 744
	<u>\$ 894</u>	<u>\$ 744</u>

On 24 March 2022, the Company entered into a new 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 forecasted R&D tax incentive claim for the year ended 30 June 2022, with a termination date of 31 October 2022. The Facility attracts interest at 1% per calendar month. Net cash received from the facility in the fiscal year was A\$1.20M (~US\$0.9M) with the difference of A\$0.1M (~US\$0.07M) withheld for establishment costs and prepaid interest. The Company also repaid A\$1.06M (~US\$0.8M) during the financial period.

*Accounting policy for borrowings*

Loans and borrowings are initially recognized at the fair value of the consideration received, net of transaction costs. They are subsequently measured at amortized cost using the effective interest method.

**NOTE 21. CONTRIBUTED EQUITY**

Contributed equity consisted of the following:

	<u>30 Jun 2022</u>		<u>30 Jun 2021</u>	
	<u>Shares (No)</u>	<u>US\$'000</u>	<u>Shares (No)</u>	<u>US\$'000</u>
Ordinary shares	110,003,700	\$ 46,537	92,603,816	\$ 44,572
	<u>110,003,700</u>	<u>\$ 46,537</u>	<u>92,603,816</u>	<u>\$ 44,572</u>

*Issued capital*

Ordinary shares are classified as equity.

Incremental costs directly attributable to the issue of new shares, warrants or options are shown in equity as a deduction, net of tax, from the proceeds.

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**NOTE 21. CONTRIBUTED EQUITY (CONTINUED)**

*Movements in ordinary shares:*

	Shares	US\$'000
<b>Balance as at 1 July 2020</b>	<b>753,209,290</b>	<b>36,462</b>
Ordinary shares issued on equity capital raise	169,670,063	4,800
Cost of raising capital	-	(250)
Shares issued in lieu of payments to employees	3,158,802	80
Share consolidation (a)	(833,434,339)	-
Foreign exchange variance	-	3,480
<b>Balance as at 30 June 2021</b>	<b>92,603,816</b>	<b>44,572</b>
<b>Balance as at 1 July 2021</b>	<b>926,038,155</b>	<b>44,572</b>
Shares issued on exercise of options (Note 23a)	152,048,619	5,237
Shares issued on vesting of performance rights (Note 23b)	12,000,000	291
Shares issued on conversion of convertible notes	7,831,467	187
Shares issued in lieu of payments to employees	1,614,480	71
Share consolidation (a)	(989,579,021)	-
Shares issued in lieu of payments to employees post share consolidation	50,000	11
Cost of raising capital	-	(102)
Foreign exchange variance	-	(3,730)
<b>Balance as at 30 June 2022</b>	<b>110,003,700</b>	<b>46,537</b>

*(a) Share consolidation*

On 16 February 2022, there was a share consolidation of the issued capital of the Company on the basis of one (1) security for every ten (10) securities held. Where the consolidation resulted in a fraction of a Share, Performance Right or Option being held, the Company rounded that fraction up to the next whole number. The prior year number of shares has been adjusted for the share consolidation to ensure the numbers are comparable.

*Terms and conditions of contributed equity*

Ordinary shares participate in dividends and the proceeds on winding up of the Company in proportion to the number of shares held. At the shareholders meetings each ordinary share is entitled to one vote when a poll is called, otherwise each shareholder has one vote on a show of hands.

*Accounting policy for ordinary shares*

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

**NOTE 22. CAPITAL AND FINANCIAL RISK MANAGEMENT**

*Capital management*

Capital managed by the Board comprises contributed equity totaling \$46.5 million (2021: \$44.5 million). When managing capital, management's objective is to ensure the entity continues as a going concern as well as to maintain optimal returns to shareholders and benefits for other stakeholders. Management also aims to maintain a capital structure that ensures the lowest cost of capital available to the entity. Managed capital is disclosed on the face of the statement of financial position and comprises contributed equity and reserves. Management may adjust the capital structure to take advantage of favorable costs of capital or higher returns on assets. As the market is constantly changing, management may issue new shares or sell assets to raise cash, change the amount of dividends to be paid to shareholders (if at all) or return capital to shareholders.

During the fiscal period ending 30 June 2022 management did not pay a dividend and does not expect to pay a dividend in the foreseeable future. The Group encourages employees to be shareholders through the CardieX Employee Share Option Plan (ESOP).

There were no changes in the Group's approach to capital management during the year. Risk management policies and procedures are established with regular monitoring and reporting. Neither the Company nor its subsidiaries are subject to externally imposed capital requirements.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE FISCAL YEARS ENDED 30 JUNE 2022 AND 2021**

**NOTE 22. CAPITAL AND FINANCIAL RISK MANAGEMENT (CONTINUED)**

**Financial risk management**

The Group's activities expose it to a variety of financial risks: market risk (primarily currency risk), credit risk, and liquidity risk. The Group's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the financial performance of the Group. The Group uses different methods to measure different types of risk to which it is exposed. These methods include sensitivity analysis in the case of foreign exchange risk and aging analysis for credit risk.

Financial risk management is carried out by the Chief Financial Officer (CFO) and overseen by the Audit & Risk Committee, a subcommittee of the Board of Directors.

**(a) Market risk**

*Foreign exchange risk*

Foreign exchange risk arises when future commercial transactions and recognized assets and liabilities are denominated in a currency that is not the entity's functional currency, which is Australian Dollars. The risk is measured using sensitivity analysis and cash flow forecasting. The Group operates internationally and is exposed to foreign exchange risk arising from currency exposures to the US Dollar and the Euro.

The Group's exposure to foreign currency exchange risk at the reporting date was as follows:

	30 June 2022		30 June 2021	
	In USD	In EUR	In USD	In EUR
Cash and Cash Equivalents	383,109	251,694	247,898	269,639
Trade Receivables	405,817	56,659	326,133	80,933
Trade Payables	(710,333)	(4,872)	(326,477)	-

*Sensitivity*

Based on the financial instruments held at 30 June 2022, had the Australian dollar weakened/strengthened by 10% against the US dollar with all other variables held constant, the Group's pre-tax result for the year would have varied by A\$10,371/(A\$11,408) (2021: A\$29,935/(A\$32,928)). Had the Australian dollar weakened/strengthened by 10% against the Euro with all other variables held constant, the Group's pre-tax result for the year would have varied by A\$41,872/(A\$46,059) (2021: A\$52,152/(A\$57,367)).

**(b) Credit risk**

Credit risk arises from cash and cash equivalents, derivative financial instruments and deposits with banks and financial institutions, as well as credit exposures to customers, including outstanding receivables and committed transactions. The Group has no significant concentrations of credit risk. For banks and financial institutions, only independently rated and reputable parties are accepted. The Group has policies in place to ensure that sales of products and services are made to customers with an appropriate credit history. Terms of trade provided to creditworthy customers are between 30 and 90 days, whilst customers deemed higher risk arrange a letter of credit or prepay for goods. The maximum exposure to credit risk at the reporting date is the carrying amount of the financial assets. Refer to Note 8 for additional information in relation to the expected credit loss (ECL) from trade receivables.

**(c) Liquidity risk**

Prudent liquidity risk management implies maintaining sufficient cash and marketable securities, the availability of funding through an adequate amount of committed credit facilities and the ability to close out market positions. The Group manages liquidity risk by continuously monitoring forecast and actual cash flows and matching the maturity profiles of financial assets and liabilities. The Group does not have any significant long-term borrowings other than lease liabilities (Note 19).

**(d) Interest rate risk**

The consolidated entity's main interest rate risk arises from long-term borrowings. Borrowings obtained at variable rates expose the consolidated entity to interest rate risk. Borrowings obtained at fixed rates expose the consolidated entity to fair value risk.

**(e) Fair value estimation**

The fair value of financial assets and financial liabilities must be estimated for recognition and measurement or for disclosure purposes. The carrying value less impairment provision of trade receivables and payables are assumed to approximate their fair values due to their short-term nature. The fair value of financial liabilities approximates their carrying values.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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**NOTE 23. RESERVES**

Reserves consisted of the following (*in thousands*):

	<b>30 Jun 2022</b>	<b>30 Jun 2021</b>
Share-based payments reserve	\$ 2,266	\$ 1,800
Foreign currency translation reserve	2,911	(3,503)
Derivative reserve	-	25
	<b>\$ 5,177</b>	<b>\$ (1,678)</b>

*Share-based payments reserve*

The share based-payments reserve records the fair value of options and performance rights on issue.

*Foreign currency reserve*

The reserve is used to recognize exchange differences arising from the translation of the financial statements of non-United States dollar operations to United States dollars. Refer to Note 1 for additional information.

*Derivative reserve*

The derivative reserve records the issue date value of the derivative financial instruments recognized in equity.

*Movements in reserves were as follows (in thousands):*

	<b>Share-based payments reserve</b>	<b>Foreign currency translation reserve</b>	<b>Derivative reserve</b>	<b>Total</b>
	\$	\$	\$	\$
Balance at 1 July 2020	936	1,456	25	2,417
Performance rights vesting expense	23(b) 675	-	-	675
Options vesting expense	23(a) 325	-	-	325
Options expired	23(a) (226)	-	-	(226)
FCTR movement	90	(4,959)	-	(4,869)
Balance at 30 June 2021	<b>1,800</b>	<b>(3,503)</b>	<b>25</b>	<b>(1,678)</b>
Performance rights vesting expense	23(b) 987	-	-	987
Options vesting expense	23(a) 340	-	-	340
Performance rights converted	23(b) (291)	-	-	(291)
Performance rights expired	23(b) (395)	-	-	(395)
Transfer to retained earnings	(25)	-	-	(25)
Conversion of convertible notes	-	-	(25)	(25)
FCTR movement	(150)	6,414	-	6,264
Balance at 30 June 2022	<b>2,266</b>	<b>2,911</b>	<b>-</b>	<b>5,177</b>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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NOTE 23. RESERVES (CONTINUED)

Share-based payments reserve

(a) Options issued as share based payments

Options on issue

	30 Jun 2022		30 Jun 2021	
	No of Options	US\$'000	No of Options	US\$'000
At the beginning of reporting period	213,555,201	602	167,423,535	459
Options vesting expense	-	340	-	325
Options issue to employees	-	-	34,500,000	-
Expired and lapsed options	(11,123,249)	-	(5,035,000)	(226)
Options converted to shares	(152,048,619)	-	-	-
Free attaching options (1 for 5) as attaching to placement	-	-	16,666,666	-
Share consolidation (Note 21a)	(45,103,333)	-	-	-
Options issue to employees post share consolidation	1,300,000	-	-	-
Foreign exchange variance	-	(50)	-	44
<b>Closing balance at reporting date</b>	<b>6,580,000</b>	<b>892</b>	<b>213,555,201</b>	<b>602</b>

Employee Share Option Plan (ESOP)

The CardieX Employee Option Plan was approved by shareholders at the 2005 annual general meeting and amendments were approved at the 2006 & 2008 annual general meetings. All staff are eligible to participate in the plan at the discretion of the directors (including executive directors) following recommendations from the remuneration committee, a sub-committee of the CardieX Limited Board of Directors.

Options are granted under the plan for no consideration. Options are granted for a 5-year period, with vesting conditions over 3 years from the date of grant. Options granted under the plan carry no dividend or voting rights. When exercisable, each option is convertible into 1 ordinary share.

The exercise price of options is no less than the weighted average price at which the Company's shares are traded on the Australian Stock Exchange during the 5 trading days immediately before the options are granted.

Set out below are summaries of options granted under the employee share option plan. All figures are post share consolidation:

2022:

Grant Date	Expiry date	Exercise price	Balance at start of the year Number	Granted during the year Number	Exercised during the year Number	Expired/ Forfeited during the year Number	Balance at end of the year Number	Exercisable at end of the year Number
15-Jan-19	15-Jan-24	A\$0.50	1,530,000	-	-	-	1,530,000	1,530,000
26-Feb-19	26-Feb-24	A\$0.50	300,000	-	-	-	300,000	300,000
15-Feb-21	15-Feb-26	A\$0.80	2,925,000	-	-	-	2,925,000	1,218,750
15-Feb-21	15-Feb-26	A\$0.50	400,000	-	-	-	400,000	166,667
11-Jun-21	11-Jun-26	A\$0.80	125,000	-	-	-	125,000	41,667
30-Jun-22	30-Jun-27	A\$0.80	-	1,300,000	-	-	1,300,000	100,000
<b>Total</b>			<b>5,280,000</b>	<b>1,300,000</b>	<b>-</b>	<b>-</b>	<b>6,580,000</b>	<b>3,357,084</b>
		Weighted average exercise price (\$A)	0.67	0.80	-	-	0.70	0.68
		Weighted average exercise price (\$US)	0.46	0.55	-	-	0.48	0.47



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NOTE 23. RESERVES (CONTINUED)

2021:

Grant Date	Expiry date	Exercise price	Balance at start of the year Number	Granted during the year Number	Exercised during the year Number	Expired/ Forfeited during the year Number	Balance at end of the year Number	Exercisable at end of the year Number
20-Aug-15	20-Aug-20	A\$2.56	153,500	-	-	(153,500)	-	-
13-Nov-15	13-Nov-20	A\$2.50	100,000	-	-	(100,000)	-	-
15-Jan-19	15-Jan-24	A\$0.50	1,530,000	-	-	-	1,530,000	768,333
26-Feb-19	26-Feb-24	A\$0.50	300,000	-	-	-	300,000	300,000
15-Feb-21	15-Feb-26	A\$0.80	-	2,925,000	-	-	2,925,000	231,250
15-Feb-21	15-Feb-26	A\$0.50	-	400,000	-	-	400,000	33,333
11-Jun-21	11-Jun-26	A\$0.80	-	125,000	-	-	125,000	-
<b>Total</b>			<b>2,083,500</b>	<b>3,450,000</b>	<b>-</b>	<b>(253,500)</b>	<b>5,280,000</b>	<b>1,332,916</b>
Weighted average exercise price (\$A)			0.80	0.77	-	2.54	0.67	0.55
Weighted average exercise price (\$US)			0.60	0.58	-	1.91	0.50	0.41

The fair value at grant date is determined using a Black-Scholes option pricing model that considers the exercise price, the term of the option, the impact of dilution, the share price at grant date and expected price volatility of the underlying share, the expected dividend yield and the risk free interest rate for the term of the option.

The model inputs for options granted during the year ended 30 June 2022 included:

Grant Date	Number issued	Exercise price	Term	Share price at grant date	Share price volatility	Expected dividend yield	Risk-free interest rate
30 June 2022	300,000	A\$0.80	5 years	A\$0.31	98%	0.00%	3.50%
30 June 2022	1,000,000	A\$0.80	5 years	A\$0.31	98%	0.00%	3.50%

The model inputs for options granted during the year ended 30 June 2021 included. Prices are displayed at pre-share conciliated amounts:

Grant Date	Number issued	Exercise price	Term	Share price at grant date	Share price volatility	Expected dividend yield	Risk-free interest rate
15 February 2021	29,250,000	A\$0.08	5 years	A\$0.07	65%	0.00%	0.44%
15 February 2021	4,000,000	A\$0.05	5 years	A\$0.07	65%	0.00%	0.44%
11 June 2021	1,250,000	A\$0.08	5 years	A\$0.09	83%	0.00%	0.70%

The expected price volatility is based on the historic volatility (based on the remaining life of the options), adjusted for any expected changes to future volatility due to publicly available information.

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NOTE 23. RESERVES (CONTINUED)

(b) Performance rights

Performance rights on issue

	30 Jun 2022		30 Jun 2021	
	No of Rights	US\$'000	No of Rights	US\$'000
At the beginning of reporting period	196,500,000	1,198	36,000,000	477
Issued under Performance Rights Plan	-	-	160,500,000	-
Rights converted during the year	(12,000,000)	(291)	-	-
Rights expired during the year	(24,000,000)	(395)	-	-
Rights vesting expense during the year	-	987	-	675
Transfer to retained earnings	-	(25)	-	-
Share consolidation (Note 19a)	(144,450,000)	-	(176,850,000)	-
Foreign exchange movement	-	(100)	-	46
<b>Closing balance at reporting date</b>	<b>16,050,000</b>	<b>1,374</b>	<b>19,650,000</b>	<b>1,198</b>

Details of performance rights relating to Directors that were issued with shareholder approval on 11 December 2020 under the Company's Performance Rights and Option Plan are as follows:

Number of performance rights	Will vest if share price trades		Issue Date	Expiry Date
	at or above:			
1,100,000	A\$1.20		11/12/2020	11/12/2023
1,100,000	A\$1.50		11/12/2020	11/12/2023
2,450,000	A\$2.00		11/12/2020	11/12/2023
5,700,000	A\$2.50		11/12/2020	11/12/2023
5,700,000	A\$5.00		11/12/2020	11/12/2023

- the fair value of the Performance Rights is based upon the price of CDX at issue date and adjusted for the probability of their performance milestones being achieved. The value of the Performance Rights, together with the probability of milestones being achieved is assessed by the Directors at least annually.
- the Performance Rights will be issued for no consideration if they vest and are exercised, the resulting Shares will be fully paid ordinary shares in the capital of the Company issued on the same terms and conditions as the Company's existing ordinary shares.
- no individual has yet received securities under this scheme; and
- no loans or other financial assistance have or will be made by the Company in connection with the issue of the relevant Performance Rights.

(c) Stock based compensation expense

Stock based compensation consisted of the following (in thousands):

	30 Jun 2022	30 Jun 2021
Rights issued under Option and Performance Rights Plan	\$ 1,014	\$ 671
Options issued under Employee Share Option Plan	359	323
Shares issued in lieu of payments to employees	86	57
	<b>\$ 1,459</b>	<b>\$ 1,051</b>

Accounting policy for share-based payments

Options issues have their fair value determined with reference to an approved valuation methodology, such as the Black-Scholes valuation method. On issue, the fair value of an option is taken to the profit or loss and other comprehensive income as equity settled compensation, with a corresponding credit to the options reserve. This is then disclosed as other comprehensive income in the Statement of Comprehensive Income to show other net profit position of the Group from a third party perspective. Shares have their value determined using the direct method of share price at date of issue multiplied by the number of shares issued.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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**NOTE 23. RESERVES (CONTINUED)**

*Critical Accounting Judgements, Estimates and Assumptions*

The Group measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by using either the Binomial or Black-Scholes model taking into account the terms and conditions upon which the instruments were granted. The accounting estimates and assumptions relating to equity-settled share-based payments would have no impact on the carrying amounts of assets and liabilities within the next annual reporting period but may impact profit or loss and equity.

**NOTE 24. FAIR VALUE MEASUREMENT**

*Fair value measurement hierarchy*

The following tables detail the Group's assets and liabilities, measured or disclosed at fair using a three-level hierarchy, based on the lowest level of input that is significant to the entire fair value measurement, being:

- Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date;
- Level 2: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and
- Level 3: Unobservable inputs for the asset or liability. Considerable judgement is required to determine what is significant to fair value and therefore which category the asset or liability is placed in can be subjective.

<b>2022</b>	<b>Level 1 \$'000</b>	<b>Level 2 \$'000</b>	<b>Level 3 \$'000</b>	<b>Total \$'000</b>
<i>Assets</i>				
Convertible notes	-	-	3,742	<b>3,742</b>
Shares at FVTPL	-	-	447	<b>447</b>
<b>Total Assets</b>	<b>-</b>	<b>-</b>	<b>4,189</b>	<b>4,189</b>
<i>Liabilities</i>				
Convertible notes	-	-	46	<b>46</b>
<b>Total Liabilities</b>	<b>-</b>	<b>-</b>	<b>46</b>	<b>46</b>
<b>2021</b>				
<i>Assets</i>				
Convertible notes	-	-	3,712	<b>3,712</b>
Shares at FVTPL	-	-	483	<b>483</b>
<b>Total Assets</b>	<b>-</b>	<b>-</b>	<b>4,195</b>	<b>4,195</b>
<i>Liabilities</i>				
Convertible notes	-	-	207	<b>207</b>
<b>Total Liabilities</b>	<b>-</b>	<b>-</b>	<b>207</b>	<b>207</b>

There were no transfers between levels during the financial year.

The carrying amounts of trade and other receivables are assumed to approximate their fair value due to their short-term nature.

The fair value of financial liabilities is estimated by discounting the remaining contractual maturities at the current market interest rate that is available for similar financial liabilities.

The following valuation techniques are used for instruments categorized in Level 3:

- Convertible notes (Level 3) – The Group's holding of convertible notes issued by Blumio and inHealth are classified as loans held at FVTPL. The Group obtained a third party valuation of inHealth for the years ended 30 June 2020, 2021, and 2022, which used a Monte Carlo Simulation to value the assets.
- Shares in inHealth (Level 3) – The fair value of this investment was also determined from the third party valuation that was obtained.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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NOTE 24. FAIR VALUE MEASUREMENT (CONTINUED)

	Shares in inHealth \$	inHealth convertible note \$	Blumio convertible note \$	Total \$
<b>Balance at 1 July 2020</b>	<b>362</b>	<b>4,071</b>	-	<b>4,433</b>
Interest income	-	155	37	192
Repayments	-	(539)	-	(539)
Foreign exchange adjustment	35	116	-	151
Fair value adjustment	86	(91)	(37)	(42)
<b>Balance at 30 June 2021</b>	<b>483</b>	<b>3,712</b>	-	<b>4,195</b>
Interest income	-	278	36	314
Foreign exchange adjustment	(40)	(80)	-	(120)
Fair value adjustment	4	(168)	(36)	(200)
<b>Balance at 30 June 2022</b>	<b>447</b>	<b>3,742</b>	-	<b>4,189</b>

*Critical estimates and judgements*

*Fair value measurement hierarchy*

The consolidated entity is required to classify all assets and liabilities, measured at fair value, using a three level hierarchy, based on the lowest level of input that is significant to the entire fair value measurement, being: Level 1: Quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date; Level 2:

Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and Level 3: Unobservable inputs for the asset or liability. Considerable judgement is required to determine what is significant to fair value and therefore which category the asset or liability is placed in can be subjective.

The fair value of assets and liabilities classified as level 3 is determined by the use of valuation models. These include discounted cash flow analysis or the use of observable inputs that require significant adjustments based on unobservable inputs.

NOTE 25. RELATED PARTY TRANSACTIONS

*Subsidiaries*

The consolidated financial statements include the financial statements of CardieX Limited and the following subsidiaries:

Name	Country of incorporation	Beneficial interest (%)*	
		30 Jun 2022	30 Jun 2021
<i>AtCor Medical Pty Limited</i>	<i>Australia</i>	100	100
<i>AtCor Medical Inc</i>	<i>USA</i>	100	100
<i>CardieX (Shanghai) Medical Technology Co., Ltd.</i>	<i>China</i>	100	100
<i>Conneqt Inc</i>	<i>USA</i>	100	100

\*Percentage of voting power is in proportion to ownership.

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NOTE 25. RELATED PARTY TRANSACTIONS (CONTINUED)

Key Management Personnel Compensation

	Salary and directors fees \$'000	Share Based Payment Benefits \$'000	Total \$'000
<b>2022</b>			
Niall Cairns	189	362	551
Craig Cooper	520	362	882
King Nelson	41	22	63
Jarrold White	85	136	221
Lesa Musatto (Appointed 26 April 2022) <sup>1</sup>	-	-	-
<b>Total Compensation</b>	<b>835</b>	<b>882</b>	<b>1,717</b>
<b>2021</b>			
Niall Cairns	152	185	337
Craig Cooper	395	408	803
King Nelson	28	11	39
Jarrold White	76	72	148
<b>Total Compensation</b>	<b>651</b>	<b>676</b>	<b>1,327</b>

1. Lesa Musatto received no remuneration in FY2022 as her remuneration is payable in the form of options, which were subject to shareholder approval at the 2022 AGM held on 30 November 2022.

Shares held by key management personnel and their associates

	Balance 01 July 2021	Additions	Share consolidation	Balance 30 June 2022
Niall Cairns	181,842,010	53,751,9222	(212,034,538)	23,559,394
Craig Cooper	177,242,010	53,751,9222	(207,894,538)	23,099,394
King Nelson	153,846	-	(138,461)	15,385
Jarrold White	4,857,577	907,933	(5,188,559)	576,951
Lesa Musatto	-	-	-	-
<b>Total</b>	<b>364,095,443</b>	<b>108,411,777</b>	<b>(425,256,096)</b>	<b>47,251,124</b>

- <sup>2</sup>A total of 47,751,922 pre consolidated shares acquired by Mr. Cairns and Mr. Cooper in the year are indirectly held by C2 Ventures, in which Mr. Cairns and Mr. Cooper are directors. These shares are subject to the Restriction Agreement and Deed of Undertaking as approved by members at the Extraordinary General Meeting held on 28 May 2018.

	Balance 01 July 2020	Additions	Balance 30 June 2021
Niall Cairns	161,960,192	19,881,8181	181,842,010
Craig Cooper	158,960,192	18,281,8181	177,242,010
King Nelson	153,846	-	153,846
Jarrold White	3,257,577	1,600,000	4,857,577
<b>Total</b>	<b>324,331,807</b>	<b>39,763,636</b>	<b>364,095,443</b>

- <sup>1</sup>A total of 18,281,818 pre consolidated shares acquired by Mr. Cairns and Mr. Cooper in the year are indirectly held by C2 Ventures, in which Mr. Cairns and Mr. Cooper are directors. These shares are subject to the Restriction Agreement and Deed of Undertaking as approved by members at the Extraordinary General Meeting held on 28 May 2018.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE FISCAL YEARS ENDED 30 JUNE 2022 AND 2021

NOTE 25. RELATED PARTY TRANSACTIONS (CONTINUED)

*Options held by key management personnel and their associates*

	Balance 01 July 2021	Exercised	Transferred	Share consolidation	Balance 30 June 2022
Niall Cairns	43,420,455	(39,920,455)	(2,000,000)	(1,350,000)	150,000
Craig Cooper	43,420,455	(39,920,455)	(2,000,000)	(1,350,000)	150,000
King Nelson	1,500,000	-	-	(1,350,000)	150,000
Jarrold White	1,897,728	(397,728)	-	(1,350,000)	150,000
Lesa Musatto	-	-	-	-	-
<b>Total</b>	<b>90,238,638</b>	<b>(80,238,638)</b>	<b>(4,000,000)</b>	<b>(5,400,000)</b>	<b>600,000</b>

<sup>2</sup>Directors Mr. Cairns and Mr. Cooper hold 150,000 options indirectly through C2 Ventures Pty Limited, of which they are both directors.

	Balance 01 July 2020	Expired	Additions	Balance 30 June 2021
Niall Cairns	39,000,000	-	4,420,455	43,420,455
Craig Cooper	39,000,000	-	4,420,455	43,420,455
King Nelson	1,500,000	-	-	1,500,000
Jarrold White	1,897,728	-	-	1,897,728
<b>Total</b>	<b>81,397,728</b>	<b>-</b>	<b>8,840,910</b>	<b>90,238,638</b>

<sup>3</sup>Directors Mr. Cairns and Mr. Cooper hold 41,920,455 options indirectly through C2 Ventures Pty Limited, of which they are both directors.

*Performance rights held by key management personnel and their associates*

On 11 December 2020 shareholders approved the issue of performance rights to be issued to the Directors under the Company's Performance Rights and Option Plan. These performance rights total 16,050,000 and expire on 11 December 2023. The terms of the Director rights on issue are as follows:

Tranche	Number of performance rights	Will vest if share price trade at or above:	Expiry Date of Performance Milestone
Tranche 1	1,100,000	A\$01.20	11/12/2023
Tranche 2	1,100,000	A\$1.50	11/12/2023
Tranche 3	2,450,000	A\$2.00	11/12/2023
Tranche 4	5,700,000	A\$2.50	11/12/2023
Tranche 5	5,700,000	A\$5.00	11/12/2023

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE FISCAL YEARS ENDED 30 JUNE 2022 AND 2021**

**NOTE 25. RELATED PARTY TRANSACTIONS (CONTINUED)**

	Balance 01 July 2021	Converted	Expired	Share consolidation	Balance 30 June 2022
Niall Cairns	68,000,000	-	-	(61,200,000)	6,800,000
Craig Cooper	104,000,000	(12,000,000)	(24,000,000)	(61,200,000)	6,800,000
King Nelson	3,500,000	-	-	(3,150,000)	350,000
Jarrold White	21,000,000	-	-	(18,900,000)	2,100,000
Lesa Musatto	-	-	-	-	-
<b>Total</b>	<b>196,500,000</b>	<b>(12,000,000)</b>	<b>(24,000,000)</b>	<b>(144,450,000)</b>	<b>16,050,000</b>

	Balance 01 July 2020	Expired	Additions	Balance 30 June 2021
Niall Cairns	-	-	68,000,000	68,000,000
Craig Cooper	36,000,000	-	68,000,000	104,000,000
King Nelson	-	-	3,500,000	3,500,000
Jarrold White	-	-	21,000,000	21,000,000
<b>Total</b>	<b>36,000,000</b>	<b>-</b>	<b>160,500,000</b>	<b>196,500,000</b>

**Employment Agreements**

Remuneration and other terms of employment for the CEO and the other key management personnel are formalized in employment agreements. Each of these agreements provide for the provision of performance related cash bonuses, other benefits including health insurance and car allowances, and participation, when eligible, in the CardieX Limited Employee Share Option Plan. Other major provisions of the agreements relating to remuneration are set out below. All contracts with executives may be terminated early by either party with variable notice periods, subject to termination payments as detailed below.

*Craig Cooper – Chief Executive Officer*

- Agreement commenced on 1 September 2021.
- Base salary of US\$420,000 per annum.
- Bonuses to be paid at discretion of the Group based on performance reviews.
- Reimbursement for reasonable expenses incurred in running the US business, paid on a monthly basis.

*Niall Cairns – Executive Chairman and Director*

- Current agreement commenced with an effective date of 1 September 2021.
- Base salary of US\$300,000 per annum.
- Reimbursement for reasonable expenses incurred.

*King Nelson – Non-Executive Director*

- Current agreement commenced with an effective date of 13 November 2015.
- Base salary of US\$50,000 per annum.

*Jarrold White – Director*

- Jarrold White is the principal of Traverse Accountants Pty Ltd, who holds an engagement with the Group covering CFO services, Company Secretarial services, and other general accountancy services.
- Mr. White received Directors Fees of A\$35,000 in shares for the prior reporting year in addition to the arms' length services paid to Traverse Accountants Pty Ltd.
- Mr. White also entered an Executive Director Service Agreement with an effective date of 21 May 2020 that provides for a base salary of A\$35,000 per annum.
- Reimbursement for reasonable expenses incurred.

**Loans to Directors and Key Management Personnel**

There were no loans made to directors or key management personnel of the Company and the Group during the period during the fiscal years ended June 30, 2021 and 2022 commencing at the beginning of the financial year and thereafter up to the date of this report.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE FISCAL YEARS ENDED 30 JUNE 2022 AND 2021**

**NOTE 26. EVENTS AFTER THE REPORTING PERIOD**

Subsequent to balance date the Group announced the following material events:

- On 29 July 2022, CardieX announced that it has changed its provider for shareholder registry services from Link Market Services to Automic Pty Ltd.
- On 22 August 2022, CardieX announced that it had completed a A\$4.33 million (~US\$3.00 million) placement.
- On 26 August 2022, CardieX announced the launch of a share purchase plan, with a target of A\$1m (~US\$0.69 million) to be raised.
- On 28 September 2022, CardieX announced the successful completion of its SPP, which closed on 26 September 2022. The Company received applications for fully paid ordinary shares (Shares) from eligible shareholders (which included Directors) under the SPP at an issue price of A\$0.30 per share in the amount of A\$1.60 million (~US\$1.10 million) (before costs) representing a 59.3% over-subscription over the originally targeted raise of A\$1.00 million.
- As disclosed in the SPP Offer Booklet (refer to ASX release 26 August 2022), the Company reserved the right to conduct either a scale-back of over-subscriptions above the targeted of A\$1.00 million, or to accept over-subscriptions above the target. In response to the strong demand from shareholders, the Company has elected to accept the full A\$1.60 million (~US\$1.10 million) of valid applications including the A\$0.6 million in oversubscriptions and therefore not conduct any scale-back.
- On 16 November 2022, CardieX announced the acquisition of the core assets from Blumio, Inc. The purchase price of the asset was US \$15,100 payable on execution of the asset purchase agreement, followed by US \$150,000 in CardieX ordinary shares, payable in two equal tranches on 15 June 2023 and 15 March 2024 subject to service-based performance criteria. The acquisition negotiations commenced after CardieX released its FY2022 annual report on the ASX (on 30 September 2022). There was no deemed control over Blumio or any of its assets prior to this time.
- On 2 December 2022, CardieX adopted a new constitution, as approved by shareholder at the Annual General Meeting held on 30 November 2022.
- On 9 December 2022, CardieX announced a significant new clinical trial agreement with Procurement Partner, CliniChain BV. The clinical trial involves the provision of ATCOR's XCEL devices and data management services over a period of approximately 30 months.
- On 6 January 2023, CardieX announced that AtCor Medical Pty Ltd had entered into a short-term working capital loan facility with Mitchell Asset Management. The facility limit is A\$880,000 at a rate of 16% per annum and matures on 30 October 2023.

No other significant subsequent event has arisen that significantly affects the operations of the Group.

**NOTE 27. OPERATING SEGMENTS**

In the 2022 financial year, the Group operated in one operating segment and has identified only one reportable segment being sales of cardiovascular devices and services to hospitals, clinics, research institutions and pharmaceutical companies.

Note 2 contains detailed information in relation to the Consolidate Group's product and services.

Geographically, the Group prepares information based on the location of its customers, being:

- Americas (includes global pharmaceutical trials business)
- Europe (includes Middle East and Africa)
- Asia Pacific (includes Asia & Australia/NZ)



NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE FISCAL YEARS ENDED 30 JUNE 2022 AND 2021

NOTE 27. OPERATING SEGMENTS (CONTINUED)

Geographical information (in thousands):

2022	Americas	Europe	Asia Pacific	Inter- segment eliminations/ unallocated	Consolidated
	\$	\$	\$	\$	\$
Sales to external customers	2,300	343	309	-	2,952
Intersegment sales	-	-	759	(759)	-
Total sales revenue	2,300	343	1,068	(759)	2,952
Interest revenue	-	-	314	-	314
Total segment revenue/income	<u>2,300</u>	<u>343</u>	<u>1,382</u>	<u>(759)</u>	<u>3,266</u>
<b>Segment loss before income tax</b>	<b>(3,323)</b>	<b>139</b>	<b>(5,069)</b>	<b>(318)</b>	<b>(8,571)</b>
Income tax expense	-	-	-	-	-
<b>Loss for the year</b>	<b>(3,323)</b>	<b>139</b>	<b>(5,069)</b>	<b>(318)</b>	<b>(8,571)</b>
Segment assets	9,752	-	49,005	(50,230)	8,527
Segment liabilities	26,289	-	39,900	(62,216)	3,973
2021	Americas	Europe	Asia Pacific	Inter- segment eliminations/ unallocated	Consolidated
	\$	\$	\$	\$	\$
Sales to external customers	3,150	291	294	-	3,735
Intersegment sales	-	-	969	(969)	-
Total sales revenue	3,150	291	1,263	(969)	3,735
Interest revenue	-	-	192	-	192
Total segment revenue/income	<u>3,150</u>	<u>291</u>	<u>1,455</u>	<u>(969)</u>	<u>3,927</u>
<b>Segment loss before income tax</b>	<b>58</b>	<b>210</b>	<b>(3,724)</b>	<b>(413)</b>	<b>(3,869)</b>
Income tax expense	-	-	-	-	-
<b>Loss for the year</b>	<b>58</b>	<b>210</b>	<b>(3,724)</b>	<b>(413)</b>	<b>(3,869)</b>
Segment assets	9,349	-	44,905	(45,186)	9,068
Segment liabilities	22,562	-	37,178	(57,219)	2,521

*Inter-segment transfers*

Segment revenues, expenses and results include transfers between segments. The group transfer inventory and finished goods between its group companies. Such transfers are priced on an “arm’s-length” basis and are eliminated on consolidation.

*Segment revenue*

There was no significant concentration of revenue attributable to one customer in 2022 (2021: \$NIL).

NOTE 28. CONTINGENT LIABILITIES AND CONTINGENT ASSETS

The Group has no other material contingent liabilities or contingent assets as at 30 June 2022 (30 June 2021: \$Nil).

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE FISCAL YEARS ENDED 30 JUNE 2022 AND 2021**

**NOTE 29. AUDITOR'S REMUNERATION**

*(in dollars)*

During the fiscal year, the following fees were paid or payable for audit services provided by BDO:

	<u>30 Jun 2022</u>	<u>30 Jun 2021</u>
<b>Audit services</b>		
Audit or review of financial statements – BDO Audit Pty Ltd	\$ 161,890	\$ 119,870
	<u>\$ 161,890</u>	<u>\$ 119,870</u>

**NOTE 30. PARENT ENTITY INFORMATION**

*(in thousands)*

	<u>Note</u>	<u>30 Jun 2022</u>	<u>30 Jun 2021</u>
Current assets		\$ 934	\$ 6,311
Inter-company loans		18,879	14,614
<b>Total assets</b>		<u>\$ 24,588</u>	<u>\$ 21,447</u>
Current liabilities		1,264	1,173
Inter-company loans		6,717	7,979
<b>Total liabilities</b>		<u>\$ 8,479</u>	<u>\$ 9,152</u>
<b>Net Assets</b>		<u>\$ 16,109</u>	<u>\$ 12,295</u>
Contributed equity		\$ 50,985	\$ 49,426
Reserves		3,298	(920)
Accumulated losses		(38,174)	(36,211)
<b>Total shareholders' equity</b>		<u>\$ 16,109</u>	<u>\$ 12,295</u>
<b>Loss of the parent entity</b>		<u>\$ (1,963)</u>	<u>\$ (2,068)</u>
<b>Total comprehensive income of the parent entity</b>		<u>\$ (1,963)</u>	<u>\$ (2,068)</u>

*Guarantees entered into by the parent entity*

No guarantees have been entered into by the parent entity during FY2022 or FY2021.

*Commitments and contingent liabilities of the parent entity*

See Note 28 for details on contingent liabilities of the parent entity.

CARDIEX LIMITED  
AND CONTROLLED ENTITIES

*ABN 81 113 252 234*

INTERIM FINANCIAL REPORT  
FOR THE HALF-YEARS ENDED DECEMBER 31, 2022  
AND 2021

**CARDIEX LIMITED AND CONTROLLED ENTITIES**  
**CONSOLIDATED BALANCE SHEETS**  
**AS OF DECEMBER 31, 2022 AND JUNE 30, 2022**

(in thousands)

	<u>Note</u>	<u>31 Dec 2022 (Unaudited)</u>	<u>30 Jun 2022</u>
<b>Assets</b>			
<b>Current assets</b>			
Cash and cash equivalents		\$ 1,682	\$ 1,003
Trade and other receivables		275	560
Inventories		976	685
Financial assets	5	3,743	-
Other current assets		1,260	1,079
<b>Total current assets</b>		<b>7,936</b>	<b>3,327</b>
<b>Non-current assets</b>			
Property, plant and equipment, net		350	277
Intangible assets		385	221
Financial assets	5	413	4,189
Right-of-use asset, net		402	460
Other non-current assets		53	53
<b>Total non-current assets</b>		<b>1,603</b>	<b>5,200</b>
<b>Total assets</b>		<b>\$ 9,539</b>	<b>\$ 8,527</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables		\$ 2,603	\$ 1,532
Unearned revenue	6	1,525	604
Provisions		368	363
Financial liabilities		-	46
Lease liabilities		97	85
Borrowings	7	1,475	894
<b>Total current liabilities</b>		<b>\$ 6,068</b>	<b>\$ 3,524</b>
<b>Non-current liabilities</b>			
Other liabilities		78	-
Provisions		1	1
Lease liabilities		388	448
<b>Total non-current liabilities</b>		<b>467</b>	<b>449</b>
<b>Total liabilities</b>		<b>\$ 6,535</b>	<b>\$ 3,973</b>
<b>Net assets</b>		<b>\$ 3,004</b>	<b>\$ 4,554</b>
<b>Equity</b>			
Contributed equity	8	\$ 49,463	\$ 46,537
Reserves	9	6,974	5,177
Accumulated losses		(53,433)	(47,160)
<b>Total equity</b>		<b>\$ 3,004</b>	<b>\$ 4,554</b>

The above consolidated balance sheets should be read in conjunction with the accompanying notes.

**CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER  
COMPREHENSIVE INCOME  
FOR THE HALF-YEARS ENDED 31 DECEMBER 2022 AND 2021 (UNAUDITED)**

(in thousands, except share and per share amounts)

	<u>Note</u>	<u>31 Dec 2022 (Unaudited)</u>	<u>31 Dec 2021 (Unaudited)</u>
<b>Revenue</b>	2	\$ 891	\$ 1,531
<b>Other income</b>	3	405	527
<b>Total revenue and other income</b>		<b>1,296</b>	<b>2,058</b>
<b>Expenses</b>			
Cost of goods sold		(224)	(381)
Research & development		(1,735)	(1,312)
Sales & marketing		(895)	(1,202)
Management & administration		(3,512)	(1,900)
Stock based compensation		(609)	(806)
Fair value gain/(loss) on financial assets		67	(1,011)
Finance costs		(87)	(104)
Other expenses		(189)	(88)
<b>Total expenses</b>		<b>(7,184)</b>	<b>(6,804)</b>
<b>Net loss before income tax expense</b>		<b>(5,888)</b>	<b>(4,746)</b>
Income tax expense		-	-
<b>Net loss for the period</b>		<b>\$ (5,888)</b>	<b>\$ (4,746)</b>
Other comprehensive (loss)/income for the period, net of tax – Exchange differences on translation to the presentation currency		(156)	(199)
<b>Total comprehensive loss for the period attributable to the members of CardieX Limited</b>		<b>\$ (6,044)</b>	<b>\$ (4,945)</b>
<b>Loss per share attributable to the members of CardieX Limited</b>			
Basic and diluted loss per share <sup>1</sup>	4	\$ (0.05)	\$ (0.05)

The above consolidated statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes.

<sup>1</sup>On 16 February 2022, there was a share consolidation of the issued capital of the Company on the basis of one (1) security for every ten (10) securities held. Where the consolidation resulted in a fraction of a Share, Performance Right or Option being held, the Company rounded that fraction up to the next whole number. The prior year weighted average number of ordinary shares has been adjusted accordingly so that the basic and diluted loss per share are comparable.

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
FOR THE HALF-YEARS ENDED DECEMBER 31, 2022 AND 2021 UNAUDITED**

(in thousands)

	<u>Contributed equity</u>	<u>Reserves</u>	<u>Accumulated losses</u>	<u>Total equity</u>
<b>Balance at 1 July 2021</b>	\$ 44,572	\$ (1,678)	\$ (36,347)	\$ 6,547
Loss after income tax expense for the period	-	-	(4,746)	(4,746)
Other comprehensive (loss)/gain for the period, net of tax – <i>Exchange differences on translation to the presentation currency</i>	(1,555)	2,314	(958)	(199)
<b>Total comprehensive loss for the period</b>	<b>\$ (1,555)</b>	<b>\$ 2,314</b>	<b>\$ (5,704)</b>	<b>\$ (4,945)</b>
<i>Transactions with owners in their capacity as owners:</i>				
Shares issued on conversion of convertible note	197	(27)	-	170
Shares issued on conversion of performance rights	307	(307)	-	-
Shares issued on exercise of options	5,516	-	-	5,516
Share issue costs	(107)	-	-	(107)
Share-based payments	50	730	24	804
<b>Balance at 31 December 2021</b>	<b>\$ 48,980</b>	<b>\$ 1,032</b>	<b>\$ (42,027)</b>	<b>\$ 7,985</b>
<b>Balance at 1 July 2022</b>	<b>\$ 46,537</b>	<b>\$ 5,177</b>	<b>\$ (47,160)</b>	<b>\$ 4,554</b>
Loss after income tax expense for the period	-	-	(5,888)	(5,888)
Other comprehensive (loss)/gain for the period, net of tax – <i>Exchange differences on translation to the presentation currency</i>	(770)	999	(385)	(156)
<b>Total comprehensive loss for the period</b>	<b>\$ (770)</b>	<b>\$ 999</b>	<b>\$ (6,273)</b>	<b>\$ (6,044)</b>
<i>Transactions with owners in their capacity as owners:</i>				
Capital placement	4,012	-	-	4,012
Share issue costs	(364)	-	-	(364)
Shares issued in lieu of payments to employees	24	-	-	24
Shares issued in lieu of payments to suppliers	24	-	-	24
Share-based payments	-	798	-	798
<b>Balance at 31 December 2022</b>	<b>\$ 49,463</b>	<b>\$ 6,974</b>	<b>\$ (53,433)</b>	<b>\$ 3,004</b>

The above consolidated statement of stockholders' equity should be read in conjunction with the accompanying notes.

**CONSOLIDATED STATEMENTS OF CASH FLOWS  
FOR THE HALF-YEARS ENDED 31 DECEMBER 2022 AND 2021 UNAUDITED**

(in thousands)

	<u>Note</u>	<u>31 Dec 2022 (Unaudited)</u>	<u>31 Dec 2021 (Unaudited)</u>
<b><i>Cash flows used in operating activities</i></b>			
Receipts from customers		\$ 2,486	\$ 1,247
Payments to suppliers and employees		(5,669)	(4,716)
Other income received		111	-
<b>Net cash used in operating activities</b>		<b>\$ (3,072)</b>	<b>\$ (3,469)</b>
<b><i>Cash flows used in investing activities</i></b>			
Payments for property, plant and equipment		(16)	(91)
Payments for intangible assets		(15)	(12)
<b>Net cash used in investing activities</b>		<b>\$ (31)</b>	<b>\$ (103)</b>
<b><i>Cash flows from financing activities</i></b>			
Proceeds from shares issued		3,971	5,564
Share issue costs		(180)	(108)
Borrowings received, net of transaction costs		536	-
Borrowings repaid		(45)	(435)
Finance costs		-	(19)
Lease principal repayments		(69)	(69)
<b>Net cash from financing activities</b>		<b>\$ 4,213</b>	<b>\$ 4,933</b>
<b>Net increase in cash and cash equivalents</b>		<b>1,110</b>	<b>1,361</b>
Cash and cash equivalents at the beginning of the fiscal period		1,003	2,756
Effects of foreign currency exchange		(431)	(151)
<b>Cash and cash equivalents at the end of the period</b>		<b>\$ 1,682</b>	<b>\$ 3,966</b>

The above consolidated statement of cash flows should be read in conjunction with the accompanying notes.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE HALF-YEARS ENDED 31 DECEMBER 2022 AND 2021**

**NOTE 1. SIGNIFICANT ACCOUNTING POLICIES**

The interim financial report includes the consolidated financial statements and notes of CardieX Limited and controlled entities ('Consolidated Group' or 'Group'). The separate financial statements and notes of CardieX Limited as an individual parent entity ('Company') have not been presented within the interim financial report as permitted by the *Corporations Act 2001*. CardieX Limited is a for-profit entity.

**BASIS OF PREPARATION**

These interim financial statements have been prepared in accordance with International Financial Reporting Standards IAS 34 "Interim Financial Reporting". The interim financial report does not include notes of the type normally included in an annual financial report and should be read in conjunction with the most recent annual financial report and any public announcements made by CardieX Limited during the interim period.

Comparative figures have been adjusted to conform to changes in classification and presentation for the current period.

*Historical cost convention*

The consolidated financial statements have been prepared on a historical cost basis, except for the financial instruments which are recorded at fair value through profit or loss (refer to individual accounting policies for details).

*Critical accounting estimates*

In the process of applying the Group's accounting policies, management has made a number of judgements, applied estimates and assumptions of future events.

The judgements, estimates and assumptions applied in the interim financial statements, including the key sources of estimation, were the same as those applied in the Group's last annual financial statements for the fiscal year ended 30 June 2022.

**GOING CONCERN**

The interim financial statements of the Group have been prepared on a going concern basis, which indicates the continuation of business activities and realization of assets and settlement of liabilities in the normal course of business.

The Group incurred a loss after tax of \$5.89 million (2021: \$4.75 million), had net cash outflows from operating activities of \$3.07 million for the half-year ended 31 December 2022 (2021: \$3.47 million) and had a net current asset position as at 31 December 2022 of \$1.87 million (30 June 2022: net current liability position of \$0.20 million). The Group also notes that it is forecast that further debt or equity financing will be required in order for the Group to continue as a going concern. The Directors have assessed that the above factors give rise to substantial doubt related to going concern that may cast significant doubt over the ability of the Group to continue as a going concern.

The Directors believe that there are reasonable grounds that the Group will be able to continue as a going concern and meet its debts as and when due, after consideration of the following factors:

- On 9 December 2022, CardieX announced a significant new clinical trial agreement with Procurement Partner, CliniChain BV. The clinical trial involves the provision of ATCOR's XCEL devices and data management services over a period of approximately 30 months. Since June 30, 2022, over US\$1 million has been received under this contract.
- On 6 January 2023, CardieX announced that AtCor Medical Pty Ltd had entered into a short-term working capital loan facility with Mitchell Asset Management. The facility limit is A\$880,000 at a rate of 16% per annum and matures on 30 October 2023.
- On 9 February 2023, CardieX announced that it had completed an A\$4.5 million placement.
- If required, the Group has the ability to continue to raise additional funds on a timely basis pursuant to the Corporations Act 2001. Based on the Group's track record of successful equity funding in the preceding financial years and subsequent to the reporting period end, the Directors believe that the Group will be able to continue to source equity or alternative funding if required.
- There is a term loan facility of A\$1.3 million repayable in October 2023, however this will be partially offset by R&D tax rebates expected in the same month. The Group is also currently reviewing options to extend or refinance the facility.
- The Group has the ability to scale back a significant portion of its development activities if required.
- The Group is currently progressing with a US listing which will provide access to alternative capital markets and equity raising opportunities.

Accordingly, the Directors believe that the Group will be able to continue as a going concern, and that it is appropriate to adopt the going concern basis in the preparation of the financial report.

Should the Group be unable to raise additional funds on a timely basis, it may be required to realize its assets and discharge its liabilities other than in the normal course of business and at amounts different to those stated in the financial statements. The financial statements do not include any adjustments to the recoverability and classification of asset carrying amounts or the amount of liabilities that might result should the Group be unable to continue as a going concern and meet its debts as and when they fall due.



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE HALF-YEARS ENDED 31 DECEMBER 2022 AND 2021**

**NOTE 2. REVENUE**

Revenue consists of the following (*in thousands*):

	<u>31 Dec 2022</u>	<u>31 Dec 2021</u>
Sale of goods revenue	\$ 486	\$ 682
Lease revenue	202	580
Other revenue	203	269
	<u>\$ 891</u>	<u>\$ 1,531</u>

**Disaggregation of revenue**

The Group derives its revenue from the transfer of goods and services at a point in time. The table above provides a breakdown of revenue by major business line. The categories above depict how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic data.

For the six-month period ended December 31, 2022, \$0.14 million of revenue recognized during the period was included in the opening balance of unearned revenue.

**NOTE 3. OTHER INCOME**

Other income consists of the following (*in thousands*):

	<u>31 Dec 2022</u>	<u>31 Dec 2021</u>
Research and development tax incentive scheme	\$ 203	\$ 223
Foreign exchange gains	-	122
Interest income	87	178
Miscellaneous other income	115	4
	<u>\$ 405</u>	<u>\$ 527</u>

**NOTE 4. LOSS PER SHARE**

The calculation of the basic and diluted loss per share is based on the following information (*in thousands, except share and per share amounts*):

	<u>31 Dec 2022</u>	<u>31 Dec 2021</u>
<b>Reconciliation of earnings used in calculating earnings per share</b>		
Loss attributable to ordinary equity holders of CardieX Limited	\$ (6,044)	\$ (4,945)
	<u>No. of shares</u>	<u>No. of shares</u>
<b>Weighted average number of ordinary shares</b>	<u>120,490,202</u>	<u>96,193,616</u>
<b>Basic and diluted loss per share</b>	<u>\$ (0.05)</u>	<u>\$ (0.05)</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE HALF-YEARS ENDED 31 DECEMBER 2022 AND 2021**

**NOTE 5. FINANCIAL ASSETS**

Financial assets consisted of the following (*in thousands*):

	31 Dec 2022	30 Jun 2022
<b>Current</b>		
inHealth Medical Services convertible note (b)	\$ 3,743	\$ -
	<u>3,743</u>	<u>-</u>
<b>Non-current</b>		
Blumio Inc convertible note (a)	-	-
inHealth Medical Services investment (b)	413	447
inHealth Medical Services convertible note (b)	-	3,742
	<u>\$ 413</u>	<u>\$ 4,189</u>
<b>Total financial assets</b>	<u>\$ 4,156</u>	<u>\$ 4,189</u>

**(a) Blumio Inc convertible note**

- On 16 November 2022, CardieX announced the acquisition of the core assets from Blumio, Inc. The purchase price of the asset was \$15,100 payable on execution of the asset purchase agreement, followed by \$150,000 in CardieX Ordinary Shares, payable in two equal tranches on 15 June 2023 and 15 March 2024 subject to service-based performance criteria. The acquisition negotiations commenced after CardieX released its FY2022 annual report on the ASX (on 30 September 2022). The face value and accrued interest owing to CardieX was extinguished as result of the acquisition. There was no deemed control over Blumio or any of its assets prior to this time.

**(b) inHealth Medical Services investment & convertible note**

- As at 31 December 2022, the face value of the inHealth Note was \$2,875,317 and \$144,160 in interest had accrued.
- As at 31 December 2022, the total convertible note asset was fair valued at \$3.74M (30 June 2022: \$3.74M).
- The current maturity date of the convertible note is November 30, 2023, and as such, the convertible note is shown as a current financial asset.
- As at 31 December 2022, the Group holds 7.64% equity in inHealth Medical Services, Inc, currently valued at \$0.4M (30 June 2022: \$0.4M).
- The CardieX Board continues to closely monitor its investment, is in regular communication with inHealth, and is currently considering available options as the current amendment of the Note nears maturity towards the end of the calendar year.

**Accounting Treatment – Asset Acquisition of Blumio, Inc.**

As disclosed above, CardieX acquired the core assets of Blumio, Inc. on 16 November 2022. Management have assessed the treatment of this transaction in accordance with *IFRS 3 Business Combinations*, and have determined that this was an asset acquisition as a result of the following factors:

- The acquired assets of Blumio, Inc. include customer leads, any servers containing the acquired assets, intellectual property including two specific patents and research data, software, and other small hardware.
- The structure of the acquisition along with the limited assets acquired confirms that only specific assets in Blumio Inc have been purchased, and no liabilities have been assumed. Cash at bank, grant receivables and liabilities, payroll liabilities and convertible note liabilities have not been assumed by CardieX. Convertible note holders are to be issued CardieX shares as part of the deferred settlement of the asset purchase however this is significantly less than the face value of the notes held on Blumio Inc's balance sheet and the difference is not assumed by CardieX; and
- The outputs of Blumio Inc's business are not easily identifiable. CardieX could not identify any planned principal activities (due to some changes in research focus at Blumio since CardieX' initial investment), and there is not an identifiable plan to produce outputs (application guidance B10 of *IFRS 3 Business Combinations*).

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE HALF-YEARS ENDED 31 DECEMBER 2022 AND 2021**

**NOTE 5. FINANCIAL ASSETS (CONTINUED)**

*Critical estimates and judgements*

*Valuation of inHealth Medical Services Convertible Notes – key assumptions used in assessment*

The valuation used to support the carrying amounts of the convertible notes are, by nature, uncertain. The valuation was performed by an external independent professional valuer. The nature and basis of the key assumptions used to estimate the valuation of the convertible notes are set out below:

- The inHealth Medical Services Convertible Notes were valued with reference to the underlying note agreement.
- Control Premium – a control premium of 15% has been used in the valuation of the convertible notes. Given that conversion of the convertible notes in inHealth would give CardieX a controlling interest in the company, a premium has been calculated. This was calculated with reference to 122 deals from the overall market for latest quarter of 2022, which were noted to have an average premium of 37.6% and a median premium of 26.5%. It was also calculated with reference to other factors affecting control premiums including, but not limited to, the performance of the entity, the number of potential buyers and the size of the business.
- Discount Rate – a discount rate of 14.75% has been used in the valuation of the convertible notes. This discount rate represents the market yield of the healthcare sector as of the valuation date.
- Time until Events – is the expected amount of time that the convertible notes will be held by CardieX prior to being converted into shares of inHealth. It has been assumed that the time until events (years) is 1.419, which represents management’s best estimate of when the convertibles notes will be converted.

**NOTE 6. UNEARNED REVENUE**

Unearned revenue consisted of the following (*in thousands*):

	<u>31 Dec 2022</u>	<u>30 Jun 2022</u>
Advances received from clinical trial contracts	\$ 1,443	\$ 529
Unearned revenue from sale of goods	6	-
Unearned revenue from customer service contracts	76	75
	<u>\$ 1,525</u>	<u>\$ 604</u>

**NOTE 7. BORROWINGS**

Borrowings includes the following liabilities carried at amortized cost (*in thousands*):

	<u>31 Dec 2022</u>	<u>30 Jun 2022</u>
R&D loan facility	\$ 879	\$ 894
Working capital loan facility	596	-
	<u>\$ 1,475</u>	<u>\$ 894</u>

*R&D loan facility*

On 24 March 2022, the Group entered into a new 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 forecasted R&D tax incentive claim for the year ended 30 June 2022, with an initial termination date of 31 October 2022, which has since been extended to 31 December 2023. Currently the Facility attracts interest at 1.33% per calendar month (16% per annum). A general security is held over the Company. Any balance owing after the 2022 R&D refund has been offset and can be:

- Paid out in cash with no interest or fees payable under the current facility terms following the month end of the FY2022 R&D payout; or
- Secured against the Company’s FY2023 R&D refund and paid on or before the end of the extended facility term of 31 December 2023.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE HALF-YEARS ENDED 31 DECEMBER 2022 AND 2021**

**NOTE 7. BORROWINGS (CONTINUED)**

*Working capital loan facility*

In December 2022, wholly owned subsidiary Atcor Medical Pty Ltd entered into a short-term working capital loan facility for up to A\$880,000, to support product and development expansion initiatives. The facility attracts an interest rate of 1.33% per calendar month (16% per annum) and expires on 30 October 2023. A general security is held over the Company. As at 31 December 2022, the facility was fully drawn, with A\$80,000 withheld for prepaid interest and establishment fees.

**NOTE 8. CONTRIBUTED EQUITY**

Contributed equity consisted of the following:

	31 Dec 2022		30 Jun 2022	
	Shares (No)	US\$'000	Shares (No)	US\$'000
Ordinary shares	129,984,144	\$ 49,463	110,003,700	\$ 46,537
	<u>129,984,144</u>	<u>\$ 49,463</u>	<u>110,003,700</u>	<u>\$ 46,537</u>

*Issued capital*

Ordinary shares are classified as equity.

Incremental costs directly attributable to the issue of new shares, warrants or options are shown in equity as a deduction, net of tax, from the proceeds.

*Movements in ordinary shares:*

	Shares	US\$'000
<b>Balance as at 1 July 2021</b>	<b>926,038,155</b>	<b>44,572</b>
Shares issued on exercise of options	152,048,619	5,237
Shares issued on vesting of performance rights	12,000,000	291
Shares issued on conversion of convertible notes	7,831,467	187
Shares issued in lieu of payments to employees	1,614,480	71
Share consolidation (a)	(989,579,021)	-
Shares issued in lieu of payments to employees post share consolidation	50,000	11
Cost of raising capital	-	(102)
Foreign exchange variance	-	(3,730)
<b>Balance as at 30 June 2022</b>	<b>110,003,700</b>	<b>46,537</b>
<b>Balance at 1 July 2022</b>	<b>110,003,700</b>	<b>46,537</b>
Shares issued from capital placements	14,433,337	2,934
Shares issued as a result of a share purchase plan	5,310,061	1,078
Shares issued in lieu of payments to employees	117,998	24
Shares issued in lieu of payments to suppliers	119,048	24
Cost of raising capital	-	(364)
Foreign exchange variance	-	(770)
<b>Balance as at 31 December 2022</b>	<b>129,984,144</b>	<b>49,463</b>

*(a) Share consolidation*

On 16 February 2022, there was a share consolidation of the issued capital of the Company on the basis of one (1) security for every ten (10) securities held. Where the consolidation resulted in a fraction of a Share, Performance Right or Option being held, the Company rounded that fraction up to the next whole number. The prior year number of shares has been adjusted for the share consolidation to ensure the numbers are comparable.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE HALF-YEARS ENDED 31 DECEMBER 2022 AND 2021**

**NOTE 8. CONTRIBUTED EQUITY (CONTINUED)**

*Terms and conditions of contributed equity*

Ordinary shares participate in dividends and the proceeds on winding up of the Company in proportion to the number of shares held. At the shareholders meetings each ordinary share is entitled to one vote when a poll is called, otherwise each shareholder has one vote on a show of hands.

**NOTE 9. RESERVES**

Reserves consisted of the following (*in thousands*):

	<b>31 Dec 2022</b>	<b>30 Jun 2022</b>
Share-based payments reserve	\$ 3,026	\$ 2,266
Foreign currency translation reserve	3,948	2,911
	<b>\$ 6,974</b>	<b>\$ 5,177</b>

*Share-based payments reserve*

The share based-payments reserve records the fair value of options and performance rights on issue.

*Foreign currency reserve*

The reserve is used to recognize exchange differences arising from the translation of the financial statements of non-United States dollar operations to United States dollars.

*Movements in reserves were as follows (in thousands):*

	<b>Share-based payments reserve</b>	<b>Foreign currency translation reserve</b>	<b>Derivative reserve</b>	<b>Total</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
<b>Balance at 1 July 2021</b>	<b>1,800</b>	<b>(3,503)</b>	<b>25</b>	<b>(1,678)</b>
Performance rights vesting expense	987	-	-	987
Options vesting expense	340	-	-	340
Performance rights converted	(291)	-	-	(291)
Performance rights expired	(395)	-	-	(395)
Transfer to retained earnings	(25)	-	-	(25)
Conversion of convertible notes	-	-	(25)	(25)
FCTR movement	(150)	6,414	-	6,264
<b>Balance at 30 June 2022</b>	<b>2,266</b>	<b>2,911</b>	<b>-</b>	<b>5,177</b>
Performance rights vesting expense	9(b) 474	-	-	474
Options vesting expense	9(a) 142	-	-	142
Options issued to brokers and consultants	9(a) 182	-	-	182
FCTR movement	(38)	1,037	-	999
<b>Balance at 31 December 2022</b>	<b>3,026</b>	<b>3,948</b>	<b>-</b>	<b>6,974</b>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE HALF-YEARS ENDED 31 DECEMBER 2022 AND 2021

NOTE 9. RESERVES (CONTINUED)

Share-based payments reserve

(a) Options issued as share based payments

Options on issue

	31 Dec 2022	
	No of Options	US\$'000
Balance at 1 July 2022	6,580,000	892
Free attaching options (1 for 3) as attaching to placement	4,811,122	-
Options issued to brokers and consultants	1,494,370	182
Options issued to Directors	1,000,000	-
Options issued to employees	1,000,000	-
Options vesting expense	-	142
Foreign exchange variance	-	(15)
<b>Closing balance at reporting date</b>	<b>14,885,492</b>	<b>1,201</b>

Employee Share Option Plan (ESOP)

The CardieX Employee Option Plan was approved by shareholders at the 2005 annual general meeting and amendments were approved at the 2006 & 2008 annual general meetings. All staff are eligible to participate in the plan at the discretion of the directors (including executive directors) following recommendations from the remuneration committee, a sub-committee of the CardieX Limited Board of Directors.

Options are granted under the plan for no consideration. Options are granted for a 5-year period, with vesting conditions over 3 years from the date of grant. Options granted under the plan carry no dividend or voting rights. When exercisable, each option is convertible into 1 ordinary share.

The exercise price of options is no less than the weighted average price at which the Company's shares are traded on the Australian Stock Exchange during the 5 trading days immediately before the options are granted.

(b) Performance rights

Performance rights on issue

	31 Dec 2022	
	No of Rights	US\$'000
Balance at 1 July 2022	16,050,000	1,374
Issued under Performance Rights Plan	6,750,000	-
Rights vesting expense during the year	-	474
Foreign exchange movement	-	(23)
<b>Balance at 31 December 2022</b>	<b>22,800,000</b>	<b>1,825</b>

NOTE 10. CONTROLLED ENTITIES

Subsidiaries

The consolidated financial statements include the financial statements of CardieX Limited and the following subsidiaries:

Name	Country of incorporation	Beneficial interest (%)*	
		31 Dec 2022	30 Jun 2022
AtCor Medical Pty Limited	Australia	100	100
AtCor Medical Inc	USA	100	100
CardieX (Shanghai) Medical Technology Co., Ltd.	China	100	100
Conneqt Inc	USA	100	100

\*Percentage of voting power is in proportion to ownership.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE HALF-YEARS ENDED 31 DECEMBER 2022 AND 2021**

**NOTE 11. EVENTS AFTER THE REPORTING PERIOD**

Subsequent to balance date the Group announced the following material events:

- On 9 February 2023, CardieX announced that it had successfully completed a placement of new fully paid ordinary shares in the Group raising A\$4.5 million at an issue price of A\$0.30 per share. As part of the placement there is a 1 for 2 free attaching unlisted option, exercisable at A\$0.50, expiring one year from the date of issue. Directors have committed to invest more than A\$0.45 million as part of this placement, which will be subject to shareholder approval at the Company's next general meeting.

No other significant subsequent event has arisen that significantly affects the operations of the Group.

**NOTE 12. OPERATING SEGMENTS**

In the interim financial period, the Group operated in one operating segment and has identified only one reportable segment being sales of cardiovascular devices and services to hospitals, clinics, research institutions and pharmaceutical companies.

Geographically, the Group prepares information based on the location of its customers, being:

- Americas (includes global pharmaceutical trials business)
- Europe (includes Middle East and Africa)
- Asia Pacific (includes Asia & Australia/NZ)

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE HALF-YEARS ENDED 31 DECEMBER 2022 AND 2021

NOTE 12. OPERATING SEGMENTS (CONTINUED)

Geographical information (in thousands):

31 December 2022	Americas	Europe	Asia Pacific	Inter-segment eliminations/ unallocated	Consolidated
	\$	\$	\$	\$	\$
Sales to external customers	683	125	83	-	891
Intersegment sales	-	-	2,752	(2,752)	-
Total sales revenue	683	125	2,835	(2,752)	891
Other income	-	-	405	-	405
Total segment revenue/income	<b>683</b>	<b>125</b>	<b>3,240</b>	<b>(2,752)</b>	<b>1,296</b>
<b>Segment (loss)/income before income tax</b>	<b>(3,642)</b>	<b>95</b>	<b>(398)</b>	<b>(1,943)</b>	<b>(5,888)</b>
Income tax expense	-	-	-	-	-
<b>(Loss)/income for the year</b>	<b>(3,642)</b>	<b>95</b>	<b>(398)</b>	<b>(1,943)</b>	<b>(5,888)</b>
Segment assets	11,130	-	53,166	(54,757)	9,539
Segment liabilities	31,235	-	40,021	(64,721)	6,535

31 December 2021	Americas	Europe	Asia Pacific	Inter-segment eliminations/ unallocated	Consolidated
	\$	\$	\$	\$	\$
Sales to external customers	1,154	250	127	-	1,531
Intersegment sales	-	-	396	(396)	-
Total sales revenue	1,154	250	523	(396)	1,531
Other income	-	-	527	-	527
Total segment revenue/income	1,154	250	1,050	(396)	2,058
<b>Segment (loss)/income before income tax</b>	<b>(2,235)</b>	<b>145</b>	<b>(2,663)</b>	<b>7</b>	<b>(4,746)</b>
Income tax expense	-	-	-	-	-
<b>(Loss)/income for the year</b>	<b>(2,235)</b>	<b>145</b>	<b>(2,663)</b>	<b>7</b>	<b>(4,746)</b>
Segment assets	9,125	-	49,826	(48,392)	10,559
Segment liabilities	24,572	-	38,487	(60,485)	2,574

*Inter-segment transfers*

Segment revenues, expenses and results include transfers between segments. The group transfer inventory and finished goods between its group companies. Such transfers are priced on an “arm’s-length” basis and are eliminated on consolidation.

*Segment revenue*

There was no significant concentration of revenue attributable to one customer in the six-months ended 31 December 2022 (2021: \$Nil).

**NOTE 13. CONTINGENT LIABILITIES AND CONTINGENT ASSETS**

The Group has no other material contingent liabilities or contingent assets as at 31 December 2022 (30 June 2022: \$Nil).

**NOTE 14. CAPITAL COMMITMENTS**

CardieX subsidiary, AtCor Medical Pty Ltd has an open purchase order to the value of \$0.3 million for microchips.

There were no other capital commitments as at 31 December 2022.



**American Depositary Shares  
representing Ordinary Shares**



**CardieX Limited**

**Prospectus**

Roth Capital Partners

, 2023

**You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information that is different from that contained in this prospectus. We are offering to sell, and seeking offers to buy, ADSs only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our securities.**

**No action is being taken in any jurisdiction outside the United States to permit a public offering of the ADSs or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable that jurisdiction.**

**Until , 2023 (the 25<sup>th</sup> day after the date of this prospectus), all dealers that buy, sell or trade in our securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.**

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**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 6. Indemnification of directors and officers**

*Australian law.* Australian law provides that a company or a related body corporate of the company may provide for indemnification of officers and directors, except to the extent of any of the following liabilities incurred as an officer or director of the company:

- a liability owed to the company or a related body corporate of the company;
- a liability for a pecuniary penalty order made under section 1317G or a compensation order under section 961M, 1317H, 1317HA, 1317HB, 1317HC or 1317HE of the Corporations Act 2001 (Cth), or Corporations Act;
- a liability that is owed to someone other than the company or a related body corporate of the company and did not arise out of conduct in good faith;
- a liability to pay a pecuniary penalty for a contravention of a provision of Part IV or Part V of the Australian Competition and Consumer Act 2010 which deal respectively with certain restrictive traded practices and carbon price reduction obligations;
- a liability to pay a pecuniary penalty for a contravention of provisions of the Australian Consumer Law dealing with:
  - unconscionable conduct;
  - unfair practices;
  - display notices;
  - unsolicited consumer agreements;
  - lay-by agreements;
  - gift cards;
  - proof of transaction and itemized bills;
  - prescribed requirements for warranties and repairers;
  - safety of consumer goods and product related services;
  - information standards;
  - substantiation notices; and
  - attempting, aiding, abetting, inducing, conspiring with others or being involved in a contravention of those provisions;

- liability to pay a pecuniary penalty for a contravention of provisions of the Australian Securities and Investments Commission Act 2001 dealing with:
  - unconscionable conduct in relation to financial services; and
  - certain consumer protection provisions in connection with financial services; or
- legal costs incurred in defending an action for a liability incurred as an officer or director of the company if the costs are incurred:
  - in defending or resisting proceedings in which the officer or director is found to have a liability for which they cannot be indemnified as set out above;
  - in defending or resisting criminal proceedings in which the officer or director is found guilty;
  - in defending or resisting proceedings brought by the Australian Securities & Investments Commission or a liquidator for a court order if the grounds for making the order are found by the court to have been established (except costs incurred in responding to actions taken by the Australian Securities & Investments Commission or a liquidator as part of an investigation before commencing proceedings for a court order); and
  - in connection with proceedings for relief to the officer or a director under the Corporations Act, in which the court denies the relief.

*Constitution.* Our Constitution provides, to the maximum extent permitted by the law, for the indemnification of every person who is or has been an officer or a director of CardieX (or a subsidiary of CardieX) against liability incurred by that person acting as an officer or director. The indemnity excludes a liability: (i) owed to CardieX or a related body corporate, (ii) for a pecuniary penalty or compensation order under certain provision of the Corporations Act, or (iii) that did not arise out of conduct in good faith. The indemnity also applies to the extent permitted by law to costs and expenses incurred by the person in defending proceedings, whether civil or criminal, in which the courts grant relief to the person under the Corporations Act.

Our Constitution also permits, to the maximum extent permitted by law, us to maintain insurance insuring a person who is or has been a director or an officer against a liability incurred by that person in that capacity (including for legal costs), unless the liability arises out of conduct on the part of the person which involves a willful breach of duty in relation to the company or arises out of a breach of directors' duties owed under the Corporations Act.

*Indemnification Agreements.* Pursuant to Deeds of Access and Indemnity, the form of which is filed as Exhibit 10.1 to this registration statement, we have agreed to indemnify our directors and officers against certain liabilities and expenses incurred by such persons in connection with claims made by reason of their being such a director or officer.

*SEC Position.* Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Pursuant to the underwriting agreement for this offering, the form of which is filed as Exhibit 1.1 to this registration statement, the underwriters will agree to indemnify our directors and officers and persons controlling us, within the meaning of the Securities Act, against certain liabilities that might arise out of or are based upon certain information furnished to us by any such underwriter.

## Item 7. Recent sales of unregistered securities

In the past three years, we have issued and sold to third parties the securities listed below without registering the securities under the Securities Act of 1933, as amended. None of these transactions involved any public offering. All our securities were sold through private placement either (i) outside the United States or (ii) in the United States to a limited number of investors in transactions not involving any public offering. As discussed below, we believe that each issuance of these securities was exempt from, or not subject to, registration under the Securities Act.

- In June 2023, we commenced an offshore offering of convertible notes (“Notes”) pursuant to a convertible note facility (“Note Facility”). We are seeking to raise up to A\$4.1 million (US\$2.7 million) under the Note Facility, through the issue of up to 4,100,000 Notes. Each Note will have a face value of A\$1.00 (US\$0.66) and maturity date of July 15, 2025. Each of C2 Ventures Pty Ltd, Carnethy Evergreen Pty Ltd, and Jarrod White (or his nominee) are proposing to participate in the Note Facility. The issue of Notes to each of C2 Ventures Pty Ltd, Carnethy Evergreen Pty Ltd, and Jarrod White (or his nominee) is subject to shareholder approval, which is to be sought at the next general meeting of shareholders of the Company.
- On February 16, 2023, we issued options to purchase 1,415,318 ordinary shares at an exercise price of A\$0.45 to MST Financial Services Pty Ltd as part consideration for acting as lead manager to the placement conducted in February 2023.
- On February 16 and 17, 2023, we issued 13,481,377 ordinary shares at A\$0.30 per share for an aggregate offering price of A\$4,044,413.10, together with 6,740,689 options at an exercise price of A\$0.50 per share, to a number of domestic institutions, family offices and sophisticated investors.
- On December 16, 2022, we issued 3,000,000 ordinary shares at A\$0.30 per share for an aggregate offering price of A\$900,000, together with 1,000,000 options at an exercise price of \$0.45 per share, to C2 Ventures Pty Limited approved at the Annual General Meeting of shareholders held on November 30, 2022.
- On December 16, 2022, we issued 334,331 ordinary shares at A\$0.30 per share for an aggregate offering price of A\$100,299.30, together with 111,444 options at an exercise price of A\$0.45 per share, to Traverse Accountants Pty Ltd approved at the Annual General Meeting of shareholders held on November 30, 2022.
- On December 16, 2022, we issued options to purchase 1,244,370 ordinary shares at an exercise price of A\$0.45 to MST Financial Services Pty Ltd as part consideration for acting as lead manager to the placement conducted in August 2022 approved at the Annual General Meeting of shareholders held on November 30, 2022.
- On December 16, 2022, we issued options to purchase 250,000 ordinary shares at an exercise price of A\$0.45 to Neddih Pty Ltd for consulting services rendered in relation to the placement conducted in August 2022 approved at the Annual General Meeting of shareholders held on November 30, 2022.
- On December 16, 2022, we issued options to purchase 500,000 ordinary shares at an exercise price of A\$0.50 to Randall King Nelson as remuneration for services as a non-executive director of CardieX approved at the Annual General Meeting of shareholders held on November 30, 2022.
- On December 16, 2022, we issued options to purchase 350,000 ordinary shares at an exercise price of A\$0.50 to Lesa Musatto as remuneration for services as a non-executive director of CardieX approved at the Annual General Meeting of shareholders held on November 30, 2022.
- On December 16, 2022, we issued options to purchase 150,000 ordinary shares at an exercise price of A\$0.50 to Lesa Musatto in lieu of a cash payment of A\$15,000 for services approved at the Annual General Meeting of shareholders held on November 30, 2022.
- On December 16, 2022, we issued 117,998 ordinary shares, at a deemed issue price of A\$0.30 per share, to Traverse Accountants Pty Ltd in lieu of a cash payment of A\$35,000 for services approved at the Annual General Meeting of shareholders held on November 30, 2022.
- On October 28, 2022, we issued 119,048 ordinary shares, at a deemed issue price of A\$0.30 per share, to Integrous Communications in lieu of a cash payment for US\$25,000 for services.
- On September 29, 2022, we issued 5,310,061 ordinary shares at A\$0.30 per share for an aggregate offering price of A\$1,593,018.30 to our shareholders with Australian and New Zealand addresses pursuant to the terms of a share purchase plan dated 26 August 2022.
- On August 29, 2022, we issued 11,099,006 ordinary shares at A\$0.30 per share for an aggregate offering price of A\$3,329,701.80, together with 3,699,678 options at an exercise price of A\$0.45 per share, to a number of domestic institutions, family offices and sophisticated investors.

- On June 30, 2022, we issued 50,000 ordinary shares, at a deemed issue price of \$0.31 per share, to an employee in lieu of a cash payment of A\$15,500 for services.
- On February 28, 2022, we completed a consolidation of all of our issued securities on a 1 for 10 basis as outlined to ASX on January 14, 2022 approved at the General Meeting of shareholders held on February 16, 2022.
- On January 13, 2022, we issued 51,021 ordinary shares, at a deemed issue price of \$0.686 per share, to Traverse Accountants Pty Ltd in lieu of a cash payment of A\$35,000 for services approved at the Annual General Meeting of shareholders held on December 16, 2021.
- On November 30, 2021, we issued 783,147 ordinary shares, at a deemed issue price of \$0.30 per share, to C2 Ventures Pty Limited pursuant to the exercise of 234,944 convertible notes approved at the General Meeting of shareholders held on February 26, 2019.
- On September 20, 2021, we issued 110,428 ordinary shares, at a deemed issue price of \$0.62 per share, to an employee in lieu of a cash payment of A\$68,465 for services.
- On January 12, 2021, we issued 6,414,000 ordinary shares at A\$0.50 per share for an aggregate offering price of A\$3,207,000 to our shareholders with Australian and New Zealand addresses pursuant to the terms of a share purchase plan dated December 7, 2020.
- On December 21, 2020, we issued 1,768,182 ordinary shares at A\$0.275 per share for an aggregate offering price of A\$468,250, together with 4,420,455 options at an exercise price of \$0.05 per share, to C2 Ventures Pty Limited approved at the Annual General Meeting of shareholders held on December 11, 2020.
- On December 21, 2020, we issued 100,000 ordinary shares, at a deemed issue price of \$0.50 per share, to an employee in lieu of a cash payment of A\$50,000 for services approved at the Annual General Meeting of shareholders held on December 11, 2020.
- On December 21, 2020, we issued 100,000 ordinary shares, at a deemed issue price of \$0.30 per share, to Traverse Accountants Pty Ltd. in lieu of a cash payment of A\$30,000 for services approved at the Annual General Meeting of shareholders held on December 11, 2020.
- On August 3, 2020, we issued 8,333,334 ordinary shares at A\$0.30 per share for an aggregate offering price of A\$2,500,000, together with 1,666,667 options at an exercise price of \$0.50 per share, to a number of sophisticated and professional investors.
- On July 2, 2020, we issued 115,881 ordinary shares, at a deemed issue price of \$0.23 per share, to an employee in lieu of a cash payment of A\$26,652 for services.

In addition, we granted the following options and performance rights to certain of our officers, directors, employees and consultants under our Performance Rights and Option Plan:

- options to purchase 1,000,000 ordinary shares at an exercise price of A\$0.50 in the period from July 1, 2022 through the date of this prospectus;
- performance rights to acquire 6,750,000 ordinary shares, subject to the satisfaction of certain vesting conditions, in the period from July 1, 2022 through the date of this prospectus;
- options to purchase 1,300,000 ordinary shares at an exercise price of A\$0.80 in FY2022;
- no performance rights to acquire ordinary shares in FY2022;

- options to purchase 3,450,000 ordinary shares at exercise prices ranging from A\$0.50 to A\$0.80 in FY2021;
- performance rights to acquire 16,050,000 ordinary shares, subject to the satisfaction of certain vesting conditions, in FY2021;
- no options to acquire ordinary shares in FY2020; and
- no performance rights to acquire ordinary shares in FY2020.

In addition, we issued the following ordinary shares upon exercise of options:

- no ordinary shares from July 1, 2022 through the date of this prospectus;
- 15,204,862 ordinary shares at an exercise price of A\$0.50 per share in FY2022;
- 451,492 ordinary shares at exercise prices ranging from A\$0.33 to A\$0.50 per share in FY2021; and
- no ordinary shares in FY2020.

In addition, we issued the following ordinary shares upon vesting and conversion of performance rights:

- no ordinary shares from July 1, 2022 through the date of this prospectus;
- 1,200,000 ordinary shares in FY2022;
- no ordinary shares in FY2021; and
- no ordinary shares in FY2020.

We believe that the issuance of these securities were exempt from registration under the Securities Act in reliance upon (i) Regulation S of the Securities Act as transactions not made to persons in the United States with no directed selling efforts made in the United States, or (ii) Rule 701 of the Securities Act as transactions pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701 or (iii) to U.S. persons pursuant to Section 4(a)(2) of the Securities Act in that such sales and issuances did not involve a public offering. No underwriters were employed in connection with the foregoing option grants and restricted stock unit awards.

#### **Item 8. Exhibits and financial statement schedules**

##### *(a) Exhibits*

See exhibit index of this registration statement.

##### *(b) Financial statement schedules*

All schedules have been omitted because the information required to be presented in them is not applicable or is shown in the consolidated financial statements or related notes.

#### **Item 9. Undertakings**

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales of the registered securities are being made, a post-effective amendment to this registration statement:
  - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
  - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;
  - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) to this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the Registration Statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the Registration Statement.
- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) To file a post-effective amendment to the registration statement to include any financial statements required by Item 8.A. of Form 20-F at the start of any delayed offering or throughout a continuous offering. Financial statements and information otherwise required by Section 10(a)(3) of the Act need not be furnished, provided that the registrant includes in the prospectus, by means of a post-effective amendment, financial statements required pursuant to this paragraph (a)(4) and other information necessary to ensure that all other information in the prospectus is at least as current as the date of those financial statements. Notwithstanding the foregoing, a post-effective amendment need not be filed to include financial statements and information required by Section 10(a)(3) of the Act or Item 8.A. of Form 20-F if such financial statements and information are contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.
- (5) That, for the purpose of determining liability under the Securities Act to any purchaser:

- (i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
  - (ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such Securities at that time shall be deemed to be the initial bona fide offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.
- (6) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
  - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
  - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
  - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.