



CURVEBEAM AI INVESTOR DECK (ASX:CVB)

July 2026

Not for release to US wire services or distribution in the United States



DISCLAIMER

THIS PRESENTATION IS NOT FOR RELEASE TO U.S. WIRE SERVICES OR IN ANY OTHER JURISDICTION WHERE SUCH RELEASE, PUBLICATION OR DISTRIBUTION IS UNLAWFUL. THIS DOCUMENT IS NOT, AND DOES NOT CONSTITUTE, AN OFFER OR INVITATION TO SUBSCRIBE FOR, BUY OR SELL SECURITIES IN ANY JURISDICTION. BY ACCEPTING, ACCESSING OR REVIEWING THIS PRESENTATION, YOU ACKNOWLEDGE AND AGREE TO THE TERMS SET OUT BELOW.

This presentation has been prepared by CurveBeam AI Limited (ACN 140 706 618) (**CurveBeam** or the **Company**) and contains summary information about CurveBeam and the business conducted by it as of 8th July 2026. The information in this presentation is for informational purposes only, does not purport to be complete and is not a prospectus, product disclosure statement or other offering document for the purposes of Chapter 6D or Part 7.9 of the Corporations Act 2001 (Cth) (**Act**) or the law of any other jurisdiction. It should be read in conjunction with CurveBeam's other periodic and continuous disclosure announcements, including its full year results for the period ended 30 June 2025, and half year results for the period ended December 31st 2025, respectively, lodged with the ASX on 28 August 2025 and 28 February 2026, available from the Australian Securities Exchange ("ASX") at www.asx.com.au.

As further detailed below, none of CurveBeam, nor its advisers (**Advisers**) nor their respective affiliates, related bodies corporate (as defined in the Act) or security holders and their respective directors, officers, employees, partners, representatives, consultants, agents or advisers (each a **Limited Party** and together, the **Limited Parties**) guarantees, recommends, or makes any representation or warranty to, or takes responsibility for, the accuracy, reliability or completeness of the information contained in this presentation or the Company's securities, including, without limitation, any liability arising from fault or negligence, for any loss arising from the use of or reliance on any of the information contained in this presentation or otherwise arising in connection with it. To the maximum extent permitted by law, each Limited Party disclaims any liability for any loss arising from the use of or reliance on such information including as to the accuracy or completeness of the information, statements, opinions or matters, express or implied, contained in, arising out of or derived from, or for omissions from, this presentation.

Not an offer or financial product advice

The information contained in this presentation is for informational purposes only and should not be considered, and does not contain or purport to contain, an offer, invitation, solicitation or recommendation with respect to the subscription, purchase or sale of any securities in CurveBeam nor does it constitute legal, taxation, financial product or investment advice. The general information in this presentation has been prepared without taking into account the investment objectives, financial situation or particular needs of any particular person. Recipients of the presentation must undertake their own independent investigations, consideration and evaluation. Neither this presentation nor any of its contents will form the basis of any contract or commitment and it is not intended to induce or solicit any person to engage in any transaction nor is it intended to be used as the basis for making an investment decision. CurveBeam recommends that potential investors consult their professional advisors as an investment in CurveBeam is subject to investment and other known and unknown risks, some of which are beyond the control of CurveBeam or its directors and therefore any investment is considered to be speculative in nature.

Forward looking statements

The information given in this presentation is given for illustrative purposes only and should not be relied upon as (and is not) an indication of CurveBeam's views on future performance or condition. Past performance cannot be relied upon as an indicator of future performance. This presentation contains certain forward-looking statements. The words "forecast", "estimate", "like", "anticipate", "opinion", "should", "could", "may" and other similar expressions are intended to identify future earnings, financial position and performance of CurveBeam. You are cautioned not to place undue reliance on these statements. These forward-looking statements are based on estimates, projections and assumptions made by CurveBeam about circumstances and events that have not yet taken place. Although due care and attention has been used in the preparation of these statements, such forward-looking statements are based on numerous assumptions regarding CurveBeam's present and future business strategies and the political, regulatory and economic environment in which CurveBeam will operate in the future and are subject to change without notice. Statements about market and industry trends, which are based on interpretations of current market conditions, may not be reasonable, and are not guarantees or predictions of future performance.

The actual results or performance of CurveBeam may be materially different from the results or performance expressed or implied by such forward-looking statements. No representation, warranty or assurance (express or implied) is given or made in relation to any forward-looking statement by any person (including any of the Limited Parties). No representation, warranty or assurance (express or implied) is given that the occurrence of the events expressed or implied in any forward-looking statement in this presentation will actually occur. Subject to any continuing obligations under applicable law, the Company expressly disclaims any obligation or undertaking to provide any updates or revisions to any forward-looking statements in this presentation to reflect any change in expectations in relation to any forward-looking statement or any change in events, conditions or circumstances on which any statement is based.

International Offer Restrictions

The distribution of this Presentation in jurisdictions outside Australia restricted by law and you should observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of applicable securities laws. In particular this Presentation may not be released to U.S. wire services. New Shares have not been, and will not be, registered under the U.S. Securities Act of 1933, as amended ("**U.S. Securities Act**"), or the securities laws of any state or other jurisdiction of the United States, and may not be offered or sold in the United States, unless they have been registered under the U.S. Securities Act or are offered or sold in a transaction exempt from, or not subject to, the registration requirements of the U.S. Securities Act and any other applicable U.S. state securities laws. The New Shares may be offered and sold in the United States only to accredited investors within the meaning of Rule 501(a) under the US Securities Act.

See also the section captioned "International Offer Restrictions" near the end of this presentation.

COMPANY HIGHLIGHTS

Combining Weight Bearing CT (WBCT) imaging equipment with AI solutions to target faster, more efficient point of care clinical assessment to aid in orthopedic restoration of function & bone health



- **FDA cleared | TGA & CE mark | NMPA (target Q4 26)**
 - U.S. & German reimbursement in place¹

- **200+ weight bearing CT (WBCT) globally**

- **USA co-Marketing & Distribution Agreement with Stryker Corp. Foot & Ankle (NYSE:SYK)**



- **Chinese Investor/partner/Manufacturer/Distributor Wego Orthopedics**



- **US sites: Mayo (3), Harvard, Penn, Duke, HSS**



- **37 granted patents | 27 pending patents**

1. <https://pubmed.ncbi.nlm.nih.gov/37921528/> - Nearly All Peer-to-Peer Reviews for CT and MRI Prior Authorization Denials for Orthopedic Specialists Are Approved



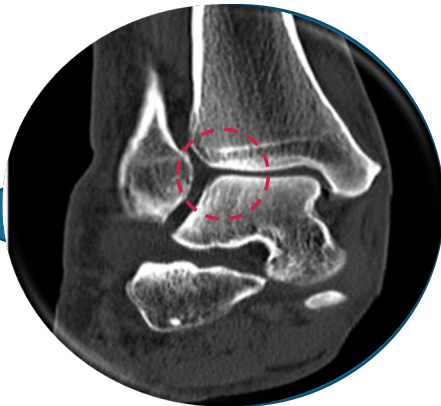
THE PROBLEM

Traditional CT Scans don't show the joint under its natural weight

Traditional CT Scan
(i.e. non-weight bearing)



TRADITIONAL CT
SCANNER



Additional Challenges:

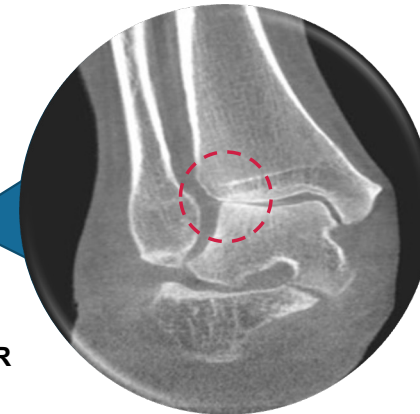
- ✗ Can be large and bulky pieces of equipment
- ✗ Requires referral out for scans, multiple visits
- ✗ Requires specialized technologist
- ✗ Requires requires advanced infrastructure, i.e. HVAC, control room, high voltage power

THE SOLUTION

HiRise™ CT Scan
(i.e. weight bearing & non-weight bearing)



HIRISE™ SCANNER



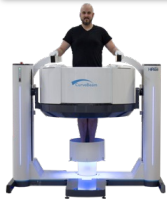
Additional Benefits:

- ✓ Small enough to fit in a group surgeons' practice
- ✓ Provides images under a person's own body weight
- ✓ Can be run by X-ray staff, lower patient radiation dose per scan
- ✓ Improves surgeon patient workflow

PRODUCT PORTFOLIO

Lead Product

HiRise™ CT Scan
(i.e. weight bearing & non-weight bearing)



- FDA cleared | CE Mark | TGA
- Foot, ankle, hip, knee, joint replacement, full leg scan and upper extremity

pedCAT®
(i.e. weight bearing)



- FDA cleared
- Foot and ankle

InReach®



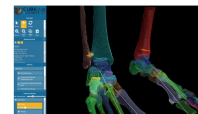
- FDA cleared | CE Mark | TGA
- Extremity cone beam CT imaging for the hand, wrist, forearm, elbow and distal lower extremities

CubeVue®



- FDA cleared
- Advanced visualization tools to enhance dataset analysis

AI Autometrics®



- Investigational use
- Automatically segments foot and ankle datasets

HIRISE™

A Weight Bearing Specialized CT Scanner



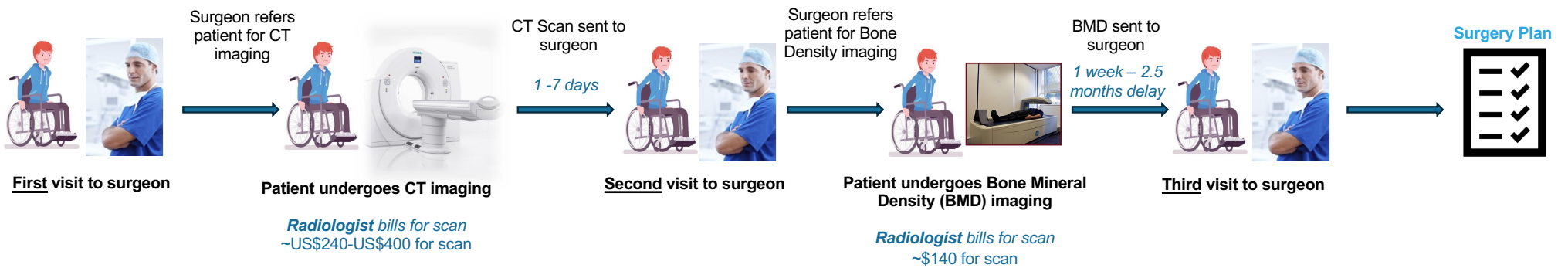
HiRise™ lets doctors image a patient's bones and joints under normal standing load (not just lying down).

This gives more accurate joint alignment & pathology information, particularly useful in orthopedics, compared with traditional CT/MRI setups

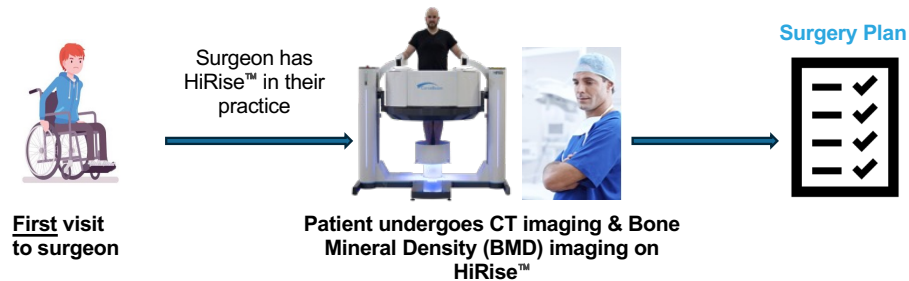
WORKFLOW FOR SURGEONS

Quicker Time to Surgery and New Revenue Stream for the Surgeon

Recommended US/European Workflow for Total Joint Replacement (TJR) – 3 PATIENT VISITS



US/European Workflow for TJR with HiRise™ - 1 PATIENT VISIT



Surgeon targeted average bill for scans
~US\$240-\$500 for CT scan
&
~US\$140 for BMD scan

Summary for typical TJR	Typical	With HiRise™
Patient Visits to Surgeon	3	1
CT Revenue to Radiologist	~US\$250	~US\$60
CT Revenue to Surgeon	\$0	~US\$190

Surgeons are incentivised to adopt HiRise™

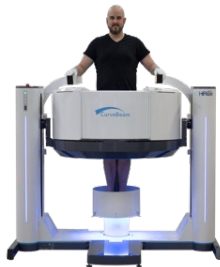
BUSINESS MODEL

U.S. Reimbursement in place

1x Sale

Capital Equipment
HiRise™

- USD\$410k - \$465k per unit¹ (A\$585K – A\$664K)
- Target customers: group surgeon practices and hospitals
- 77 units sold (49 in the U.S.)



Recurring revenue opportunity

Bone Mineral Density (“BMD”) Testing
SaaS Model

- Expand BMD testing capability into the surgeon group practice setting
- New SaaS revenue stream from HiRise placements
- Targeting an annuity of ~US\$225K per unit (A\$320K per unit)
- BMD MDCT FDA clearance anticipated H2 2026 followed by HiRise clearance anticipated Q1 2027



1. Depending if an extended warranty is purchased

Expansion into SaaS Business Model

Targeted Bone Mineral Density (BMD) SaaS Business Model

- Each HiRise in knee & Hip TJR targeting 10 BMD reports per day (5-day week, 50-week year)
- Surgeon reimbursement ~US\$140 (\$100 to \$180) per BMD report (avg. private/Medicare)
- CurveBeam AI targets a charge to surgeon of US\$90 (~A\$140) per SaaS report
- Ten BMD reports/day - **100 USA HiRise in Group Surgeon offices – circa US\$22.5m revenue (A\$32m; or A\$320K per unit)**
- Targeting payment under **CPT code 77078** – CT, BMD study, under **NCD 150.3 (Medicare)**

Complementing our capital equipment business with a long-term recurring SaaS revenue business model



PURCHASE ORDERS

Fiscal Year Period Ending June 30

	FY24	FY25	FY26	Total
HiRise	16	6	2	24
HiRise v2	0	10	11	21
pedCAT	3	3	0	6
InReach	0	3	1	4
LineUP	3	4	2	9
Total	22	26	16	64

	FY24	FY25	FY26	Total
Q1 (9/30)	3	3	4	10
Q2 (12/31)	4	10	5	19
Q3 (3/31)	5	7	5	17
Q4 (6/30)	10	6	2	18
Total	22	26	16	64

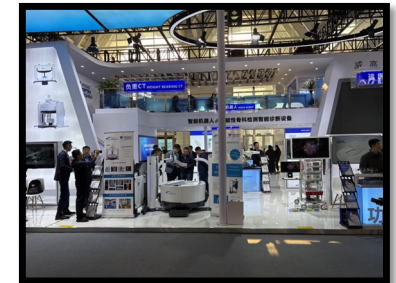


GLOBAL GROWTH STRATEGY

Successful placement of HiRise™ devices four continents



GREATER CHINA
Recently announced partnership with WEGO
1 HiRise™ Placement



Japan /ASIA
4 Distributors

MENA
1 Distributor

AUSTRALIA
Corporate Office HQ
SE ASIA Mgt
Direct sales
2 HiRise™ Placements
stryker

SOUTH AMERICA
2 Distributors

NORTH AMERICA
Operations HQ (Penn.)
4 FTE Sales reps
Marketing Team
Partner Management (Stryker)
50 HiRise™ & 56 Pedcat Placements
stryker



Over 70+ HiRise™ placements globally



STRYKER PARTNERSHIP

Partnership with Stryker Foot and Ankle (F&A)

EXISTING OPPORTUNITY

~500 Stryker Reps / 40 Regional Managers

- Selling in the U.S. & Australia/NZ
- Access to ~17,000 potential U.S. installation sites
- Stryker sells HiRise™ for ~US\$460,000 (extended warranty)
- CVB transfers HiRise™ for ~US\$360,000
- US Cat 1 CPT Code & NCD in place – pre-authorizations

Validated with Stryker's Prophecy

- HiRise™ CT is already validated for Prophecy patient specific total ankle cut guides
- Stryker F&A sells the Prophecy – to date used in 65,000+¹ cases and counting

1. WWW.STRYKER.COM/US/EN/FOOT-AND-ANKLE/PRODUCTS/PROPHECY.HTML

2. KURTZ ET AL (2007). PROJECTIONS OF PRIMARY & REVISION HIP & KNEE ARTHROPLASTY IN THE US FROM 2005 TO 2030. JBJS 89(4), 780-785

12 3. [HTTPS://WWW.BORDERLESS.NET/NEWS/LIFE-SCIENCES/STRYKER-STARTS-LIMITED-RELEASE-OF-MAKO-RPS-HANDHELD-KNEE-ROBOT/](https://www.borderless.net/news/life-sciences/stryker-starts-limited-release-of-mako-rps-handheld-knee-robot/)



NEXT OPPORTUNITY

Validation with Stryker's Robot

- We are working with Stryker to validate the use of HiRise™ CT in conjunction with its market leading robotic TKA and THA device.
- Uses CT scans for 3D preplanning for cut guides
- HiRise™ validation with the Stryker robot would create a unique ecosystem that could improve practice workflow & revenue.
- HiRise™ primary target (US Knee & Hip – 2030 projection 4m total joint cases/year)²
- **In 2026 an estimated 3,000 Stryker robots placed globally³ – US estimate of 2,000+**



GREATER CHINA MARKET OPPORTUNITY

Chinese Partner Opens up China, SE ASIA and Large Addressable Market



Further Milestone Payments

\$10m equity investment by CVB's Asia licensing partner

Agreed valuation @ \$0.405 per share

A\$4M already received

Up to A\$6M in further milestone payments to CVB

✓ China NMPA approval for HiRise™

\$1m investment

✓ Wego first 10 HiRise™ orders

\$1m investment & Circa sales of A\$4.3m

✓ Wego next 40 HiRise™ orders (50 total)


\$2m investment & Circa sales of A\$17.6m

✓ NMPA China Produced HiRise™ & SkyRise™

\$1m investment & \$1m investment

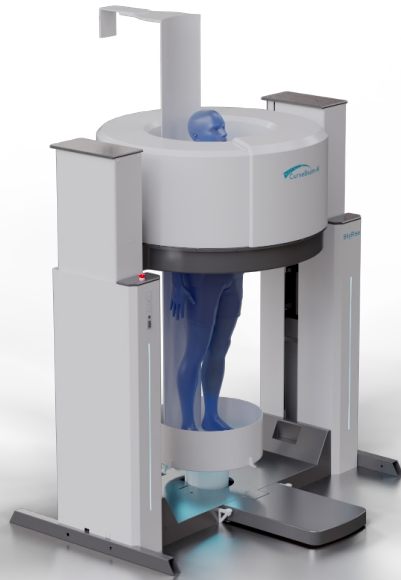
NEAR TERM TARGETED MILESTONES

A number of near-term value-driving operational and commercial milestones

1	First \$4m License Payment received from China Partner	Q1 CY26 
2	Chinese FDA (NMPA) approval for US manufactured HiRise™ & further \$1m Wego Equity Investment	Q4 CY26
3	Chinese Wego order - 10 US manufactured HiRise™ (circa \$4.3m sales) & further \$1m Wego Equity Investment	Q4 CY26
4	Bone Mineral Density MDCT (BMD) CT FDA clearance	H2 CY26
5	Chinese Wego order – next 40 US manufactured HiRise™ totalling 50 (circa an additional \$17.6m sales) & further \$2m Wego Equity Investment	H1 CY27
6	HiRise™ cut guides validated across multiple robotic surgical platforms	Various

NEXT GENERATION WBCT SCANNER IN DEVELOPMENT

SKYRISE™



Entire body CT Scan – covers spine & shoulder

Entire CT Scan under natural body weight

Small enough for surgeon practices

First prototype targeting December 2026

Developing with Strategic partner - WEGO

SKYRISE™
Next Generation
Capability

COMPETITION

Lacking a one size fits all approach

- Size of competitor devices not conducive to surgeon setting
- Many still are limited by multi detector computed tomography (MDCT) and the high-level radiation scans

Compact but non-natural weight bearing



PlanMed Verity

Example of Large CT Scanners



Canon Aquilion RISE



SinoVision



PlanMed XFI



Angel WR

✘ Requires shielded room & CT Technologists to perform scan

✘ Cone Beam CT limited by height restrictions, no dual lying down (non-weight bearing) option

BOARD OF DIRECTORS

Experienced and personally invested Board



ROBERT LILLEY

Non-Executive Chairman,
BA (Yale)

- 35 years' experience in medical device and diagnostics industry. Previously senior vice president of global sales and marketing, Digene Corporation (Nasdaq:DIGE), a molecular diagnostics company, which was subsequently acquired by Qiagen N.V. (NYSE:QGEN)
- Currently Chair of Immunexpress Pty Ltd, an Australian molecular diagnostics company



GREGORY BROWN

Chief Executive Officer,
B.app.Sc, MBA

- 35 years healthcare experience
- Previously Baxter Diagnostics (Australia & UK), Roche Molecular (Switzerland/New York), Digene Corp (Washington DC/Germany)
- 2006-2012 ImpediMed CEO (IPD:ASX)
- 2014 – 2022 StraxCorp (Chairman & CEO)
- Board experience: Trinity Biotech (NASDAQ), Immunexpress (IXP), IPD(ASX), UniQuest (UQ)



PATRICK FISHER

Non-Executive Director
B. of Arts, MBA

- Orthofix President of Global Biologics & Limb Reconstruction.
- Mr. Fisher previously served as Vice President and General Manager of the Foot & Ankle business unit with Stryker.
- Served as the President of Lower Extremity & Biologics for Wright Medical Technology, which was acquired by Stryker in 2020.
- He joined Wright Medical in 2002 and held multiple roles including Vice President of U.S. Sales.
- Expertise spans global marketing, R&D, sales, clinical research & medical education, with a focus on integrity, ethics, & compliance.



ARUN SINGH

Executive Director, COO, CTO-
CT, US president

BSc & Masters Degree in
Electrical Engineering

- Founder, President and CEO of CurveBeam LLC
- Led the development of the first commercially viable Cone Beam CT imaging system for dental and maxillofacial imaging, with 9,000+ systems deployed today globally
- Awarded Lifetime Achievement Award by the AADMRT in 2016 for his visionary contributions to the advancement of cone beam CT



HASHAN DE SILVA

Non-Executive Director

BSc (Medicine), MCom, CFA
charter holder

- Founder and Managing Partner of KP Rx, a specialist healthcare fund manager
- Previously head of healthcare research at Karst Peak Capital, equity research analyst in healthcare at CLSA Limited and Senior Research Associate Analyst at Macquarie Group
- Director Pharmaxis Limited (ASX:PXS)

CAPITAL RAISING SUMMARY

Sources and use of funds

Use of Funds	A\$m
Sales & Marketing incl. China market launch prep	\$2.1m
R&D costs incl. product enhancements for HiRise™	\$2.3m
Supply Chain Costs incl. preparing for China market launch	\$0.4m
General Working capital purposes in capital raising fees	\$0.2m
Total Uses¹	\$5.0m

Sources	A\$m
Cash Balance as at 30 June 2026	\$1.6m
Offer proceeds	\$5.0m
Total Sources¹	\$6.6m

INTERNATIONAL OFFER RESTRICTIONS

International Offer Restrictions

This document does not constitute an offer of new ordinary shares (“New Shares”) of the Company in any jurisdiction in which it would be unlawful. In particular, this document may not be distributed to any person, and the New Shares may not be offered or sold, in any country outside Australia except to the extent permitted below.

Hong Kong

WARNING: This document has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong (the “SFO”). Accordingly, this document may not be distributed, and the New Shares may not be offered or sold, in Hong Kong other than to “professional investors” (as defined in the SFO and any rules made under that ordinance).

No advertisement, invitation or document relating to the New Shares has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that 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 New Shares that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted New Shares may sell, or offer to sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities.

The contents of this document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the offer. If you are in doubt about any contents of this document, you should obtain independent professional advice.

New Zealand

This document has not been registered, filed with or approved by any New Zealand regulatory authority under the Financial Markets Conduct Act 2013 (the “FMC Act”).

The New Shares are not being offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) other than to a person who:

- is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;
- meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;
- is large within the meaning of clause 39 of Schedule 1 of the FMC Act;
- is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or
- is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

Singapore

This document and any other materials relating to the New Shares have not been, and will not be, lodged or registered as a prospectus in Singapore with the Monetary Authority of Singapore. Accordingly, this document and any other document or materials in connection with the offer or sale, or invitation for subscription or purchase, of New Shares, may not be issued, circulated or distributed, nor may the New Shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore except

pursuant to and in accordance with exemptions in Subdivision (4) Division 1, Part 13 of the Securities and Futures Act 2001 of Singapore (the “SFA”) or another exemption under the SFA.

This document has been given to you on the basis that you are an “institutional investor” or an “accredited investor” (as such terms are defined in the SFA). If you are not such an investor, please return this document immediately. You may not forward or circulate this document to any other person in Singapore.

Any offer is not made to you with a view to the New Shares being subsequently offered for sale to any other party in Singapore. On-sale restrictions in Singapore may be applicable to investors who acquire New Shares. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.

United Kingdom

Neither this document nor any other document relating to the offer has been delivered for approval to the Financial Conduct Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended (“FSMA”)) has been published or is intended to be published in respect of the New Shares.

The New Shares may not be offered or sold in the United Kingdom by means of this document or any other document, except in circumstances that do not require the publication of a prospectus under section 86(1) of the FSMA. This document is issued on a confidential basis in the United Kingdom to “qualified investors” within the meaning of Article 2(e) of the UK Prospectus Regulation. This document may not be distributed or reproduced, in whole or in part, nor may its contents be disclosed by recipients, to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of the FSMA) received in connection with the issue or sale of the New Shares has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of the FSMA does not apply to the Company.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 (“FPO”), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (“relevant persons”). The investment to which this document relates is available only to relevant persons. Any person who is not a relevant person should not act or rely on this document.

Germany

This document has not been, and will not be, registered with or approved by any securities regulator in Germany or elsewhere in the European Union. Accordingly, this document may not be made available, nor may the New Shares be offered for sale, in Germany except in circumstances that do not require a prospectus under Article 1(4) of Regulation (EU) 2017/1129 of the European Parliament and the Council of the European Union (the “Prospectus Regulation”).

In accordance with Article 1(4)(a) of the Prospectus Regulation, an offer of New Shares in Germany is limited to persons who are “qualified investors” (as defined in Article 2(e) of the Prospectus Regulation).



RISK FACTORS

The following is a summary of the material business risks of the Group (which are not listed in order of importance or likelihood). These risks may adversely impact on the Group's financial and operating performance and prospects. Additional business risks can be found in the Group's Annual Reports. Risks include, but are not limited to:

- The Group will require, and intends to apply for, further regulatory clearances in key jurisdictions (e.g. USA FDA), as well as internal validation with key vendors, to execute its business plan. If current trials or applications are unsuccessful (e.g. HiRise™ MAKO validation through Stryker, HiRise™ Chinese NMPA), the Group might need to lodge a subsequent request with the regulators, which could extend the clearance process by 6 to 24 months. Regulatory clearance processes are expensive, time consuming and have uncertain outcomes. No assurance can be given that the Group will obtain all clearances or targeted claims and that such clearances will not be subject to significant limitations.
- The Group's existing cleared products and future cleared products will be subject to continual review and periodic inspections by regulatory agencies. Potentially costly follow-ups or post-marketing clinical studies may be required, and previously unknown problems may result in restrictions on the sale and marketing, and possibly the withdrawal from sale of previously cleared products. If the Group fails to comply with applicable regulatory requirements, relevant regulatory agencies may take a range of actions against the Group.
- The commercial success of the Group's products and services is critically dependent on the availability (coding and coverage policy) and amounts of available reimbursement (payment). Without reimbursement, or an adequate level of reimbursement, there is little to no incentive for medical providers (and their patients) to use the Group's products and services. The Company believes that it has a favorable coding and coverage policy reimbursement position for its current, cleared CT products in the U.S. and Germany. In the USA, Prior Authorization is becoming another layer of approval needed for use of CT and payment. Current coverage policies do not always guarantee future payment or payment at the current levels and future coverage may require additional clinical trials. Reimbursement coverage for OssView will require a clinical trial to validate its benefits in the future and the Group may also need to implement a specific reimbursement strategy related to its clinical assessment SaaS modules (which can be a lengthy process). No assurance can be given that reimbursement will be provided at all, or that the reimbursement will be adequate for the Group's products and tools.
- An important aspect of the Group's business is to continue to invest in innovation and related product development opportunities. CT product and software development as well as integration into third party products is expensive and inherently risky. Products and solutions in development may not meet design objectives or be successful in either pre- or post-clinical testing. It often takes many years to develop medical software and CT devices to a point where there is a saleable product for diagnostic, economic, technical and/or regulatory reasons. Accordingly, even when such work is successful, it can be many years before the Group earns a return on its investment.
- Sales of the Group's products and services depends on the extent to which they are accepted by the market and the level of competitor activity. There is a risk that the Group's existing devices, and next generation devices, and future products may not gain targeted levels of market acceptance.
- The Group's long-term revenue and profit growth is dependent on the utilization of its SaaS based clinical assessment aids. It may be difficult to persuade some customers to change existing legacy on premises and manual solutions and adopt SaaS-based clinical assessment solutions like the Group's products.
- The Group may need to raise additional funds in the future to support its operations and business. The Group may elect to raise additional funds through the issuance of new equity securities, debt, or a combination of both. Additional financing may not be available on favorable terms, or at all, and such financing may be dilutive to Shareholders.