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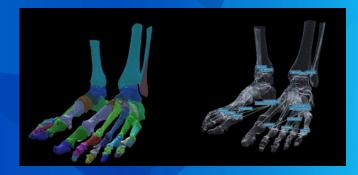
#### Financial information

All numbers in this presentation are stated in Australian dollars (A\$) unless stated otherwise.





# INVESTMENT



Deep Learning AI for automated bone segmentation, separation, measurement

# CurveBeam AI is a medical device company focused on commercialising weight bearing CT scanners

First to Market

- First to market natural bilateral weight bearing CT scanners
- HiRise CT provides in-office high-resolution 3D scans with Al aided clinical assessment (subject to regulatory clearance)

**Large TAM** 

- Large A\$10b for device sales plus A\$2.7b for BMD screening per annum addressable markets
- A\$11.5 million revenue in FY23

Regulatory Clearance

- FDA cleared & TGA listed, CE marked CT imaging equipment
- Targeting regulatory submissions for Deep Learning AI & AI aided clinical assessment support

Favourable Revenue Model

 Favourable revenue model with upfront sales followed by targeted high margin annuity streams

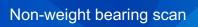
**Global Distribution** 

- Over 170 generation 1 & 2 scanners placed globally
- Users include key hospitals such as Mayo, Penn, Duke & HSS
- Top tier US distributor (Stryker Corp. mkt cap: ~US\$136b)



# CURVEBEAM AI OVERVIEW







T

Weight bearing scan

# **Background**

- A joint not under its natural weight can look normal, yet the pain is real
- Natural bilateral weight bearing helps to show what is really going on in a joint

# **CurveBeam Al's differentiators**

- Improves patient workflow in a group practice setting while creating CT revenue
- HiRise offers both weight bearing and non-weight bearing (supine) scans
- Deep learning AI solutions targeting point of care clinical assessment support
- Radiation dose lower than traditional CT up to 30% less than traditional CT



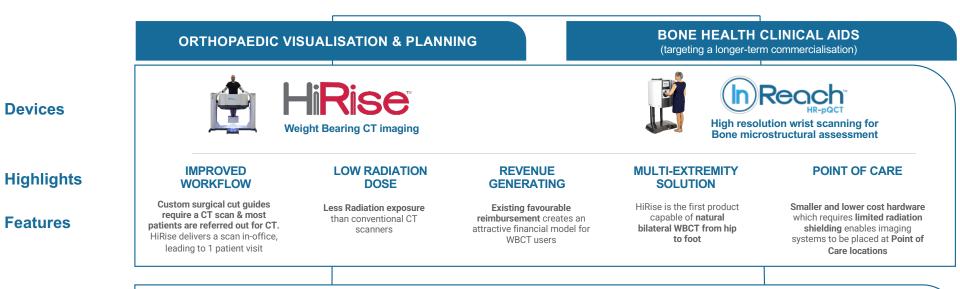
CurveBeam Al's HiRise weight bearing CT



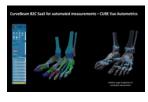


# **CurveBeam AI CT Devices & AI Output**

CurveBeam AI has a range of CT imaging devices with visualisation applications in orthopaedics and bone health



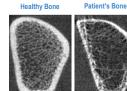
**Al Output** 



**CubeVue Autometrics** 



**Bone Mineral Density** 

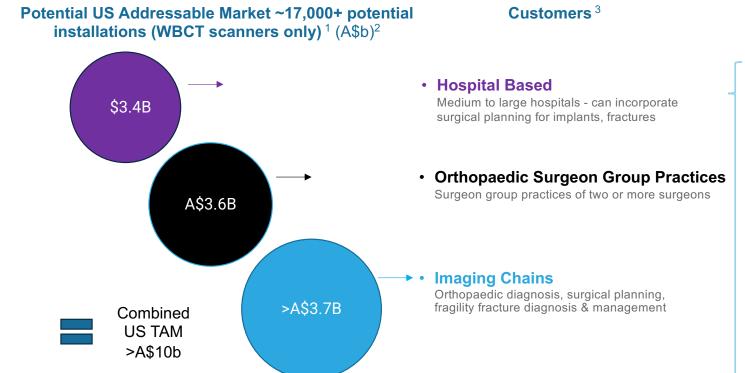


OssView (SFS)

CurveBeam Al

<sup>\*</sup> Does not include all CurveBeam Al products

# Large Market Opportunity & Adoption by Leading Customers



#### Examples

- o Mayo Clinics (all 3 major locations)
- o NYU Langone Health
- o UCLA Orthopedic Institute for Children
- o Kent State University College of Podiatric Medicine
- o Duke Orthopedics
- o Midwest Orthopedics at Rush, Chicago
- o Penn Medicine Pennsylvania Hospital
- o Hospices Civils De Lyon, France
- o Massachusetts General Hospital, Boston
- Schön Klinik, Munich, Germany
- Hospital for Special Surgery, New York
- Ghent University Hospital, Belgium





- Source: Frost & Sulliva
- 2. US HiRise indicative price US\$410,000 x \$1.50 USD/AUD potential installation sites in the US
- 3. ~17,352 potential installation sites in the US (5,892 orthopaedic practices, 6,000+ Standalone imaging centres, 5,460 non-psychiatric hospitals)

# **Two Business Models**

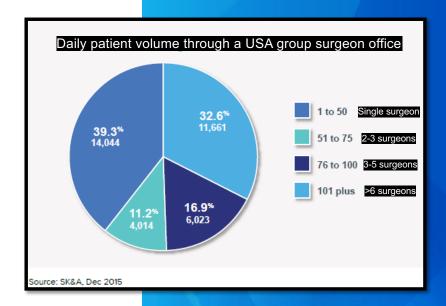
Existing reimbursement codes target an attractive business model for investors

#### 1. Present HiRise Business Model

- Stryker sells HiRise for US\$410,000 (circa A\$630,000)
- CurveBeam AI transfers to Stryker targeted 50% GP
- US CPT code 73700 CT scan of the lower extremity, under NCD 220.1

#### 2. Targeted Bone Mineral Density (BMD) SaaS Business Model

- Each HiRise is targeting 5 to 15 BMD reports per day (5-day week, 50-week year)
- Surgeon reimbursement ~US\$140 per BMD report (ave. of private & Medicare)
- CurveBeam AI targets a charge to surgeon of US\$90 (~A\$140) per SaaS report
- At 10 BMD's per day + 100 USA devices deployed A\$35m revenue
- Targeting US CPT code 77078 CT, bone mineral density study, under NCD 150.3





# **Land & Expand Commercialisation Strategy**

Over 170 first & second-generation installations worldwide, CurveBeam AI is well placed to upgrade its global install base to the HiRise for targeting high margin AI module revenue

- ~17,000+ potential installations
- Utilises a combination of specialist distributors and direct salesforce to drive global sales
- Significant sales pipeline to build on over 170 existing installations worldwide
- Approx. 75% of placements in the US market
- Targeting an installed base of HiRise systems across key global markets





# **Key US Revenue Driver and Growth Opportunity**

CurveBeam AI & Stryker Foot and Ankle (F&A) US Co-Marketing & Distribution Partnership



- US multinational Stryker Corporation is one of the world's leading medical technology companies
- HiRise units will be preloaded with Stryker Prophecy surgical planning protocols to further solidify Stryker incentives for placing devices
- May 2023 CurveBeam became an approved supplier of Stryker, who began promoting and distributing the HiRise with financing options
- Working to validate HiRise for custom data sets for knee and hip robotic and non-robotic systems in FY24, a major requirement for group surgeons' settings



# **BMD** and **OSSVIEW** Overview

Proprietary SaaS solutions leverage CT scans generated from its HiRise device

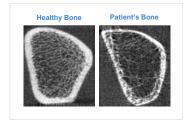
HiRise a change agent





#### **BONE MINERAL DENSITY**

- Al driven BMD report utilising CurveBeam Al's high resolution CT scans for BMD (hip) & bone microstructure (ankle) assessment. Possible only on the HiRise.
- Under development target FDA 510(k) filing H2 CY2024
- Upon FDA clearance, the company expects to be able to provide BMD reports in conjunction with imaging for total joint, knee & hip replacements, with a goal to aid in preventing revision surgery
- Favourable reimbursement in place in the US market



#### OssView (SFS)

- Al generated report for aiding physicians in the assessment of fracture risk with non-osteoporotic BMD
- OssView awarded <u>FDA Breakthrough Device Designation</u>. Ossview (wrist) with HR-pQCT under review by FDA
- To be developed on the HiRise at the ankle (feature under development)



# **Next Generation WBCT Platform: SKYRISE**

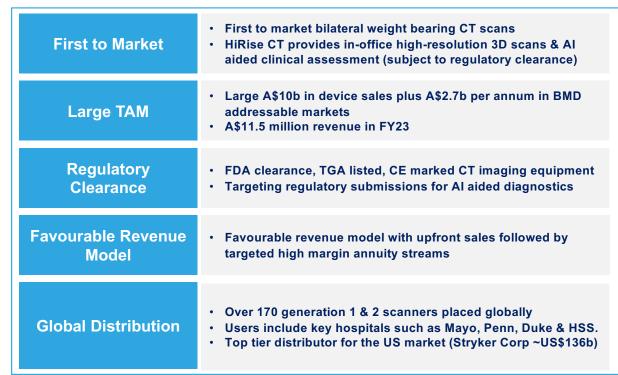
#### SPINE & SHOULDER future applications being developed

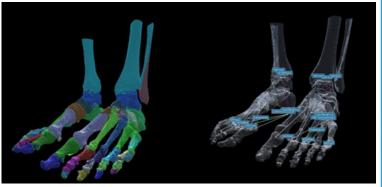
- Targeted AI for the spine AI to target each vertebrae using an anatomical landmark recognition system this way implants can be optimised to the right site & trajectory
- SkyRise, in WBCT mode targets to give dynamic structural information about spinal alignment, joint orientation, & supporting muscles with SkyRise. Plus, bone density & microstructure measures for better surgical planning & pretreatments
- SkyRise targets to employ a patent protected dual imaging capability to optimise clinical assessment of soft and hard tissue for surgical planning – paraspinal muscles (PSM), primarily thoracolumbar spine measures
- WBCT is targeting to image the lumbar & cervical spine in a standing (WB) & non-WB position. Both scans are proposed to be used to aid surgical decisions by assessing spinal stability & to improve investigation around occult back & leg pain
- Likewise for the shoulder, soft & hard tissue are considered important for planning TJR both tissues are critical in assessing how the shoulder hangs for surgical planning
- Shoulder targeting bone density & bone microstructural assessment, even before the first surgical cut is made into the shoulder, bone health can form part of the surgical plan





# **Summary**







## **KEY INVESTMENT RISKS**

#### **Regulatory clearances**

- The Group will require, and intends to apply for, further regulatory clearances in key jurisdictions (e.g. USA FDA) to execute its business plan. If current applications are unsuccessful, the Group might need to lodge a subsequent request with the FDA, which could extend clearance by 2 to 3 years and in turn could impact the ability of the Company to grow its longer-term business and delay potential revenues.
- 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. Timelines can also be impacted by available funds.

#### **Regulatory compliance**

- 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.

#### Reimbursement availability

- The commercial success of the Group's products and services is critically dependent on the availability and amounts of available reimbursement. 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.
- In the future, the Group may 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.

#### **Development risk**

 An important aspect of the Group's business is to continue to invest in innovation and related product development improvements and opportunities. CT product and software development is expensive and inherently risky and 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 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.

#### **Market acceptance**

 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.

#### **Adoption of SaaS diagnostic solutions**

 The Group's long-term revenue and profit growth is highly dependent on the utilisation 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.

#### Protection of IP

If the Group is unable to protect its IP, its
competitors could develop and market products and
services similar to those of the Group, and demand
for the Group's products and services, or the price
that the Group is able to charge for such products
or services, may decline. Equally, if competitors are
successful in obtaining patent protection of
technologies relevant to the Group's activities, this
may limit the Group's ability to execute its business
strategy.

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## **KEY INVESTMENT RISKS**

#### **Additional funding risk**

 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 favourable terms, or at all, and such financing may be dilutive to Shareholders.

#### **Key person risk**

 There is a risk that the Group may not be able to attract and retain key personnel or be able to find effective replacements for any departures. If the Group's CTO (AI), or CTO (CT) were to leave the Group, the Company would lose significant technical and business expertise which could have an adverse impact on the ability of the Group to implement its planned product development and business strategy.

#### Reliance on distributors

 CurveBeam relies on distributors to distribute its products in many markets. The loss of a key distribution relationship, or an underperforming partner, may impact the Group's CT sales and revenue.

#### Cyber risk and data breach

• There is a risk that the measures that the Group takes to prevent data breaches may prove to be inadequate which may result in successful cyberattacks and unauthorised access to or use of data. Any data breaches or other unauthorised access to the Group's information technology systems or sensitive data may result in, among other things, reputational damage, a disruption of services or breaches of obligations under applicable laws or agreements. The Group may also incur costs as a result of rectifying system vulnerabilities or introducing additional safeguards to minimise the risk of data breaches.



