

ASX: CVB

14 November 2023

CEO Presentation at Bell Potter Healthcare Conference

CurveBeam AI Limited CEO Greg Brown is giving the attached presentation on the company today at the Bell Potter Healthcare Conference.

Ura P Auckland
Company Secretary

About CurveBeam AI Limited

CurveBeam AI (ASX:CVB) develops, manufactures and sells specialised medical imaging (CT) scanners, coupled with AI SaaS-based clinical assessment solutions, to support medical practitioners in the management of musculoskeletal conditions. The Company's flagship CT scanner, HiRise™, performs weight bearing CT scans as well as traditional non weight bearing CT scans, providing a range of advantages over the use of traditional CT or MRI devices. CurveBeam AI has more than 70 employees with its corporate office, AI and IP functions located in Melbourne, VIC, Australia and global operations headquarters in Hatfield, Pennsylvania, USA.

For further information go to <https://curvebeamai.com>

Investor / media enquiries

Matthew Wright
NWR Communications
+61 (0) 451 896 420
matt@nwrcommunications.com.au



BELL POTTER HEALTHCARE CONFERENCE PRESENTATION

November 2023



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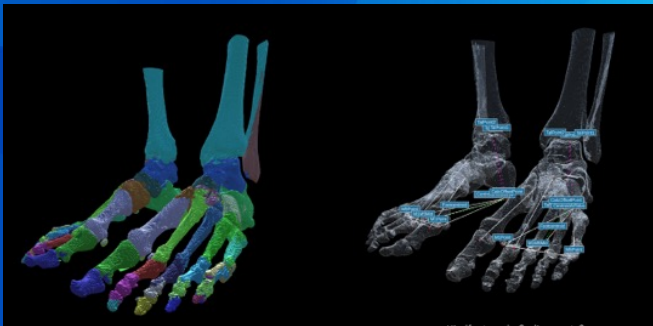
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Financial information

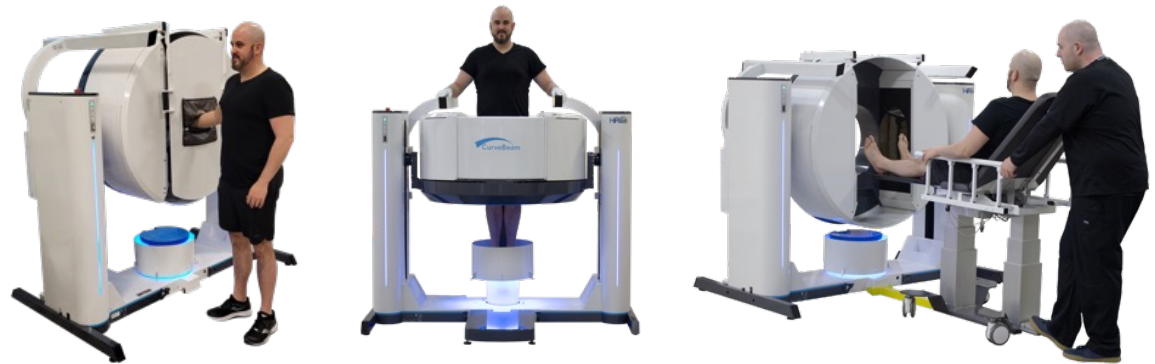
All numbers in this presentation are stated in Australian dollars (**A\$**) unless stated otherwise.

INVESTMENT HIGHLIGHTS

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



CurveBeam AI's HiRise
Weight bearing CT



First to market

Natural bilateral WBCT & Non WBCT, point of care imaging with targeted proprietary AI solutions

Advanced Regulatory

FDA cleared; TGA & CE marked CT imaging equipment. Targeting regulatory submissions for AI modules

Favourable US Reimbursement in Place

Coding, payment & coverage under existing policies

Large Market Opportunities

Large billion-dollar addressable markets

US partnership established with market leader

Co-marketing & distribution agreement with Stryker Corporation US Foot & Ankle division (NYSE:SYK)

Growing sales

Circa A\$11.5m FY23 revenue, circa 50% growth – CT footprint key to building SaaS annuity from AI modules with circa ~90% gross margins

KOL & Clinical Validation

Key KOL sites as users – Mayo, Duke, HSS
10 years of publications on bone fragility & WBCT

Institutional register - Karst Peak, Tenmile, Firetrail, Acorn, SG Hiscock, Ilwella, Frazis Capital, Prism Ventures (Part of Cap M Group US)

Building IP position

37 granted patents and 27 pending patents internationally



CURVEBEAM AI CT DEVICES & AI SOLUTIONS

CurveBeam AI has a range of CT imaging devices with visualisation applications in orthopaedics and bone health. CurveBeam AI's imaging devices have regulatory clearances and will provide the platform for the company's AI modules (post regulatory clearances)



ADVANCED CT IMAGING SYSTEMS (FDA, CE Mark and ARTG cleared)

ORTHOPAEDIC VISUALISATION & PLANNING



HiRise™
Weight Bearing CT imaging



InReach™
HR-pQCT
High resolution wrist scanning for
Bone microstructural assessment

IMPROVED FX DETECTION

35% improved simple fracture detection rate and 2-fold improved identification of complex fracture over x-ray

LOW RADIATION DOSE

Up to 66% less Radiation exposure than conventional CT scanners

REVENUE GENERATING

Existing favourable reimbursement creates an attractive financial model for WBCT users

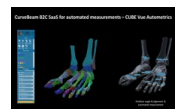
MULTI-EXTREMITY SOLUTION

HiRise is the first product capable of natural bilateral WBCT from hip to foot

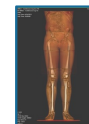
POINT OF CARE

Smaller and lower cost hardware which requires limited radiation shielding enables imaging systems to be placed at Point of Care locations

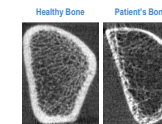
AI SOLUTIONS (subject to FDA clearance)



CubeVue Autometrics



Bone Mineral Density



OssView (SFS)

* Does not include all CurveBeam AI products



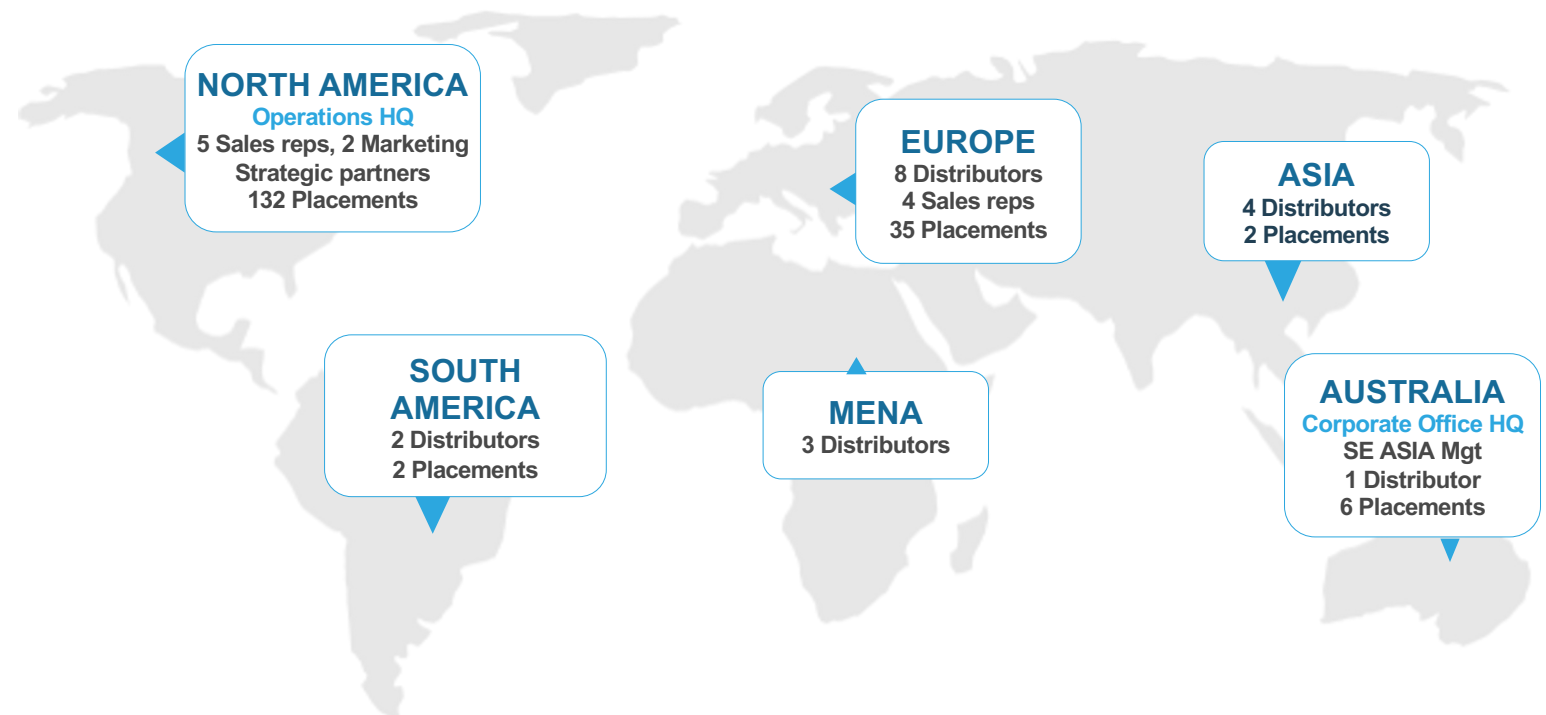
01

COMMERCIALISATION STRATEGY

LAND & EXPAND COMMERCIALISATION STRATEGY

With 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

- CurveBeam AI utilises a combination of specialist distributors and direct salesforce to drive global sales
- Fast growing sales pipeline to build on over 170 existing installations worldwide
- 42 HiRise units placed since FDA clearance in late 2020. Circa 75% of placements in the US market
- Targeting an installed base of HiRise systems across key global markets including the US and Germany
- Targeting commencement of SaaS revenue from AI modules by late FY25



LARGE MARKET OPPORTUNITY AND ONGOING ADOPTION BY LEADING CUSTOMERS

CurveBeam AI's target customer groups	Potential US WBCT Installation Sites ¹	Potential US Addressable Market ²	Select CurveBeam AI customers
Orthopaedic Surgeons & Group Practices Surgeon group practices that have imaging capability	5,829	A\$3.6b	<ul style="list-style-type: none"> • Mayo Clinics (all 3 major locations) • NYU Langone Health
Imaging Chains Orthopaedic Diagnosis, Surgical planning, fragility fracture diagnosis & management	>6,000	>A\$3.7b	<ul style="list-style-type: none"> • UCLA Orthopedic Institute for Children • Kent State University – College of Podiatric Medicine • Duke Orthopedics
Hospital based Medium to large hospitals - can incorporate surgical planning for implants, fractures	5,460	A\$3.4b	<ul style="list-style-type: none"> • Midwest Orthopedics at Rush, Chicago • Penn Medicine – Pennsylvania Hospital • Hospices Civils De Lyon, France
Integrated Healthcare Networks (IHN) Imaging departments for today, new Point of Care solutions for the future			<ul style="list-style-type: none"> • Massachusetts General Hospital, Boston • Schön Klinik, Munich, Germany • Hospital for Special Surgery, New York
Total	>17,352	>A\$10b	<ul style="list-style-type: none"> • Ghent University Hospital, Belgium

1. Source: Frost & Sullivan

2. US HiRise indicative price US\$410,000 x \$1.50 USD/AUD potential installation sites in the US

STRONG INVESTMENT PROPOSITION FOR SURGEONS

Existing reimbursement codes create an attractive financial model for HiRise users

- The average Medicare reimbursement rate for scans of the lower extremity CPT code relevant to the HiRise™, pedCAT™ and LineUP™ was US\$138.77 per scan in 2022.
- With an initial capital cost of USD\$410,000 and assuming 10 scans per day, the payback period for a HiRise™ (excluding costs) is 1 year and 5 months
- If financed under a lease with an interest rate of 9%, the breakeven number of scans required to pay the machine off over a 5-year term is 2.83 scans per day (excluding costs)



1. US Payment and coverage varies extensively city to city, state to state and this example represents a specific model for a specific region of the US market.

Atlantic Orthopedic Specialists,
Virginia Beach, VA

Actual CurveBeam Customer - PedCat

Device up front cost: \$179,000

Volume: 35 scans per month

Breakeven: 17 scans/month

Reimbursement range: \$99.74 to \$294.31

Average reimbursement: \$242.11

Gross revenue / month: \$7014.08

Device payback period of 2.5 years



STRYKER CO-MARKETING & DISTRIBUTION PARTNERSHIP

US Foot & Ankle division agreement



CURVEBEAM AI & STRYKER PARTNERSHIP

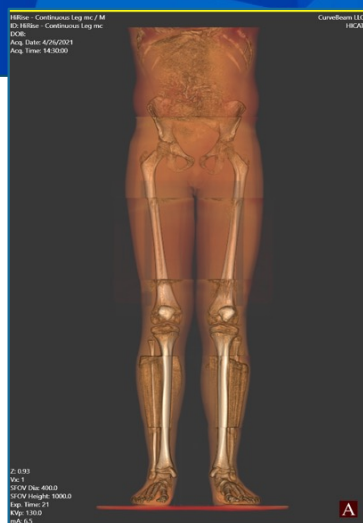
- US Co-marketing & Distribution partnership - Stryker Foot & Ankle Division
- The HiRise will be Stryker's first imaging solution sold through its Foot & Ankle division
- HiRise units will be preloaded with Stryker Prophecy surgical planning protocols, to further solidify Stryker incentives for placing devices
- In May 2023, Stryker Foot & Ankle unit officially launched its HiRise promotion, distribution and financing program, and qualified CurveBeam as an approved supplier. This includes access to Stryker's various financing options for customers
- Working to validate a new higher energy HiRise (v2) for custom data sets for robotic systems in FY24

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ORTHOPAEDIC DIAGNOSIS AND PLANNING

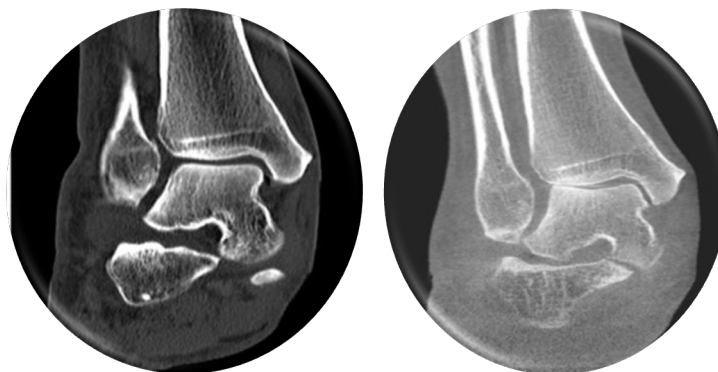
WEIGHT BEARING CONE BEAM CT FOR TOTAL ALIGNMENT

- ✓ **Quicker and easier** to scan than traditional CT and MRI, with faster image acquisition time
- ✓ **High resolution** and **3D visualisation** enables **development of new AI based assessment tools**
- ✓ **Radiation dose lower** than traditional CT – up to 66% less than traditional CT
- ✓ **Smaller and lower-cost hardware** requiring limited radiation shielding infrastructure



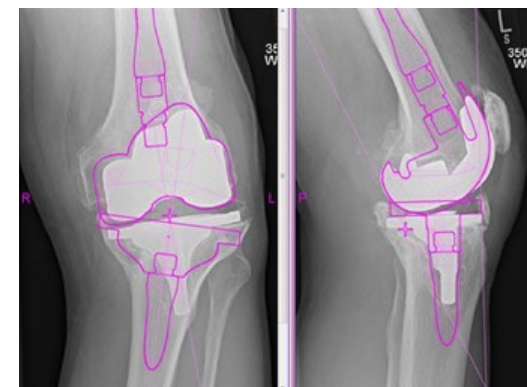
Hip to Foot in standing 3D

HiRise is the first product capable of WBCT of hip to foot in standing 3D



Weight bearing imaging key to accurate diagnosis

WBCT provides unique alignment data required to accurately access bone positioning under standing load



Serves more applications

The HiRise serves various orthopaedic sub-specialties in total knee, hip and ankle replacement planning in addition to implant manufacturers and 3D printed solution providers

HIRISE: WEIGHT BEARING CT

The HiRise currently provides many advantages in improving CT visualisation of clinical issues to improve diagnosis and surgical planning



Comfortable patient experience for weight bearing hip, knee and foot scans as well as upper extremity and supine positions



Included visualisation software, CubeVue, displays dynamic 3D renderings, multiplanar slices and digitally reconstructed radiographs in about 3 minutes per scan region.



Approximately 1-3 minutes per scan per joint, with less than 30 seconds of X-ray exposure

APPLICATIONS CURRENTLY SERVED

- Suspected hip, knee and ankle fractures
- Suspected osteoarthritis
- Bunions
- AAFD reconstructions
- Joint Replacements
- Charcot foot reconstruction
- High Ankle sprain (Syndesmosis)
- Lisfranc Injuries
- ORIF (calcaneus, pilon, ankle)
- Triple arthrodesis

ADVANTAGES

- In-clinic scanning
- Faster diagnosis and follow up
- Reduced risk of revision surgery
- Improved treatment and patient satisfaction
- Improved outcomes and reduced adverse outcomes



AI MODULES WILL TARGET HIGH MARGIN REVENUE ON HIRISE INSTALL BASE

CubeVue AutoMetrics aims to reduce 16 hours of CT dataset preparation prior to pre-surgical planning to a scan available in 15 minutes



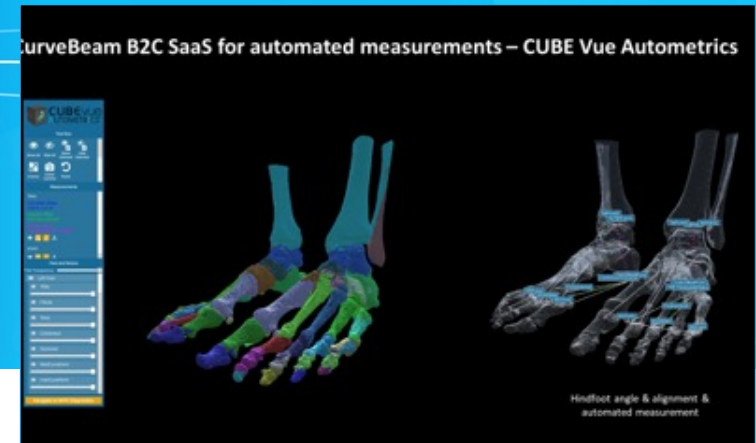
"To minimize future predicted costs, morbidity, & mortality from increasing numbers of fragility fractures in our rapidly aging population, the AAOS recommends that bone fragility should become a national public health priority"

- American Association of Orthopedic Surgeons (AAOS)

THE PROBLEM

Aids in bone segmentation for accurately identifying key anatomical points

- Orthopaedic pre-treatment planning involves understanding of the structure and alignment of the foot – 26 bones & 33 joints
- To segment the bones in the foot and accurately assess bone geometry & alignment requires ~6 hours of manual effort. Not feasible in practice
- Typically, surgeons will make crude manual measurements on 2D radiographs
- No reimbursement in place at this point



THE SOLUTION

CurveBeam AI DLAI segmentation-as-a-service model

- Working 3D model with measurements in minutes for surgeons
- WBCT images drive improvements in accuracy & consistency
- CBAI has several key patents awarded in DLAI & non-AI for bone segmentation
- Targeting this IP for a platform solution for other CT modalities, in addition to WBCT (B2B)
- FDA filing expected in FY2024





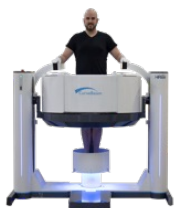
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BONE HEALTH DIAGNOSTICS

BMD AND OSSVIEW OVERVIEW

CurveBeam AI's proprietary SaaS solutions leverage CT scans generated from its HiRise device

HiRise a change agent



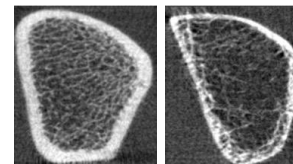
HiRise™



BONE MINERAL DENSITY

- AI driven BMD report utilising CurveBeam AI's high resolution CT scans for BMD (hip) & bone microstructure (ankle) assessment. Possible only on the HiRise
- Under development - target FDA 510(k) filing in FY24
- On FDA clearance, the company expects to be able to provide BMD reports in conjunction with imaging for total joint replacements, with a goal to prevent revision surgery
- **Favourable reimbursement in place in the US market**

Healthy Bone Patient's Bone



OssView (SFS)

- AI generated report for aiding physicians in the assessment of fracture risk with non-osteoporotic BMD
- OssView awarded **FDA Breakthrough Device Designation**. Ossview (wrist) with HR-pQCT under review by FDA (targeting clearance in FY24)
- Also, to be enabled by HiRise (feature under development)
- Company is targeting payment for OssView through 2 programs, 1) under a capitated system clinical validation trial & 2) a fee for service (FFS) payer coverage. The FFS program will target AMA to assign an existing CPT code to Ossview. Coverage and payment to be targeted through clinical trials demonstrating strong health economics of OssView

BONE HEALTH: CURRENT BONE HEALTH DIAGNOSTIC (DEXA) MISSES THE MAJORITY OF FRAGILITY FRACTURES

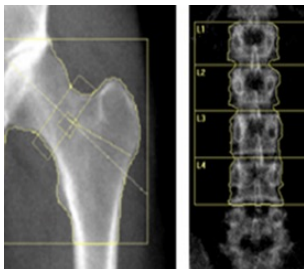
Bone fragility is caused by loss of bone microstructure, BMD measures only bone density & not microstructure

BONE MINERAL DENSITY (BMD): CURRENT STANDARD OF CARE

Commonly administered, limited performance



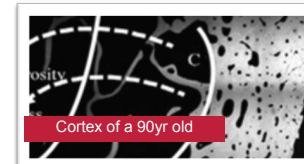
DEXA: Dual-energy X-ray is a means of measuring bone mineral density (BMD).



It basically looks at a silhouette of bone for determining density, as compared to a normal healthy population.

Small changes in bone density can mask major microstructural changes in the cortical and trabecular bones

BONE MICROSTRUCTURE


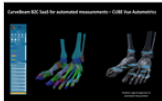

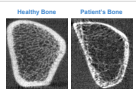



3 electron micrographs – a normal bone density control & female patients of age

- Note - loss of bone microarchitecture is associated with aging
- While loss of bone density contributes to fragility, the major cause of fragility is loss of microstructure
- Bone loss may reduce BMD modestly & it can mask major microstructural changes

CURVEBEAM TECHNOLOGY PLATFORM OVERVIEW

CurveBeam AI has regulatory clearances for WBCT devices in-market with a deep pipeline of complimentary high margin AI modules to be launched in FY25 and beyond

	SOLUTION	PRODUCTS	REGULATORY/COMMERCIAL STATUS	US MARKET OPPORTUNITY	GROSS MARGIN	REVENUE OPPORTUNITY
ORTHOPAEDICS	Weight Bearing CT for Orthopaedic visual diagnostic support and treatment planning	HiRise, PedCAT		In market		
	Next generation AI bone segmentation and 3D modelling	AutoMetrics	 FDA filing targeted for FY24 User subscription based value-add tool	~A\$10b ¹ (capital sales)	~50%	US\$410,000 per HiRise unit
BONE HEALTH	High resolution CT for assessing fracture risk with bone microstructure analysis of the wrist (OssView)	HR-pQCT	 • CT device FDA cleared • Filed OssView with FDA for the wrist • FDA Breakthrough Device Designation • FDA clearance targeted for FY24	~A\$1.4b per annum ² (OssView scan revenue)	Targeting 90%+	~US\$100,000 - 125,000 future p.a SaaS target per HiRise ³ (for BMD scans only)
	AI processed Structural Fragility Score of the ankle (OssView)	AI Generated OssView Report on the HiRise ankle scan – opportunistic scan only	 FDA filing targeted for FY24			
	AI driven Bone Mineral Density assessment for hip to knee scans	AI Generated CT BMD Report on the HiRise at the hip – opportunistic scan only	 FDA filing targeted for FY24	A\$2.7b+ per annum ⁴ (BMD scan revenue)		

1. U.S. indicative install price (direct to clinician and partner sales) of HiRise™ x ~17,352 potential installation sites in the US (5,892 orthopaedic practices, 6,000+ Standalone imaging centres, 5,460 non-psychiatric hospitals)
2. 30.6m women over 65 recommended for screening based on US Preventive Services Taskforce screening recommendations x A\$90, screened every 2 years (Medicare provides BMD reimbursement every 2 years)
3. Assumes 4 to 5 BMD CT scans per day, 6 days a week, 50 weeks a year at a target scan price of US\$85 per Scan (\$85 x 100 to 125 scans per month)
4. US\$100,000 (per target SaaS revenue in note 3) x \$1.50 (being US\$1.00 = A\$1.50) x ~17,352 potential installation sites in the U.S.

NEXT GENERATION PRODUCT PIPELINE: SKYRISE

- Next generation point of care weight bearing CT imaging platform
- It will cover the spine, neck and shoulder to existing arm and lower extremity imaging.
- Dual CT scanners
- Prototyping stage - Beta site testing targeted for FY25



INVESTMENT SUMMARY

CurveBeam AI produces and sells market leading weight bearing CT scanners. The Company has established key recognised clinical customers and a leading vendor partner.

Regulatory Clearances	First to market, FDA cleared, TGA and CE Marked Point of Care Weight Bearing Cone Beam CT imaging
Significant addressable market	Large A\$10b plus A\$4.1b per annum addressable markets
Commercial stage	Commercial stage company with circa A\$11.5m revenue in FY23 – 50% growth
Favourable Reimbursement	Favourable reimbursement for CT scans (US/Germany) and BMD HiRise targeted annuity (US only)
Tier 1 Partnership	Distribution partnership with the foot and ankle division of Stryker (NYSE:SYK) to aid in driving growth
Established global footprint	170+ Device placements worldwide including top tier institutions – e.g. Mayo, Duke, HSS 42 HiRise placements since FDA clearance in late 2020
High margin AI solutions	Installed CT devices to underpin incremental high margin AI module revenues commencing late FY25



08

KEY RISKS

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 the clearance process by 2 to 3 years and in turn could impact the ability of the Company to grow its longer-term business and delay any potential revenues generated by OssView™.
- 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.

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 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.



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 cyber-attacks 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.

Taxation matters (post-merger)

- The merger agreement includes a mechanism pursuant to which a portion of the consideration payable to the original unitholders in CurveBeam US was withheld to cover potential tax liabilities. There is a risk that potential tax liabilities may exceed the value of this contingent consideration or that tax liabilities arise or are identified after the contingent merger consideration is paid. If additional tax liabilities are identified, the Group would be required to pay such liabilities from its cash reserves. Any such payment will reduce the Group's cash reserves.



THANK YOU

