



# CURVEBEAM AI (ASX: CVB) INVESTOR DECK

September 2025

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## Financial information

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



# OVERVIEW OF CURVEBEAM AI

## Commercialising a New Medical Device in CT Scanning

### Introducing the HiRise™:

- A cone beam CT scanner that scans a patient's lower extremity (i.e. hip, knee, ankle, foot) whilst under the patient's own body weight
- Being able to scan a patient under their own body weight:
  - evaluates how joints and bones behave under load – improving the diagnostic image
  - gives the most realistic, detailed, & actionable view of the skeleton for surgical planning

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



HiRise™ CT Scan  
(i.e. weight bearing)



### Brief Overview of HiRise™

- FDA Cleared, TGA listed, CE marked (MDR)
- Clinically validated (dozens of studies published)
- Adopted by leading medical institutions and by recognised clinical thought leaders:



Massachusetts General Hospital  
Founding Member, Mass General Brigham

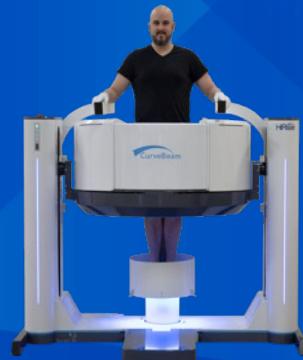
#### • Partnership with Stryker Corporation:

- Foot & Ankle division only
- Nasdaq listed (SYK)
- One of the largest orthopaedic companies
- Mkt Cap: ~US\$144 billion

**stryker**

## HIRISE™ PROVIDES BOTH:

WEIGHT BEARING  
CT CAPABILITIES



TRADITIONAL CT  
CAPABILITIES



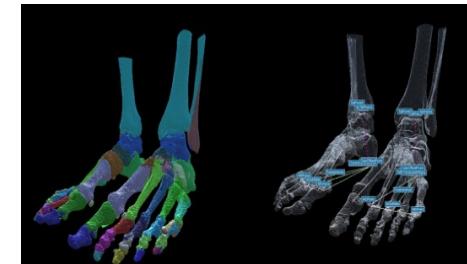
## ADDITIONAL CAPABILITIES

Providing greater capabilities than traditional CT device

### 3D Capabilities

The HiRise™ is capable of providing 3D images:

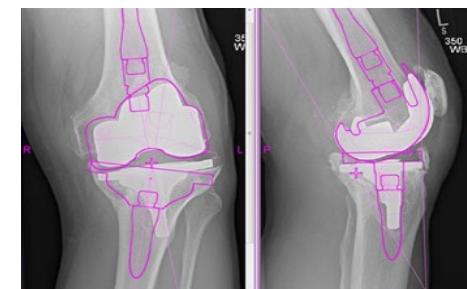
- In the surgeons' office
- High resolution, precision measurements
- CVB AI creates 3D models & automated anatomical measurements



### Superior Diagnostic Imaging

Superior diagnostic image allows for:

- More precise corrections
- Better clinical assessment in F&A conditions
- More informed planning



### Further Benefits

- ✓ **Quicker and easier to scan** than traditional CT and MRI, with faster image acquisition time
- ✓ **Improves clinic workflow** – one visit to surgeon for patient vs multiple (discussed later)
- ✓ **Radiation dose lower** than traditional CT – up to 66% less than traditional CT

# TARGETING SURGEONS

## WHY SURGEON PRACTICES?

- Easy to use at the point of care (PoC)
- Saves them time (results within minutes)
- Provides surgeons with an additional profit centre
- Allows surgeons to more efficiently plan their surgery
- Saves their patients multiple visits
- Surgeons manage entire surgery plan (entire process)

~5,800 orthopaedic practices in the US alone

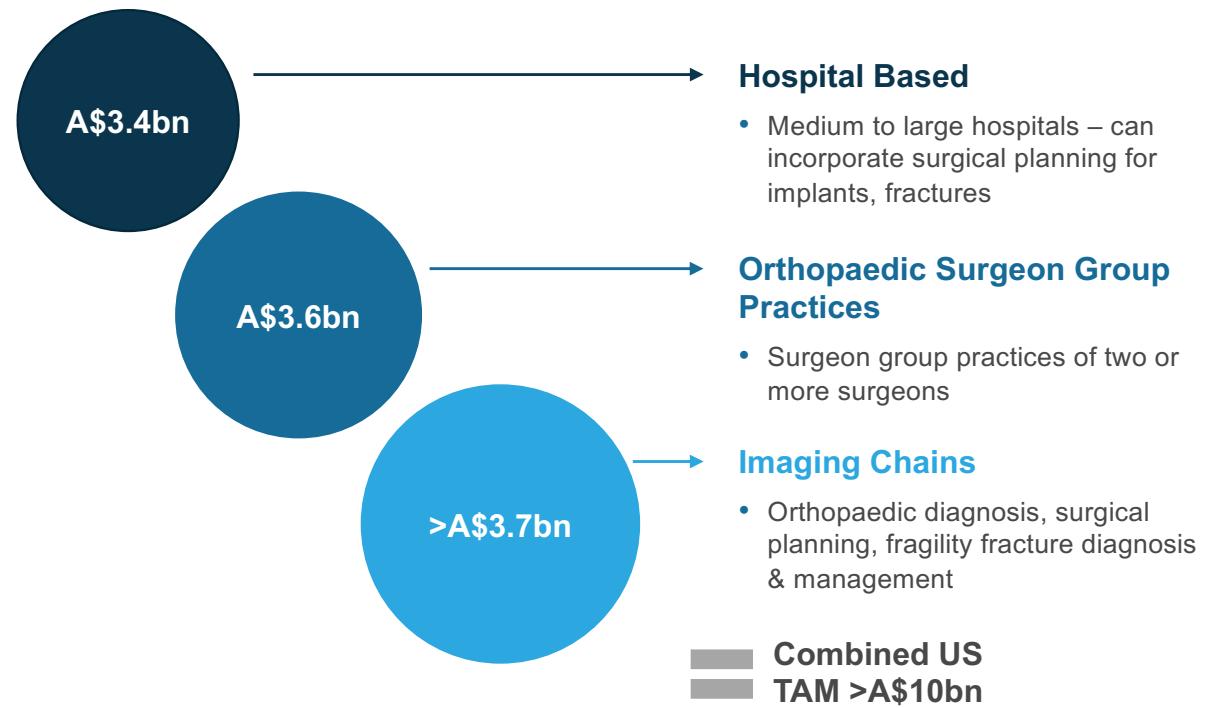
## Economics of HiRise™ (US)

- Stryker sells HiRise™ for ~US\$410,000
- CurveBeam AI transfers HiRise™ to Stryker
- CurveBeam AI aims for ~50% gross margin

# MARKET OPPORTUNITY (US)

Potential US Addressable Market ~17,000+ potential installations (WBCT scanners only)<sup>1</sup> (TAM ~ A\$10bn)<sup>2</sup>

Customers<sup>3</sup>

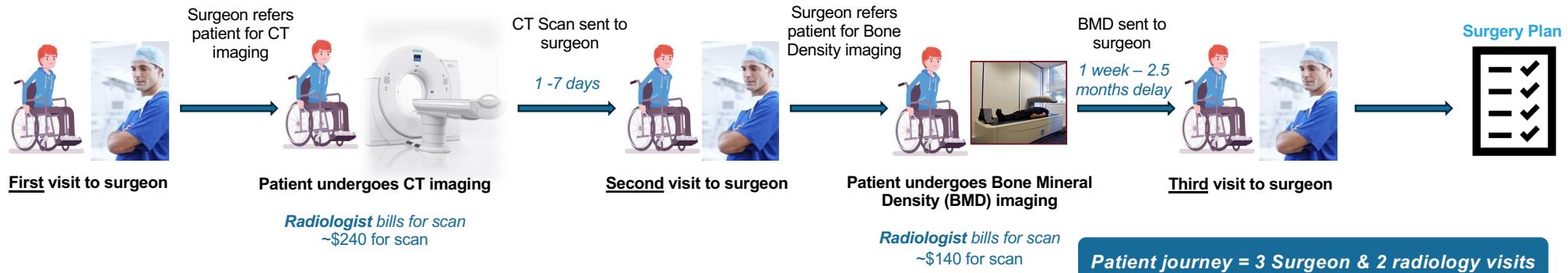


1. Source: Frost & Sullivan
2. US HiRise™ indicative price US\$410,000 x \$1.50 US\$/A\$ potential installation sites in the US
3. ~17,352 potential installation sites in the US (5,892 orthopaedic practices, 6,000+ Standalone imaging centres, 5,460 non-psychiatric hospitals)

# WORKFLOW FOR SURGEONS WITH HIRISE

Improved workflow speaks for itself

## Workflow for Total Joint Replacement (TJR) incorporating bone quality assessment



## Workflow for TJR incorporating bone health assessment with HiRise™



### Key Benefits of HiRise™:

- ✓ One surgeon visit vs multiple for patient
- ✓ Surgeon profits from scans (not radiologist)
- ✓ Convenient for patient with limited mobility
- ✓ Optimal workflow



# OPTION TO PURCHASE OR FINANCE

The addition of vendor financing creates an attractive financial model for practices

- Orthopaedic offices are often capital-intensive, which can limit outright purchasing capabilities
- By introducing vendor financing, those practices that may be capital constrained now have ability to purchase HiRise™
- CVB is positioned to access more sales across North America & Europe
- A €10 million (~A\$18 million) facility has been secured through a Swiss specialist medical device financier, with the umbrella contract now fully executed

## Vendor financing mechanics

- Vendor covers the cost of the HiRise™ plus overhead ~US\$220,000
- The lease amount is then paid down quarterly over 4 years from the monthly lease charge to the account for the full purchase HiRise™ price

Comparison: Outright Purchase vs. Vendor Financing		
Considerations	Outright Purchase Model	Vendor Financing Option
Upfront Cost	US\$410,000 (without service)	US\$220,000 Covers cost of HiRise plus overheads
Ownership	Immediate ownership for practices	Ownership after lease term (4 years)
Financing Terms	N/A	Upfront cost + 14.8% over 4 years
Cash Flow Impact	Full revenue recognised up front	Spread over 4 years via quarterly lease payments
Payback Period	1 Year + 5 Months Capital Recovery	4 Years Lease Term to Ownership
Gross Profit Margin	~50%	Recurring margin over lease term
Target Market	Larger, well-funded practices	Smaller or mid-sized practices with limited capital
Breakeven Volume	10 scans per day	3 scans per day <sup>1</sup>
Benefits to CVB	Outright Purchase Model	Vendor Financing Option
1.	Greater upfront revenue	Expands market reach
2.	No further repayment risk	Increase potential sales
3.		Builds baseline annuity revenue
4		Allows for better cash flow forecasts

<sup>1</sup>Assumed over 4-year term

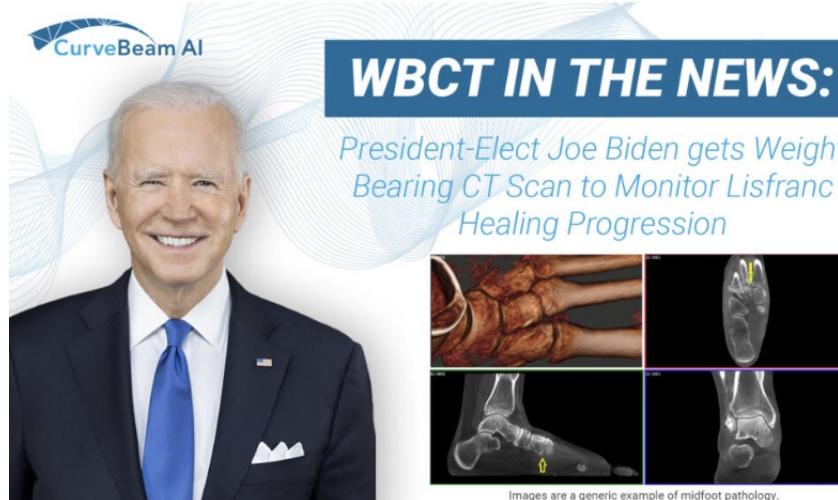
# MARKET PENETRATION

## HIRISE™ ALREADY ADOPTED BY LEADING CLINICS



# HIGH PROFILE CASE STUDY

## PRESIDENT JOE BIDEN GETS WEIGHT BEARING CT SCAN



"A weight-bearing CT scan has all the benefits of a standard CT scan with the additional advantages of revealing the stability of the midfoot"

"Weight bearing CT scans can reveal any subluxation/dislocation (abnormal positioning) of the involved joints. MRI studies can create better images of soft tissues, but are not required to diagnose a Lisfranc injury."

Dr. Steven Neufeld, MD, an orthopedic surgeon in Virginia.

## PRESIDENT JOE BIDEN GETS WBCT SCAN TO ASSESS HIS LISFRANC INJURY

December 12, 2020    Curvebeam    News, Weight Bearing CT

President-elect Joe Biden's physician recommended he get a weight bearing CT scan to monitor the healing progression of a sustained hairline fracture, according to an AP report.

President-elect Joe Biden's medical visit to Philadelphia made headlines over the weekend after his physician recommended he receive a "special" weight bearing CT scan. Biden visited Pennsylvania Hospital, a Penn Medicine facility, to obtain the imaging exam.

Pennsylvania Hospital utilizes the CurveBeam pedCAT weight bearing CT system.

<https://curvebeamai.com/weight-bearing-ct/president-elect-joe-biden-gets-wbct-scan-to-assess-his-lisfranc-injury/>



# GROWTH STRATEGY

Worldwide partner and distribution network to target an increase in sales

## United States (Primary Market)

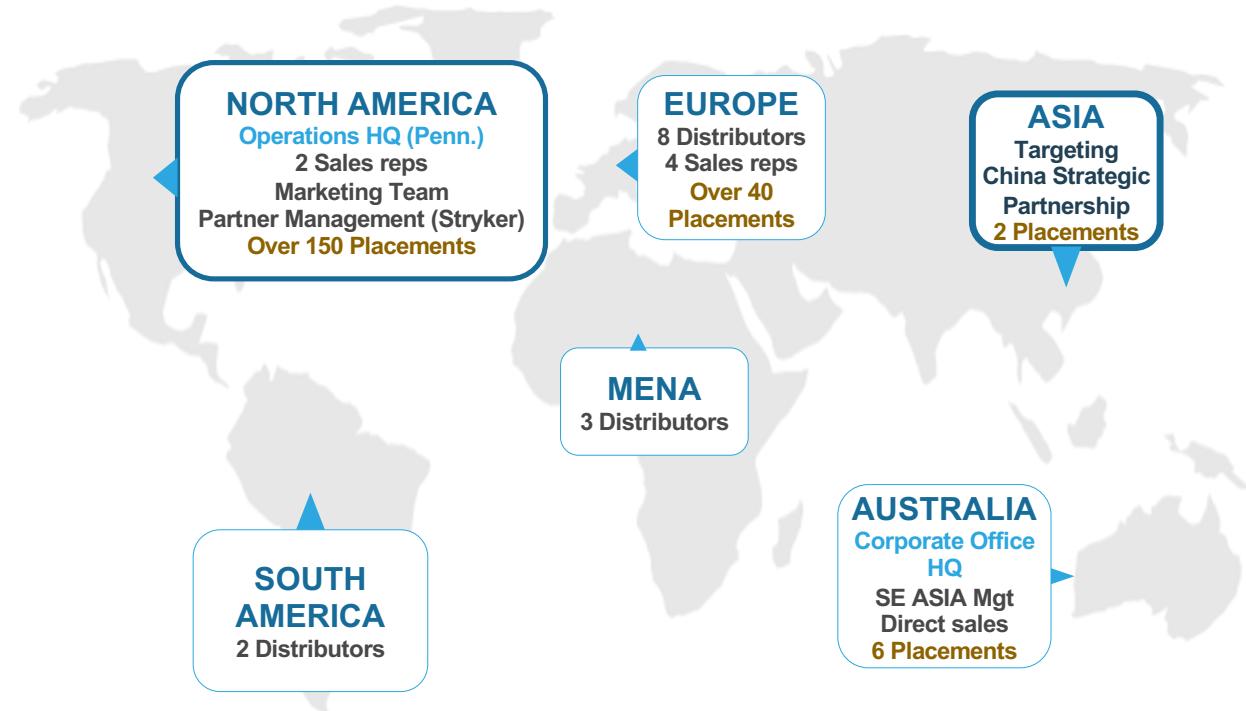
- ~17k potential installation sites in the US alone
- Approx. 70% of placements to date have been in the US market

## Partnership Agreement with **stryker**

- One of the largest Orthopedic companies
- Agreement with Foot & Ankle (**F&A**) division
- HiRise™ provides scans & is used with Stryker's Prophecy device for **foot & ankle**

## Next Opportunity:

- Validation of enhanced HiRise™ with a leading robotic arm assisted surgery device for **knee & hip** with US partner



Over 200 existing global installations

# ENHANCED HIRISE™ VALIDATION IN KNEE/HIP

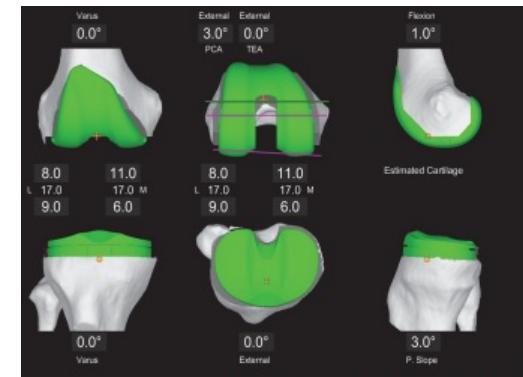
## Validation ongoing with multiple suppliers of knee products

- CVB is currently working to validate HiRise™ for multiple knee suppliers for non-robotic surgery
  - 1) Restor3d/Conformis, 2) Medacta Knee Osteotomy PSI<sup>1,3</sup> Newclip - knee Osteotomy PSI<sup>1</sup>
- CVB focused on a specific robotic validation that uses CT scans – once validated it is expected to increase HiRise™ sales
  - A leading robotic device used globally for knee & hip is presently being reviewed
  - Each surgical plan for the device requires a CT scan
  - If HiRise™ can integrate to provide the CT scan, it is likely to increase the value proposition for the HiRise™ (as can be used in conjunction with a leading robotic surgery device)

## Summary & update on validation

- The Company is pleased with the increased engagement from the vendor of a major robotic system for the validation of the enhanced HiRise™
- CVB has conducted several meetings, including a system demonstration with the vendor R&D team, during Q1FY26 demonstrating the latest scanning procedure & the new upgraded movement mitigation mechanism
- Company continues to remain confident that its document and data submission meets their requirements to complete validation and corresponding labelling changes
- Discussions have been constructive & continue – positive feedback on new movement mitigation methods
- Please note that **the process is an internal one to the vendor's organisation**, subject to their judgment, and their priorities, that makes it difficult for the Company to provide guidance on completion at this point

## What is a robotic cut guide



## What is a motion rod

**⚠️ During the scan, the pelvis, leg, and Motion Rod must remain motionless.**

- Position patient supine, feet first with foot secured in an upright position with a rolled towel or blanket wrapped around the bottom of the foot to secure the ankle as shown.
- Elevate the knee of the patient slightly with a rolled towel or blanket.
- Wrap the velcro strap one complete revolution around the rod as shown in Figure 2. Do this for both Velcro straps, one at the hip position and one at the ankle position as shown.
- Set the Motion Rod on the patient to pass from just proximal of Hip Center to distal of Ankle Center as shown in Figure 3.
- Adjust the femoral and tibial straps to secure the rod.
- Verify the rod is in both anterior/posterior and medial/lateral field of views for all scan regions.

**⚠️ The velcro strap must be wrapped around the rod in one complete revolution, before wrapping around the leg. Straps should be snug, but not excessively tight.**

**3. CONSIDERATIONS**

- Scan patient anytime before procedure (up to 8 weeks in advance)
- Ensure the patient is comfortable and relaxed. This is critical for achieving a motionless scan.
- If metallic components are present in the operative leg, it may not be possible to obtain an image of significant quality to support a scan procedure. If metallic components are present in the non-operative leg (e.g. knee components), attempt to isolate the non-operative leg from the scan region.

Figure 2.

Figure 3.

## CHINA STRATEGY

CVB has entered into a confidential and non-binding term sheet with a Chinese medical device distributor/ manufacturer (*Partner*) regarding a potential agreement (Proposal) which involves the following key elements:

- Appointment of the Partner for a 10-year term to distribute CVB's products in China, Hong Kong, Macau and Taiwan (*the Territories*) on an exclusive basis;
- Licensing of the Partner for a 10-year term to manufacture CVB's products in the Territories (with market standard royalties), exclusively for sale in the Territories and also for CVB to sell outside of the Territories. CVB will also continue to manufacture in the USA; and
- An equity investment in CVB by way of an issue of new ordinary shares to raise a total of A\$10 million:
  - A\$4 million payable upon signing of binding agreements;
  - further A\$6 million payable in tranches based on achievement of certain performance milestones; and
  - all equity investment expected to be priced at a premium to the current market price of CVB's shares.

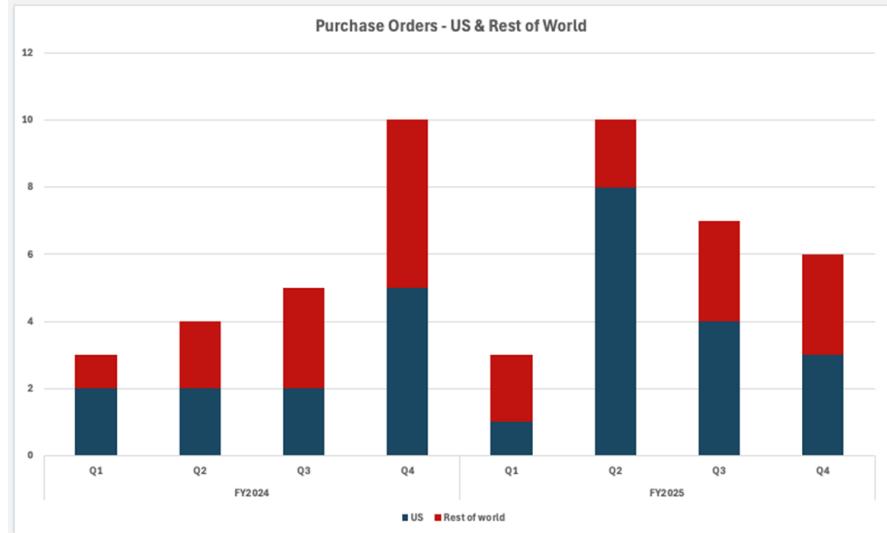
It is presently expected that the total shares to be issued if all milestones are achieved would be no more than approximately 5% of the total issued share capital of CVB.

**CVB is continuing to engage with the proposed Partner, however the Proposal is incomplete and remains subject to satisfaction of a number of further conditions and approvals, including agreement of final terms, execution of necessary transaction documents, Board and other necessary approvals. There can be no certainty that the Proposal will result in the announcement or completion of binding agreements.**

# SALES & GROWTH DRIVERS

## Continuing to roll-out HiRise™ devices

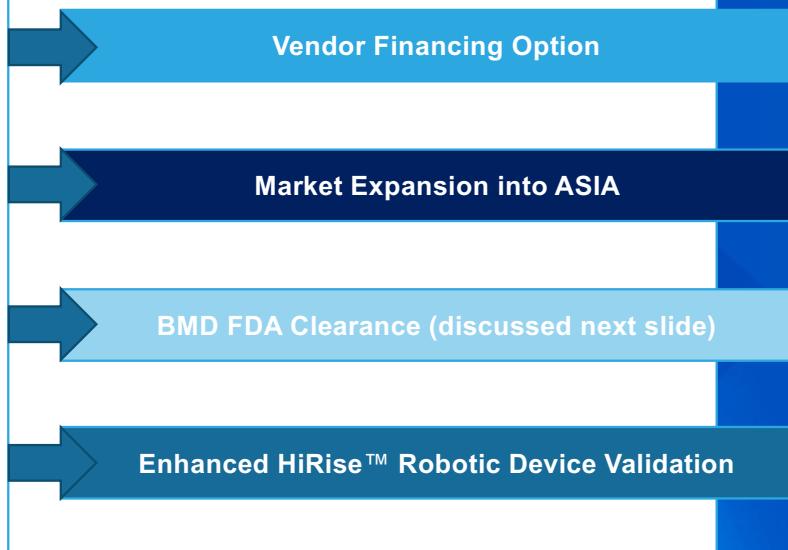
Device Purchase Orders	FY2024				FY2025			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
US	2	2	2	5	1	8	4	3
Rest of world	1	2	3	5	2	2	3	3
Quarter Totals	3	4	5	10	3	10	7	6
Half Year Totals		7		15		13		13
Financial Year Totals				22				26



### Q1 FY 26

- 2 HiRise™ purchase orders to date
- Expecting a further 2 orders
- Tracking on 4 orders for quarter

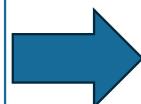
## KEY POTENTIAL GROWTH DRIVERS



## OPPORTUNITY FOR A SAAS MODEL

- CurveBeam is developing AI based models which are run on the HiRise™ & other CT scanners (**MDCT**)
- Most advanced is bone mineral density (**BMD**) to diagnose osteoporosis & aid in presurgical planning for knee and hip replacements

Traditional CT Scanners & HiRise™ would be capable of identifying osteoporosis



- Model capable of interacting with both traditional CT scanners & HiRise™ increases its likely broader adoption
- BMD **reimbursement** targeted in the US under CPT Code 77078 with an average reimbursement rate of **~US\$145**
- CMS has a National Coverage Determination (NCD) in place
- CVB targeting ongoing revenue sharing model with the centres
- CurveBeam AI targeting a gross margin of **~90%**
- Targeting FDA clearance for H1 CY26

Annuity Revenue

High Gross Margins

Category I CPT Code

Broad Adoption Appeal

# IN SUMMARY: 2 BUSINESS MODELS

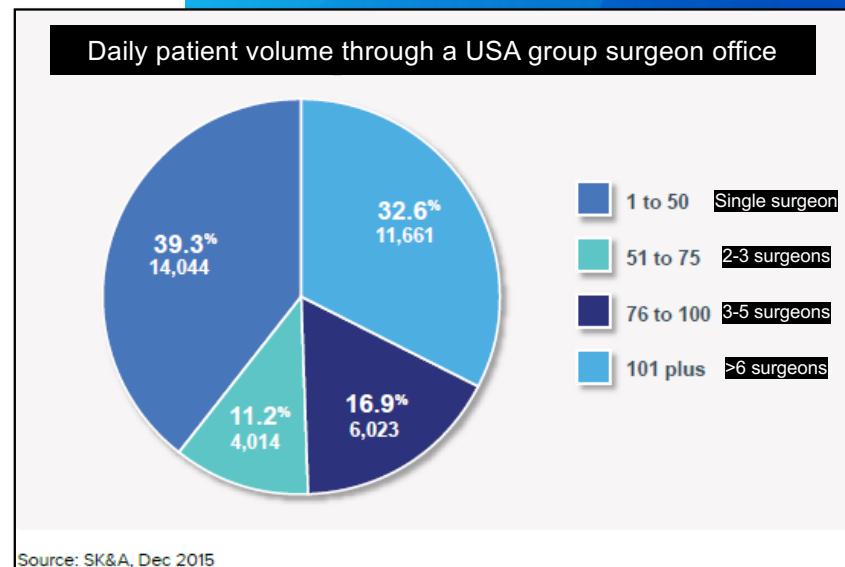
Existing reimbursement codes/coverage targeted to drive both business models

## 1. HiRise CT Business Model

- Stryker sells HiRise™ for US\$410,000 (circa A\$630,000)
- CurveBeam AI transfers HiRise™ to Stryker
- Targeting US CPT code 73700 – CT scan lower extremity, under NCD 220.1
- Targeting circa 50% Gross Profit

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

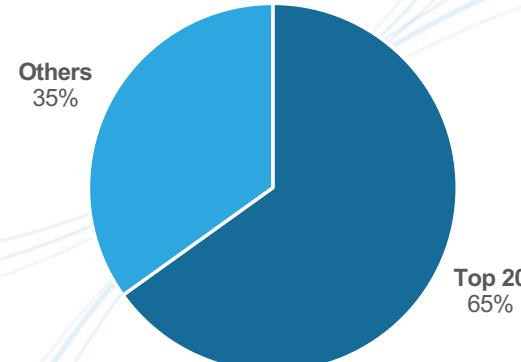
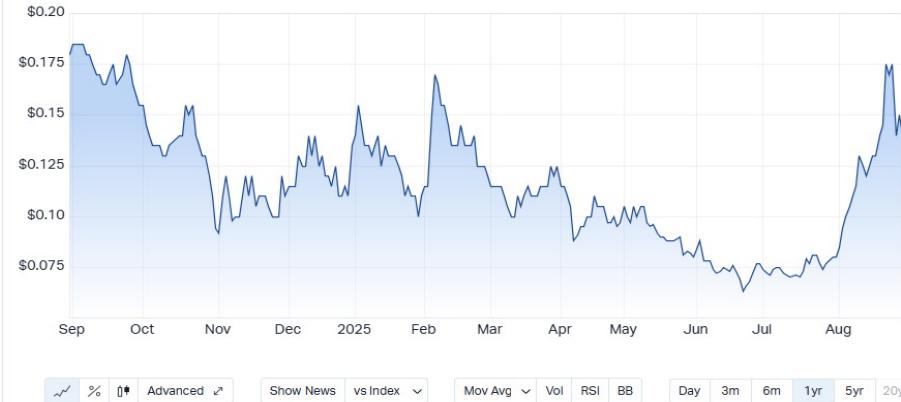
- Targeting FDA clearance for H1 CY26
- HiRise™ – targeting 5 to 15 BMD reports per day with knee/hip surgeons only
- Reimbursement ~US\$145 per BMD report (ave. payment)
- At 10 BMD's per day + 100 USA devices deployed – A\$35m revenue
- Targeting US CPT code 77078 – CT, BMD study, under NCD 150.3
- Targeting 90%+ Gross Profit



# CORPORATE SNAPSHOT

Mkt Cap	~\$44 million
Cash at bank June 30 <sup>th</sup> 2025	\$5 million
FY24 Revenue	~\$6.5m
FY25 Revenue	~\$12.1m
FY24 Loss from ordinary activities	~\$23.1m
FY25 Loss from ordinary activities	~\$16.8m
Institutional shareholding	~50%
Directors, Employees & Related Parties	~27%

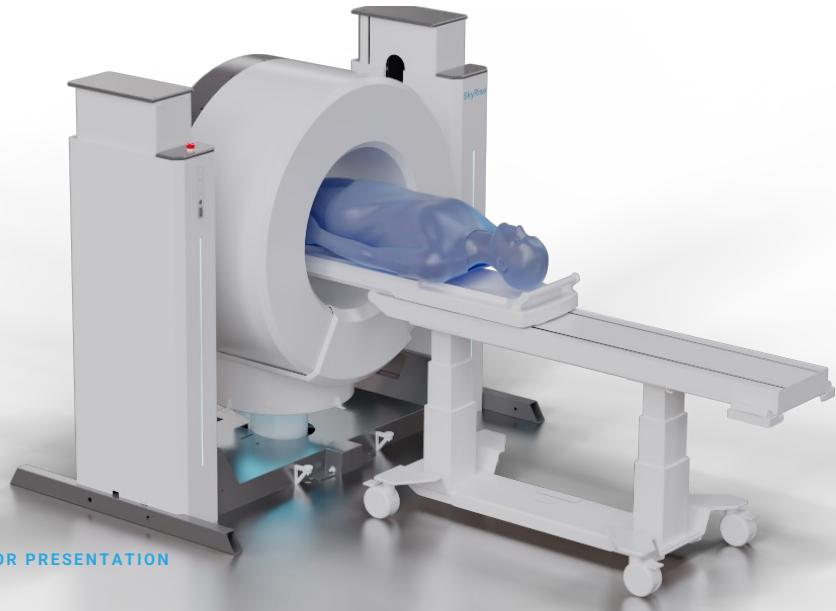
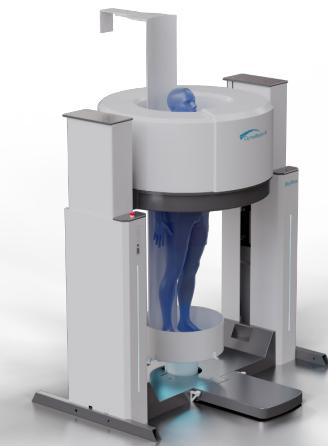
CVB ASX Chart



Substantial Shareholders	%
Firetrail Investments	11.25%
Arun Singh (Director)	10.8%
Ilwella	7.7%
Greg Brown (Director)	4.9%
Frazis	4.6%

## NEAR TERM TARGETED MILESTONES

1	Potential commercial partnership in China	H2 CY2025
2	Vendor financing – first draw downs and proposals available	H2 CY2025
3	Bone Mineral Density (BMD) CT FDA clearance	H1 CY2026
4	Chinese FDA (NMPA) approval for US manufactured HiRise™	H2 CY2026
5	Enhanced HiRise™ Robotic Device Validation	Ongoing



INVESTOR PRESENTATION

## UNDER DEVELOPMENT: Next Generation SKYRISE™ (entire body scan)

- SkyRise targets scans for dynamic structural detail about spinal alignment, joint orientation and supporting muscles. With future bone density & microstructure measures for better planning
- AI will target vertebrae with anatomical landmark recognition – to optimise right site & trajectory
- Longer term SkyRise will introduce a patented dual imaging capability to optimise assessment of soft & hard tissue – detail for paraspinal muscles (PSM) and thoracolumbar spine muscles
- SkyRise targets lumbar and cervical spine through a weight bearing (WB) and non-WB position. Both scans used to aid surgical decisions by assessing spinal stability and improved detail around occult back and leg pain
- Likewise for the shoulder, soft and hard tissue are considered important for planning total joint replacement – both tissues are important in assessing how the shoulder hangs for planning
- SkyRise Shoulder – targeting bone quality detail before first surgical cut is made into the shoulder

# WBCT COMPETITORS – MAINLY LIMITED TO HOSPITALS

## PlanMed Verity

- Available today – FDA, CE, TGA
- Partial foot, Ankle, knee
- Unilateral and not natural bilateral weight bearing
- Difficult for elderly to access – must pull full weight onto affected joint
- To do the knee, contralateral limb approaches a perpendicular position



## Large MDCT scanners – not suited for group surgeon settings



Canon Aquilion RISE



SinoVision

## PlanMed XFI – WBCT – in development/future competition

- No known regulatory clearances to date
- Space & height limits access in group surgeon settings



# CAPITAL RAISING



# CAPITAL RAISING SUMMARY

Successful capital raising of A\$6.5 million, supported by existing and new institutional & sophisticated investors

Placement structure and size	<ul style="list-style-type: none"><li>• A single tranche non-underwritten placement to raise A\$6.5 million (before costs) (<b>Placement</b>).</li><li>• The Company will issue of approximately 72.2 million new fully paid ordinary shares (<b>New Shares</b>) utilising the Company's available placement capacity under Listing Rules 7.1 and 7.1A</li></ul>
Offer Price	<p>The Placement price of A\$0.09 per share ("Placement Price") represents:</p> <ul style="list-style-type: none"><li>• A discount 18.2% to the last close of A\$0.11 on Wednesday, 24<sup>th</sup> September 2025</li><li>• A discount 21.5% to the 5-day VWAP</li><li>• A discount 24.4% to the 15-day VWAP</li></ul>
Ranking	<ul style="list-style-type: none"><li>• New Shares issued under the Placement will rank pari-passu with existing fully paid ordinary shares on issue from their issue date</li></ul>
Syndicate	<ul style="list-style-type: none"><li>• Euroz Hartleys Limited ("Euroz Hartleys") and SP Corporate Advisory Pty Ltd ("Spark Plus") acted as Joint Bookrunners and Joint Lead Managers to the Placement</li></ul>

# CAPITAL RAISING SUMMARY

## Sources, use of funds and indicative timetable

Use of Funds	A\$m
Sales & Marketing	\$2.8m
Research & Development	\$2.0m
Supply Chain	\$0.4m
General Working Capital including Capital Raising Fees	\$1.3m
<b>Total Uses</b>	<b>\$6.5m</b>

Sources	A\$m
Cash Balance as at 30 June 2025	\$5.0m
Offer proceeds	\$6.5m
<b>Total Sources</b>	<b>\$11.5m</b>

Key Event <sup>1</sup>	Indicative Date
Trading halt	Thursday, 25 September 2025
Bookbuild opened & closed	Thursday, 25 September 2025
Results of Placement announced and shares resume trading on ASX	Monday, 29 September 2025
Settlement of Placement	Monday, 6 October 2025
Allotment of New Shares under the Placement	Tuesday, 7 October 2025

<sup>1</sup>Note: This timetable is indicative only and the Company reserves the right to vary the timetable for the Placement at any time before the issue of the relevant securities without notice, subject to the ASX Listing Rules and the Corporations Act and other applicable laws. The commencement of trading and quotation of New Shares is subject to ASX confirmation.

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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

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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).





# INVESTMENT RISKS

# KEY INVESTMENT RISKS

## Potential Chinese distribution/manufacturing partner

- CVB is continuing to engage with the proposed Chinese Partner, however the Proposal is incomplete and remains subject to satisfaction of a number of further conditions and approvals, including agreement of final terms, execution of necessary transaction documents, Board and other necessary approvals. **There can be no certainty that the Proposal will result in the announcement or completion of binding agreements.**

## Reimbursement availability

- 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 favourable coding and coverage policy reimbursement position for its current, cleared CT products in the U.S. and Germany. However, 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 WBCT scans is under a US Medicare National coverage Determination NCD220.1. CT scanning pre-authorization is often needed by surgeons from Medicare Advantage, Blue Cross Blue Shield, and most private insurers –it can be time-consuming and complex and can end in denials. This can impact closing of accounts.
- 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.

## 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.

## 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 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.

## Regulatory clearances

- While the enhanced HiRise™ is FDA cleared, before it can be used as an approved CT for the specific robotic surgical cut guides of a leading robotic knee and hip surgery device, it must meet all validation requirements of the Vendor - both for CT scan image suitability, processing times and/or labelling changes. No assurance can be given that the Group will obtain validation of the enhanced HiRise™
- 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.
- 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.

## 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.

# KEY INVESTMENT RISKS

## 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.

## 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.

## 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.

## Manufacturing and supply chain risk

- The Group's business plans contemplate increasing sales (and production) of its CT machines. If there is a rapid increase in orders, the Group will need to scale its manufacturing activities to meet customer orders in a timely way. A failure to do so could result in production delays, increased costs, and a delay in deliveries resulting in customer dissatisfaction.
- The Group must also carefully monitor its supply chain and manage the risk of issues caused by external events. There is a risk that the Group's measures are insufficient in which case the Group risks not having enough product to meet demand.

## 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, an underperforming partner, as well as potential deficiencies in compliance by distributors with their regulatory obligations, may impact the Group's CT sales and revenue.

# KEY INVESTMENT RISKS

## Cybersecurity and data protection risks

- Laws relating to data privacy are evolving across all jurisdictions. Data privacy, data protection, data localisation and security laws are evolving, and the interpretation and application of these laws in Australia, the United States and Europe (including compliance with the General Data Protection Regulation) are uncertain, contradictory and changing.
- 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.
- The Company's business model is heavily dependent on hosting and accessing protected health information (PHI) and electronic protected health information (ePHI), which is regulated by the United States Health Insurance Portability and Accountability Act of 1996 (HIPAA).
- As the Group is a third-party service provider, its customer base often requires it to enter into agreements which subject the Group to the same obligations relating to the security of PHI/ePHI as those that apply directly to covered entities under the HIPAA. The Group incorporates HIPAA guidance in its product design and development and the Company seeks to mitigate risk of inadvertent disclosure and breach of privacy relating to PHI and ePHI. If the Group were to breach any of its obligations in this regard, it may be exposed to claims for damages and suffer damage to its reputation and brand.

## 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.

## Healthcare and medical device industry risk

- There are a range of competitive risks in the healthcare and medical device industries which may affect the Group's ability to grow its market position and achieve profitability. These include competitors increasing their market share by developing new or improved products with superior specifications, through major strategic alliances with industry vendors and bodies, favourable distribution partnerships and price discounting. Competing products may also be designed to be offered at lower prices or with more favourable reimbursement, through improved payment and coverage access. Further, revenue streams may be impacted by the complex and changing global government regulations which impact healthcare and medical device spending. These include changes in pricing or means of delivery of healthcare and medical device products and services, consolidation of industry participants and reductions in government funding.

## Patient safety and product liability

- The Group faces product liability exposure with respect to its products. This exposure is likely to increase as commercial sales increase. While the Group conducts comprehensive safety and performance testing of new and current technology and regularly reviews customer complaints, there is a risk that the Company's products could cause harm or injury to users or be used off label or not in accordance with instructions for use. Regardless of the merits or eventual outcome, a claim may result in decreased demand for the Group's products, injury to the Group's reputation, withdrawal of clinical trial participants, costly litigation, substantial monetary awards to physicians or patients and others, loss of revenues or an inability to sell the Group's products. In an attempt to reduce the risks, the Company works with well recognised global insurance brokers to have the appropriate levels of targeted insurance coverage in place.

## Foreign exchange risk

- The Group's financial statements are presented in Australian dollars. A substantial portion of current sales revenue and costs are denominated in currencies other than Australian dollars, particularly United States dollars. Future changes in the exchange rates in the jurisdictions in which the Group operates may adversely impact the Group's financial performance. Changes in exchange rates can happen quickly and while the Group works on a natural hedging strategy based on forward estimations of spend in each currency, this does not guarantee that the Company could not be adversely affected by exchange rate fluctuations.