# Superior radiology imaging

CurveBeam AI (ASX:CVB) is a medical technology company that is developing and commercialising medical CT scanners. The company's current flagship product, is HiRise which has been FDA cleared since 2020 and is a 3rd generation product. CVB also has AI algorithms underpinning its scanners and are eventually intended to be commercialised as stand-alone products.

| | |
|---|---|
| Market cap. (A$ m) | 88.2 |
| # shares outstanding (m)^ | 375.4 |
| # shares fully diluted (m) | 407.5 |
| Market cap ful. dil.  (A$ m) | 95.8 |
| Free float | 61% |
| 52-week high/low (A$) | 0.54 / 0.14 |
| Avg. 12M daily volume ('1000) | 161.1 |
| Website | https://curvebeamai.com |

*Source: Company, Pitt Street Research*
*^ Including Placement shares to be issued subject to shareholder approval*

## Better results for doctors and patients

HiRise is a point of care CT scanner that uses Cone Beam Technology and is functional - Weight Bearing. These features allow medical professionals (such as orthopaedic specialists) to do their job better by generating better images more likely to capture medical ailments and do so faster than competing technologies. It also results in lower costs for patients and higher margins. These also help patients by diagnosing conditions that could not otherwise have been detected and potentially enabling a speedier resolution, because the scan and surgical plan could be done in a single visit (point of care).

**Share price (A$) and avg. daily volume (k, r.h.s.)**



*Source: Refinitiv Eikon, Pitt Street Research*

## Already commercialised, with more to come

Although CurveBeam AI has over 170 first- and second-generation scanners placed across the world, there is still significant upside. The company is transitioning to a discrete SaaS model whereby, in addition to upfront costs, it can charge per report. CVB is also hoping to commercialise further devices and the underlying software in its own right. CVB believes there is a combined Total Addressable Market of >A$10bn for CT scanners. This is split across medium to large hospitals ($3.4bn), Orthopaedic Surgeon Group Practices ($3.6bn) and Imaging Chains ($3.7bn). This would equate to more than 17,000 potential installations.

| Valuation metrics | |
|---|---|
| DCF fair valuation range (A$) | 0.60-0.79 |
| WACC | 11.1% |
| Assumed terminal growth rate | 2% |

*Source: Pitt Street Research*

## Significant upside potential

We value CVB at $317.9m in our base case and $417.6m in our bull case. Accounting for shareholder dilution in our model, these figures equate to $0.60 per share and $0.79 per share respectively. We see potential for CVB to create shareholder value as it commercialises its BMD test and increases market penetration of HiRise, both of which will grow revenues and margins. The key risks facing the company, outlined in further detail on p.21 include (but are not limited to) regulatory, commercial, key personnel and capital risks.

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# CurveBeam AI

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## Introducing CurveBeam AI (ASX:CVB)

*CurveBeam AI was formed in 2022 from a merger of StraxCorp and CurveBeam.*

CurveBeam AI was formed in 2022 from a merger of StraxCorp Pty Ltd and CurveBeam LLC. CurveBeam manufactured CT imaging machines that had very low radiation and were capable of imaging someone when they are weight-bearing, and StraxCorp had artificial intelligence software as a service in the cloud that could be used with these machines, specifically to assess bone fragility. The companies had been working together for more than four years before formally joining forces. CurveBeam AI Limited was listed on the ASX in 2023.

*The company's flagship product is the CT scanning device HiRise.*

The company's flagship product is the CT scanning device HiRise, which is a 3rd generation scanner. It is also working on next generation scanners In-Reach and Skyrise, as well as AI algorithms for the manual processing of BMD (Bone Mineral Density) and bone microstructure in OssView.

## Ten Key reasons to look at CurveBeam AI

1) **CurveBeam AI offers the best of both worlds for investors.** It offers the investors a degree of certainty thanks to having a product commercialised and having significant experience with it. And it also offers significant upside with potential for further market penetration and for new products to be approved (specifically the discrete SaaS BMD). It is rare for an ASX medical technology company to be in such a situation.

2) **HiRise possesses a solid distribution network and client book.** The company's key distributor for the US market is Stryker Corp Foot and Ankle division, which is one of the world's leading medical technology companies specialising in orthopaedics. Over 170 generation 1 and 2 scanners have been placed across leading healthcare institutions around the world such as the Mayo Clinic, Duke Health and NYU Langone. Furthermore, the company's order book is growing rapidly, quarter by quarter, with 10 received in 4Q24, up from 6 in 3Q, 4 in 2Q and 3 in 1Q. CurveBeam AI's aim is not just to win new clients but to upgrade existing clients to its latest generation HiRise devices.

*HiRise is the first device that allows a diagnosis and surgical plan in the same visit.*

3) **HiRise is a point of care scanner that can generate better and faster results, and consequently better outcomes for patients**. Since HiRise devices are weight-bearing they can detect ailments that would be impossible to detect with non-weight bearing devices. Moreover, because HiRise can generate faster and more accurate results, they tend to promote shorter and less frequent clinician visits. Indeed, HiRise is the first device that allows a diagnosis and surgical plan in the same visit. Another benefit is that HiRise uses less radiation, and hence make it possible to be used by clinicians which may not find it feasible to install the necessary radiation shielding infrastructure.

4) **CurveBeam AI is building a high-margin business model.** Right now, the company sells its devices for upfront payments and ongoing service charges. The company is targeting a 50% gross profit on each HiRise machine. In the future, the company hopes to sell through a discrete SaaS Model where it receives a fee for each BMD report generated through each machine. The company has estimated that a mere 100 devices across the US (out of a potential maximum of 17,000 devices) generating 10 BMD reports per day would target A$35m in revenue at 90%+ gross profit.

5) **A substantial and highly lucrative market awaits CurveBeam AI**. CVB believes there is a combined Total Addressable Market of >A\$10bn. This is split across medium to large hospitals (\$3.4bn), Orthopaedic Surgeon Group Practices (\$3.6bn) and Imaging Chains (\$3.7bn). This would equate to more than 17,000 potential installations. More broadly, musculoskeletal disorders affect about 1.7 billion people worldwide, 700 million of which suffer from osteoporosis or osteoarthritis.

6) **The company has a secure supply chain**. CurveBeam has two manufacturing cells in place in Hatfield, PA. Each cell can produce one HiRise per week which equates to 96 per year across the two of them. The facility could expand to 10 cells if required, equating to 480 per year. In its inventory and committed supply chain, CurveBeam AI has the components that would support the construction of up to 100 HiRise units. This is important in an era of constrained supply chains that has hindered even the largest of healthcare companies.

7) **BMD presents the opportunity for further upside**. CurveBeam's BMD is an AI software product that automates the manual processing steps to measure bone fragility, named after the metric (Bone Mineral Density) that it tests for. The BMD report, delivered to physicians under a discrete SaaS model, can identify fracture risk and potentially treating or preventing conditions or accidents that may occur. The company expects to submit to the FDA in December 2024/ January 2025 with US commercialisation planned shortly after clearance (expected within 6-12 months of submission).

8) **CurveBeam AI has a quality leadership team with skin in the game.** This is a legacy of the former two merged companies coming together. StraxCorp CEO Greg Brown is CEO of the merged company while Former CEO of CurveBeam LLC Arun Singh is a director, Chief Technology Officer, Chief Operating Officer and President of the USA and Europe. Both served in their positions at the former entities for over a decade and oversaw the development and early commercialisation of their respective technologies. Mr Brown and Mr Singh also have significant skin in the game, owning over 18% of the business between them. Also worth noting is Non-Executive Director and renowned biotech investor Hashan De Silva who as former Head of Research oversaw the investment by Karst Peak Capital who own 6.8%. Other key managers and directors own a further 4%[1].

9) **There are several upcoming catalysts to drive shareholder value.** These include: The FDA clearance and consequent distribution of enhanced version of HiRise; regulatory approval for BMD (which is anticipated in mid CY25); the continued development of SkyRise; and growing revenues through introduction of the 2nd revenue model that will be a subscription based SaaS model and recurring.

10) **CurveBeam AI is undervalued at the current share price.** We have valued the company at 60 cents per share base case and 79 cents per share in our optimistic case and believe there is a realistic chance the company could re-rate if it can achieve some or all these catalysts.

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[1] See Appendix II & IPO prospectus p.20

## CurveBeam AI's History

*Both StraxCorp and CurveBeam's products were based on several years of successful and peer-reviewed academic research.*

As a company that only came to be two years ago from an M&A deal, the history of CurveBeam AI is tied up in the individual stories of the two companies (StraxCorp Pty Ltd and CurveBeam LLC.). Both companies' products were based on several years of successful and peer-reviewed academic research. The merger of these companies was a win-win situation, with both companies' products complementing each other.

### StraxCorp's origins

Straxcorp had its origins at the University of Melbourne, where researchers were developing AI algorithms to accurately model a person's anatomy and to assess bone fragility. These algorithms were spun out to be commercialised in 2009 and underwent over a decade of clinical validations using bone microstructure analysis. It is these algorithms that have evolved into OssView.

The research culminated in a clinical validation study that enrolled 2000 women and ran over 8 years to a clinical end point of a fragility fracture. The results of which were published on the Journal of Bone and Mineral Research in late 2019[2]. The problem the research sought to solve was that 70% of women sustaining fractures had 'normal' Bone Mineral Density (BMD) – or osteopenia - and so would not have their injuries identified if radiographers used BMD alone. The study found that by using a Structural Fragility Score (SFS) for a joint's microstructure, not only could women who went on to fracture be identified when they otherwise would have gone unidentified by BMD, but potentially those at imminent and longer-term fracture risk.

### CurveBeam's origins

**CurveBeam** was also formed in 2009. Arun Singh, who is still involved with the company today as COO, CTO and President of the US and Europe, founded CurveBeam after fracturing his own foot and saw that specialists could only guess the extent of his injuries. Back then, CT scans were only possible with the patient lying down. Although X-rays could be done with a patient upright, they were limited because they were two-dimensional images of complex three-dimensional objects.
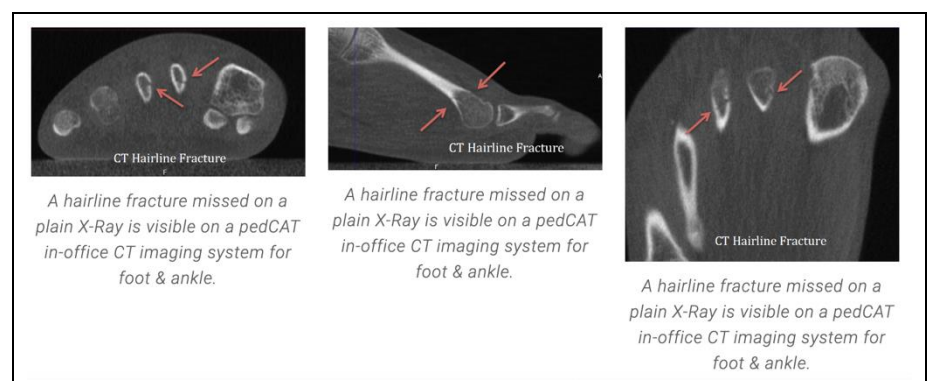
Mr Singh designed a weight bearing CT scanner for the lower extremities using his successful experience in designing and commercialising the i-CAT for dental offices. In approximately one year after the company's 2009 founding, its team went from prototype to investigational studies that were published. FDA clearance for CurveBeam's first-generation device (Pedcat) followed just two years thereafter (in 2012). A limitation of Pedcat was that it could only scan the feet and ankles, although this was partially resolved in the second-generation device (Lineup) that could also scan the knees and was cleared by the FDA in 2019. The third generation was HiRise which is the flagship product of the merged company. FDA clearance came for HiRise in late 2020, and Pedcat and Lineup were consequently discontinued.

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[2] https://onlinelibrary.wiley.com/doi/full/10.1002/jbmr.3924

In late 2020, the company counted US President Joe Biden as a patient. Just prior to his inauguration, America's Commander in Chief suffered a hairline[3] foot fracture and underwent a weight bearing CT scan using one of CurveBeam's devices to monitor the fracture's healing[4]. The President's experience was an eye-opening event for the US medical imaging market, not just the fact that CVB's scanner (it was PedCat in this instance) confirmed a hairline fracture, but also that the initial X-Ray did not show any obvious injury because it was too small to be picked up. Even existing CT scanners can struggle to pick up hairline fractures (Figure 1), although CurveBeam AI's scanners are able to.

**Figure 1: Example of hairline fractures – not President Biden's fractures**



A hairline fracture missed on a plain X-Ray is visible on a pedCAT in-office CT imaging system for foot & ankle.

A hairline fracture missed on a plain X-Ray is visible on a pedCAT in-office CT imaging system for foot & ankle.

A hairline fracture missed on a plain X-Ray is visible on a pedCAT in-office CT imaging system for foot & ankle.

Source: Company

## The merger and its aftermath

*CurveBeam and StraxCorp had been collaborating since October 2017. The companies merged, effective 12 October 2022, and the company was named CurveBeam AI.*

CurveBeam and StraxCorp had been collaborating since October 2017 when the pair teamed up to create, test and ultimately sell a modified CurveBeam machine to provide a consistent high resolution scan for StraxCorp's AI based SaaS product in the cloud. The companies merged, effective 12 October 2022, and the merged entity was named CurveBeam AI. It was also in 2022 that the company entered into a co-promotion and distribution agreement with NYSE-listed medical technology distributor Stryker. This partnership, with their foot and ankle division, has proven to be critical in raising awareness of CVB's products and achieving the sales growth that it has up to now, and inevitably will continue to be.

*The company has a base of nearly 200 CT devices globally, more than two thirds of which are in the United States.*

Less than a year following the merger, in August 2023, the company listed on the ASX. The company raised $25m in its public listing, on top of $25m it had raised earlier in late 2022 and early 2023 in its last pre-IPO funding round. Since the merger, the company has enjoyed a strong period of sales growth of its CT devices, receiving 16 device purchase orders in 3Q23 and 4Q24 combined (Figure 2). The company has a base of nearly 200 CT devices globally, more than two thirds of which are in the United States.
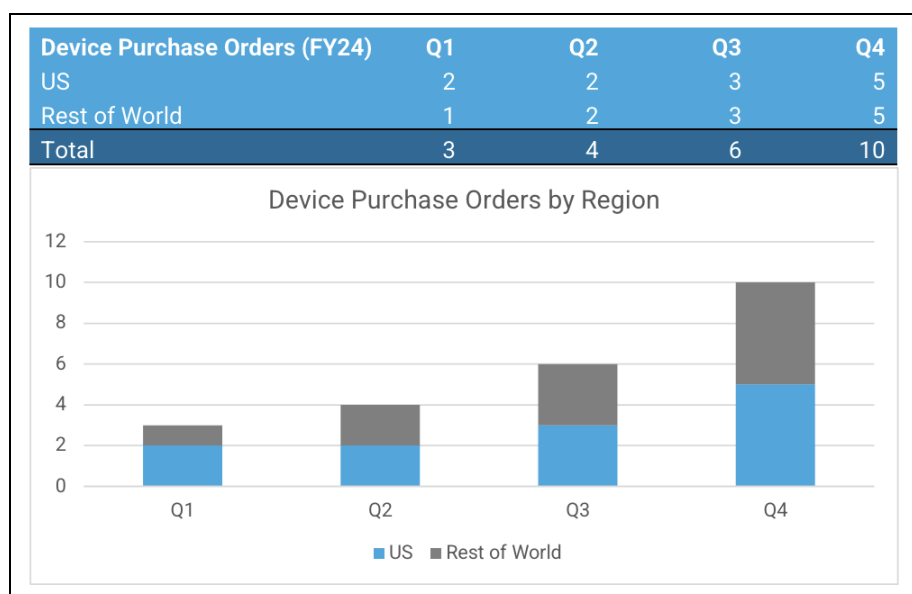
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[3] A very small fracture
[4] https://www.inquirer.com/business/biden-hurt-foot-curvebeam-x-ray-ct-scan-singh-20210118.html

**Figure 2: CurveBeam AI's Device Purchase Orders in FY24[5]**

| Device Purchase Orders (FY24) | Q1 | Q2 | Q3 | Q4 |
|---|---|---|---|---|
| US | 2 | 2 | 3 | 5 |
| Rest of World | 1 | 2 | 3 | 5 |
| Total | 3 | 4 | 6 | 10 |



*Source: Company*

All the while, development of the company's product pipeline continued, including enhanced versions of existing devices as well as the new product suite of algorithms (particularly BMD). In early 2024, the first total non-robotic knee replacement surgery based on a HiRise was planned and completed. The scan was used to create custom cut guides and custom prothesis. Also in early 2024, a study was published showing that the company's Autometrics DLAI platform could provide automated measurements that were as accurate as surgeon generated manual measurements, while being 97% faster.

## CurveBeam AI's Technology and Product Suite

CurveBeam AI's current product suite consists of CT scanners and AI software products (Figures 3 and 4). CT (short for Computed Axial Tomography) scanners use X-rays to create cross-sectional images of the body's internal structures. It combines multiple X-ray measurements taken from different angles and uses computer processing to produce tomographic (cross-sectional) images and using these images to form a 3D representation of the scanned area.

**Figure 3: CurveBeam AI CT scanner product suite**

| Name | Limbs examined | Commercial status |
|---|---|---|
| InReach CT Scanner | Hand, wrist, forearms, elbow & lower extremities | Commercialised |
| HiRise CT Scanner | Feet, ankle, knees and hips | Commercialised |
| SkyRise CT Scanner | Feet, ankles, knees, hips, spine and shoulder | Under development |

*Source: Company, Pitt Street Research*

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[5] Includes all devices, not just HiRise

**Figure 4: CurveBeam AI product suite (Software)**

| Name | Purpose | Commercial status |
|------|---------|-------------------|
| CT BMD | Measures BMD reports from HiRise CT scans | Awaiting clearance |
| SFS | Triages BMD results from HiRise CT ankle scans and (for patients over 70) screen non-osteoporotics from InReach CT scans | Development on hold |
| CubeVue | Provides visualisation tools on a desktop to enhance analysis of datasets collected with CT scanners, including digitally creating synthesised x-ray views from original CT scans. | Clearance in 2018 |
| Autometrics | Measures the geometric properties of bones to support orthopaedic specialists in the evaluation for pre- and post-surgical analysis | Awaiting clearance |
| Axiometrics | Measures the geometric properties of bones to support orthopaedic specialists for pre- and post-surgical analysis | Awaiting clearance |

*Source: Company, Pitt Street Research*

CurveBeam's flagship product at present is HiRise. At the moment, the company generates revenues from up-front capital costs of HiRise (US$410,000/A$645,000 as at FY24) and from service fees. In the future, it is envisioned that CVB will commercialise its BMD scanning IP, making it available to existing HiRise customers, charged on a per scan basis. The idea is that the scanners can provide an easy scan, and the company's AI analysis products can make a quick analysis and provide reports to surgeons, enabling them to determine whether or not surgery may be needed, and if surgery is needed, develop a customised plan that is appropriate for the individual patient's circumstances (Figure 5).

**Figure 5: CurveBeam AI's Imaging equipment combined with OssView or BMD[6]**
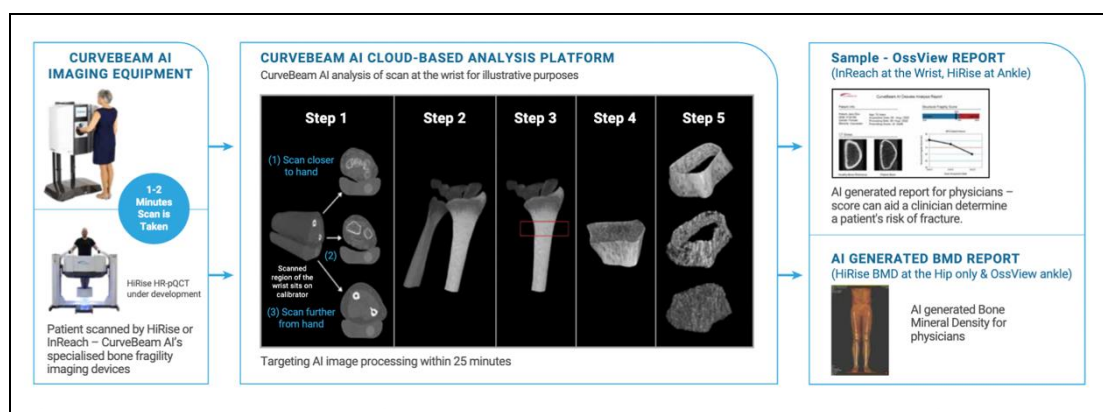


*Source: Company*

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[6] OssView at the wrist is developed and OssView at the Ankle for HiRise is under development. The Ankle product needs further development before the company can proceed to a clinical trial. BMD for HiRise is the highest priority.

## The 3 important traits of HiRise's technologies

Before we delve into further details about HiRise and other technologies the company has, it is necessary for us to explain 3 important traits underpinning HiRise's CT scanners including that they:

- Are weight bearing, and capable of being used for non-weight bearing
- Use Cone Beam CT, so are point of care (Surgeon office capable) and
- Assess BMD at the WHO assigned anatomical point of the femoral neck.

Understanding these will make it easier for investors to understand the competitive advantages the company has.

## What are weight bearing images?

Weight bearing images are images taken when a joint is 'weight-bearing', where weight is put on part of the body and hence more stress is placed on them. Weight bearing images provide a more precise evaluation of joint alignment, weight distribution and movement especially weight-bearing activities, particularly pressing objects of any kind. Because the joint or limb is subject to more force, images that are taken when a joint is weight-bearing can help identify conditions that may not be apparent with non-weight bearing images. This is particularly true with feet and ankle disorders (Figure 6) where conditions such as flatfoot, high arch and foot deformities may be missed entirely when the feet and ankles are in a non-weight bearing position. The two images below are of the same joint, but while the non-weight bearing image shows a healthy joint, the weight-bearing images does not.

*Images taken when a joint is weight-bearing can help identify conditions that may not be apparent with non-weight bearing images.*

**Figure 6: Weight bearing v non-weight bearing comparison**



Non-weight bearing image      Weight bearing image
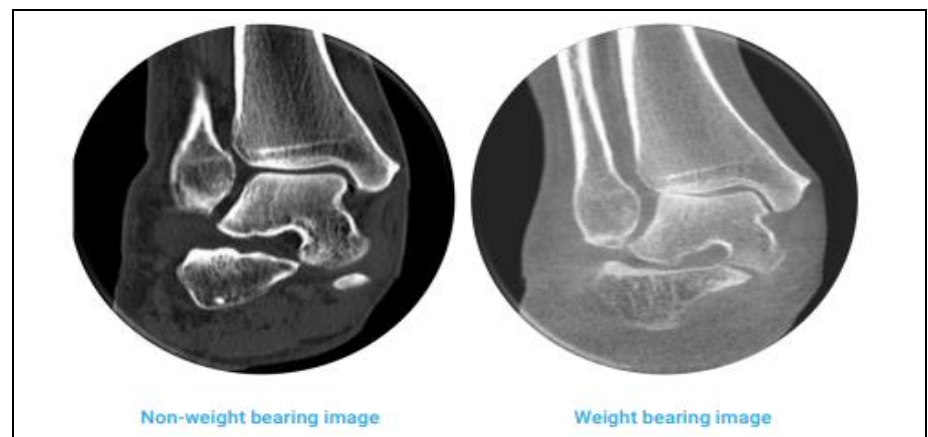
*Source: Company*

You may wonder how a foot can bear weight when there is a fracture without pain to the patient. This is where a non-weight bearing image would be more appropriate, but weight-bearing images can diagnose conditions that are not so obvious – they may not be apparent when the joint is non-weight bearing.

## What is Cone Beam CT?

Cone Beam CT is so-called because of the conical-shaped beam it produces. It has the source at one end of the diameter, the target at the other end and the object in the middle. This compares to traditional CT scanners which use a fan-shaped beam and need multiple sequential slices to reconstruct images.

Cone Beam CT is an advantageous method of CT because:

- It provides more accurate images, not just because they are 3D but the cone-shape ensures the reconstructed virtual 3D object matches the dimensions and density of the original object with high accuracy. This allows for better visualisation and analysis.

- It operates faster than traditional CT scans (being able to scan with just one rotation) and can allow the imaging, diagnosis and surgical plan to be done in the surgeons office (point of care), all in the same visit; and

- Despite being more comprehensive, CBT machines tend to be simpler and smaller in design, resulting in lower maintenance and operational costs.

## What is Bone Mineral Density (BMD)?

Bone Mineral Density, in a general sense as opposed to CVB's product, is the volume of calcium and other minerals in a given area of bone. The denser the bones are, and thus less likely to fracture. Bones become less dense as we age and/or develop medical conditions and the lower the BMD, the more fragile these are. BMD is widely used to diagnose or monitor osteoporosis as well as to risk the assessment of fractures. Guidelines from the American Academy of Orthopaedic Surgeons (AAOS) require a bone quality assessment to make decisions in total joint replacements and BMD can fulfil this objective.

**How is BMD currently diagnosed?** Presently, BMD assessments are done through **DEXA (Dual-energy X-Ray Absorptiometry) technology** which utilises two X-ray beams with different energy levels which are aimed at the person's bones. BMD is determined by subtracting out soft tissue absorption in the second image. The most common DEXA X-ray lines are Lunar iDXA (GE), and Horizon DXA (Hologics).

Although the DEXA technique is widespread, DEXA underserves the market because it has shortcomings so far as identifying patients at risk of fracture are concerned for several reasons including that:

- Under current US Medicare guidelines, patients need to have osteoporosis in the first place in order to access treatment. Yet bone fragility can be identified at an earlier stage (at osteopenia), particularly postmenopausal women and elderly men.

- DEXA cannot identify the loss of bone microstructure which is a key indicator of fracture risk.

- Because of the size of devices, training requirements and time taken to conduct the tests (up to 20 minutes), machines tend to only be found in large clinical centres.

For all these reasons, very few of those recommended for screening are actually screened – 1 of 12 of those recommended for screening in the US and only 12.3% of elderly woman in Germany[7]. And so, patients at risk of fracture are not even screened before they suffer a fragility fracture. These is a need for solutions that assess the bone density with the bone microstructure and

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[7] P.37 of the company's prospectus, derived from a Frost & Sullivan report released in April 2023 that was commissioned by the company.

hence aid in the detection of fracture risk of patients in the early stage of bone fragility. This could reduce adverse events in total joint replacement patients and prevent first fragility fractures and consequently make substantial savings across healthcare systems by reducing the need for fracture related treatments and services. This is where CVB's solutions (the company's scanners and AI software) come in.

## CVB's CT scanners

### HiRise

*HiRise is the first product capable of conducting weight bearing CT imaging of the feet, ankle, knees and hips.*

HiRise is CVB's flagship CT scanner. It is FDA-cleared, CE-marked and ARTG listed in Australia. HiRise is the first product capable of conducting bilateral weight bearing CT imaging of the entire lower extremities in a surgeon office setting (point of care) - the feet, ankle, knees and hips – and can also perform non-weight bearing CT imaging too. It has the flexibility to scan with patients in a variety of positions from standing 'in' the device (Figure 7) to seated on a medical bed with the feet in the scanner or with their hand or wrist in the device. It scans with a radiation dose 30 to 60% less than traditional CT. It is compact, with a footprint of 185cm x 145cm, can be plugged into standard 230VAC/30A plugs and has simple protocols that can easily be learned by frontline healthcare staff. It takes less than 55 seconds to scan per joint and provides less than 18 seconds of X-ray exposure. HiRise is offered to customers with CVB's CubeVue software that fully integrated with the device to provide powerful 3D visualisation tools to enhance dataset analysis, as well as to provide interpretation and treatment planning tools.

**Figure 7: HiRise (used with the patient in a standing position)**



*Source: Company*

CVB has been developing an enhanced version of HiRise that has a higher X-ray energy CT with clearer images for a broader range of patient body types. This is required for custom protocols for hip and knee robotic surgical systems that use Patient specific instrumentation (PSI) - a modern technique in knee replacements where specific moulds are used as cutting guides during the surgery, with those moulds created through pre-operative scans. In mid-July 2024, this version was cleared by the FDA, allowing it to be used in routine medical practice settings in the same way as the existing HiRise device.

The enhanced version is expected to convert a significant proportion of the company's sales pipeline, because feedback from prospective clients have suggested that once robotic assisted surgical system PSI's, for all patient types, are validated this should allow would-be clients committing. The new device is targeting validated protocols for the knee and hips by 1Q FY25, something that will also increase the market given there are more than 4 times the number of knee and hip replacements than ankle procedures in the US[8].

## InReach

InReach is a scanner that is capable of low- and high-resolution CT scanning of the hand, wrist, elbow and distal lower extremities. The device is designed for the limb to be placed inside it. From undergoing scanning, a patient's fracture risk can be diagnosed. InReach was FDA cleared in 2017. In the future - after BMD has been cleared and is commercialised - it is envisioned that OssView (CVB's proprietary cloud based SaaS product based on the successful clinical trial in France) could be integrated with the device and add to the utility of the BMD results for surgeons.

## SkyRise

*SkyRise aims to overcome obstacles associated with current methods of spinal imaging.*

CVB is developing SkyRise, a weight-bearing CT imaging platform that will be the 4th generation platform the company has developed (Figure 8). SkyRise will have neck to foot capability, but its specialty will be spine and shoulder imaging. SkyRise aims to overcome obstacles associated with current methods of spinal imaging including natural movement occurring from breathing and the presence of metal implants. The first version of the product will be CBCT only. In the second version, it uses a patented dual technology scanner, capable of soft tissue and hard tissue assessment in both weight bearing and non-weight bearing CT. It has a streamlined design with a small footprint and a low height requirement. Beta site testing of prototypes is targeted for version one (CBCT) for FY25.

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[8] Frost & Sullivan data.

**Figure 8: SkyRise**



*Source: Company*

## BMD assessments

*CurveBeam is developing its own SaaS-based CT BMD assessment that could be generated from HiRise scans.*

CurveBeam is developing its own SaaS-based CT BMD assessment that could be generated from HiRise scans. This will assist surgeons in identifying fracture risk and potentially pre-treating bone fragility, as part of the treatment plan for a patient's other conditions. The assessment is automated for the surgeon and means a patient can have their diagnosis and surgery plan done at the same appointment, avoiding the need for another DEXA scan. The company is seeking a dedicated FDA clearances for BMD scans at the hip. When it is approved, the company will charge a fee of US$90 per scan and envisions there is a revenue opportunity of $35m just from just 100 scanners, a very small proportion of the 17,000+ devices the company estimates as a market opportunity.

## Other products

**OssView** is a bone microstructural assessment at the ankle based on the SFS algorithm that was clinically proven in France and published in 2020. It has been given an FDA Breakthrough Device Designation. The company has placed this on the backburner deferring investment while it advances BMD first, so OssView will not be mentioned further in this report.

**CubeVue** is software that integrates with the company's scanners, providing 3D visualisation tools to assist with the interpretation of images and planning of ailment treatment.

**CubeVue Autometrics** uses AI to identify and segment each individual bone and automatically calculate key biometrics of the foot and Ankle utilising Depp Learning AI to generate a fully segmented bone model within an hour, without any requirement for manual inputs. It will also be available for the knee and the hip in the future. In March 2024, a study was published in the Foot & Ankle Surgery journal, depicting that the AI-aided automated measurements were as accurate as surgeon generated manual measurements while being 97% faster[9]. FDA clearance for this product is targeted for FY26.

**Axiometrics** is a software application that measures the geometric properties of bones to support orthopaedic specialists in the evaluation for pre- and post-surgical analysis.

## The Market Opportunity for CurveBeam AI

### The Total Addressable Market

CVB believes there is a combined Total Addressable Market of >A$10bn, just for HiRise (Figure 9). This is split across medium to large hospitals ($3.4bn), Orthopaedic Surgeon Group Practices ($3.6bn) and Imaging Chains ($3.7bn). This would equate to more than 17,000 potential installations[10]. A further 4,387 centres have been estimated to exist in Germany[11].

For BMD, the company has estimated there is an A$2.7bn market per annum. This assumes A$350,000 per target SaaS revenue and the same number of installation sites as assumed in the forecast for HiRise's TAM. It also assumes 10 CMD CT scans per day, 5 days a week for 50 weeks a year at a price of US$90 per scan.

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[9] https://www.sciencedirect.com/science/article/pii/S1268773124000419?via%3Dihub
[10] This figure was calculated by multiplying the indicative install price of a HiRise in the US by the estimated 17,000+ potential installation sites in the US, derived from Frost & Sullivan research.
[11] Also from Frost & Sullivan research.

**Figure 9: The Market Opportunity for CVB's key products**



CURVEBEAM TECHNOLOGY PLATFORM OVERVIEW

CurveBeam AI has regulatory clearances for WBCT devices in-market, including the new Enhanced HiRise™ – CVB target first automated BMD report for surgical planning for mid 2025

| | 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™ | | In market. Enhanced HiRise™ FDA 510(k) cleared | ~A$10bn¹ (capital sales) | ~50% | A$645,000 per HiRise unit |
| | Next generation AI bone segmentation and 3D modelling | AutoMetrics | | FDA filing targeted for FY25. User subscription-based SaaS | | | |
| BONE HEALTH | AI delivered CT Bone Mineral Density (BMD) assessment for surgical planning for hip & knee scans | AI Generated BMD Report on the pre-existing MDCT & HiRise scans – SaaS based product | | Enhanced HiRise™ FDA 510(k) cleared | TAM A$2.7B per annum² (BMD scan market) | Targeting 90%+ | ~A$350,000 future p.a SaaS target per HiRise³ (for BMD scans only) |
| | | AI Generated CT BMD Report on the Enhanced HiRise at the hip – opportunistic scan only | | BMD FDA filing targeted for end CY24 | | | |
| | AI processed Structural Fragility Score of the ankle (OssView) | AI Generated OssView Report on the HiRise ankle & wrist scan – triage product for BMD result | | In Development – OssView of the ankle; OssView wrist (developed but on hold) | | | |

*Source: Company*

## Why customers would want CVB's solutions

1. **They can ensure more time and money for the doctors,** since:
   i) **There is lower capex than for traditional CT scanners**,
   ii) **There are faster and immediate results (point of care scanning)**, as we've noted above. This reduces the number of visits and the need for patients to be referred to outside imaging.
   iii) **The provider can make a solid margin on the products**. It is possible to achieve break-even with HiRise with as few as 1.5 reimbursed scans per day each month. Moreover, paying US$90 to CVB and being reimbursed US$140 represents a 55.5% gross margin.
2. **Patient satisfaction will increase**. The speed and accuracy of results will be the primary cause of this increased satisfaction.
3. **Less radiation is used.** Radiation has potential to cause damage, specifically because it can remove tightly bound electrons from atoms, creating ions, which can lead to cellular and molecular damage. A one-off scan in a healthy patient may be unlikely to cause substantial damage, but the same thesis cannot be said in respect of repeated images and images in patients with existing conditions. Radiation can also be a problem for medical facilities that use CT scans, since the need to install shielding infrastructure may make the products economically unfeasible for certain medical practices. Also, when patients have to be referred onward to another specialist, the time before a scan and a diagnosis increases. CT scans are more effective than X-rays, but they tend to use higher doses. This is not the case with CVB's machines, which use up to 30 to 60% less radiation than traditional CT. And the fact that only one scan will be required helps reduce the radiation risk even further.

## CurveBeam AI's Business model

### Manufacturing

The company manufactures its devices at a facility in Hatfield, Pennysylvania that also serves as a hub for the company's customer care, IT and other support units. Certain parts of the device (such as the devices' mechanical structure and frame, most electronic and electromechanical component, statutory labels and the covers) are produced by two third party suppliers that operate within short distance from Hatfield. The exact split is the company's discretion, and it is envisioned that suppliers in Pennsylvania and neighbouring states could easily be engaged if required. The company's algorithms and SaaS products are developed and coded by an in-house technology team in Melbourne, and it is deployed utilising Amazon Web Services (AWS) on-demand computing resources and data storage capacities in the cloud.

### Distribution

Since August 2022, CurveBeam has partnered with the foot and ankle business of Stryker Corporation to sell HiRise (and in turn its financing program for customers) in the US only. The NYSE-listed company has the highest market share for several key foot and ankle procedures, including primary ankle replacement, total ankle fusion and midfoot fixation. CurveBeam AI will continue to rely on Stryker for the foreseeable future.

### Reimbursement

*The average Medicare reimbursement rate in the USA was as low as circa US$100 to 140 per scan in 2022.*

Medical reimbursement in the USA requires a CPT (Current Procedural Terminology) code, with an assigned payment and medical coverage policy to bill for procedures. There is a CPT code for the CT scan - diagnostic radiology of the lower extremities, and the US Medicare reimbursement rate was as low as US$100 per scan ranging to $140 in 2022. US private insurers can be as high as $290 per scan. An average of US$220 is seen in parts of the USA market based on payer mix. It is important to note that there would be a separate reimbursement in the event that CT BMD was commercialised.

There is no distinction between weight-bearing and non-weight bearing scans, although prior authorisation of the insurer is often required for any scan. One of CVB's clients has observed that it is able to achieve break-even on the costs of the device purchase, plus room conversion, with as few as 1.5 reimbursed scans per day each month. CVB believes multiple existing codes will cover BMD upon clearance, including for BMD from a scan CT, subject to the conditions of those codes (such as age, gender, comorbidities and other risk factors).

In Germany, eligibility for reimbursement is established by statutory health insurance (Gesetzliche Krankenversicherung or GKV). There are specified reimbursement rate in a medical fee schedule, but these can be augmented based on special situations and the type of insurance carried by the patient. Reimbursement is based on digital volumetric tomography (DVT), an imaging method cased on Cone Beam CT. Patients with GKV are only eligible for 2D diagnostics (through X-ray or in certain circumstances, CT and MRI), but have the option to pay for 3D diagnostics. Private insurance cover CT and DVT.

## Could CurveBeam AI be Pro Medicus 2.0?

Maybe not in the sense that CVB could reach PME's ~$13.6bn market cap[12] anytime soon. But is not unreasonable to see similarities between CVB's business model and PME's. We want our readers to think again for a moment about our above observations that surgeons would make a substantial gross margin using CVB's solutions. A high margin model has been the secret sauce of PME's success with its own radiology solutions in the US market, along with its success amongst investors. In 1HY24 (the 6 months to 31 December 2023), PME only made A$76.3m in revenue, but it made a 99% gross margin and 48% net margin. And so, PME can make a lot of revenue and profits even with just a small market share. PME estimates A$608m in revenue over the next 5 years[13] and that it has only penetrated 7% of the potential market[14].

*Although CVB and PME sell different solutions, both increase a surgeon's productivity by speeding up tasks.*

It is important to note that CVB and PME sell somewhat different products. CVB sells the imaging devices themselves and will eventually sell an AI based diagnosing mechanism (BMD). PME has a software (Visage) that allows the sharing and analysis of images taken by other devices – rather than streaming thousands of 3D images, all of them are merged into a 3D image and can be streamed to a doctor or radiologists' office, computer or phone in a file size appropriate for those smaller devices. Both, however, achieve a similar feat in increasing a surgeon's productivity by speeding up tasks that other technologies can only accomplish in time-consuming manners.

There are a couple of disadvantages CVB has compared to PME that would limit CVB's potential growth. Firstly, while PME's Visage software can integrate into *any* brand or type of imaging hardware, CVB intends to sell it only through HiRise devices. Second, although CVB has a 'per use model' per scan, it is not as stingy as Visage which has a 'per click' model where it is charged just for viewing images. It is plausible these realities could eventually change.

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[12] As at 12 August 2024
[13] Pro Medicus Macquarie Conference Presentation May 2024, slide 6.
[14] Ibid, slide 18.

## CurveBeam AI's leadership

The company's current board and leadership composition is as follows (Figure 10).

**Figure 10: CurveBeam AI's leadership team**

| Name | Designation |
|------|-------------|
| Rob Lilley | Non-executive Chair |
| Greg Brown | CEO and Managing Director |
| Arun Singh | Executive Director |
| Kate Brown | Non-Executive Director |
| Hashan Silva | Non-Executive Director |

*Source: Company, Pitt Street Research*

**Rob Lilley** is Non-Executive Chair. Mr Lilley has over 35 years experience in the medical device and diagnostics industries. Mr Lilley previously served as senior vice president of global sales and marketing for Digene Corporation (Nasdaq:DIGE), a molecular diagnostics company, which was subsequently acquired by Qiagen N.V. (NYSE:QGEN). Mr Lilley is currently the Chair of Immunexpress Pty Ltd, an Australian molecular diagnostics company.

**Greg Brown** is CEO and Managing Director. He has 35 years experience in the healthcare industry, in medical devices (including in vitro diagnostic medical devices) and personalised medicine. Prior to joining CurveBeam, Mr Brown held marketing roles at Baxter Diagnostics (Australia and United Kingdom), Roche Molecular Systems Inc. (Switzerland and U.S.) and Digene Corporation (U.S. and Germany) and was Chief Executive Officer at ImpediMed Limited (ASX:IPD). Until April 2023, Mr Brown was a director of Australian biotechnology company Immunexpress Pty Ltd. He is also a director of an Australian management consulting company, Cintra Consulting Pty Ltd. He has previously served as a director of Trinity Biotech plc (Nasdaq: TRIB), ImpediMed Limited (ASX:IPD), Minomic International Limited and the University of Queensland's commercialisation company, UniQuest Pty Ltd.

**Arun Singh** is Chief Operating Officer, Chief Technology Officer and an Executive Director. Mr Singh has over 34 years experience in the technology industry, with in medical imaging. Since 2009, he has served as President and Chief Executive Officer of CurveBeam US, prior to which Mr Singh co-founded and served as the Vice President and Chief Technology Officer of Imaging Sciences International Inc. (ISI), which was subsequently acquired by Danaher Corporation.

**Kate Robb** is a Non-Executive Director and Chair of the Audit & Risk Committee. Ms Robb has over 25 years finance, governance, risk management and compliance experience. Ms Robb commenced her career at PwC and has held senior audit and risk roles at United Energy Limited (ASX:UEL), ANZ Banking Group Limited (ASX:ANZ) and AGL Energy Limited (ASX:AGL). Ms Robb previously served as a non-executive director and chair of the audit committee of unlisted public company Sandringham Community Financial Services Ltd, a Bendigo Bank Community Bank. Ms Robb was appointed to the board of directors of Solvar Limited (formerly Money Corporation Ltd) (ASX:SVR) (SVR) in September 2019. She is also chair of SVRs

audit and risk committee and a member of the nominations and remuneration committee over the same time period.

**Hashan De Silva** is Non-Executive Director and Chair of the Remuneration & Nomination Committee. Mr De Silva was appointed to the Board of the Company in 2021 as a nominee of Karst Peak Capital (Karst Peak). Mr De Silva is currently the Founder and Managing Partner of KP Rx, a healthcare fund manager on innovative healthcare companies based in Australia and New Zealand. Previously he held the role of head of healthcare research at Karst Peak, an investment management firm based in Sydney and Hong Kong, which has a focus on healthcare companies and its successes include Avita Medical and Neuren Pharmaceuticals. Mr De Silva previously served as an equity research analyst in healthcare at CLSA Limited and at Macquarie Group. Mr De Silva also serves on the board of Syntara (ASX:SNT) – once known as Pharmaxis - having been appointed in January 2023.

## Our Valuation of CurveBeam AI

*We value CVB at $317.9m in our base case and $417.6m in our bull case, which equate to $0.60 per share and $0.79 per share, after accounting for estimated future dilution*

We value CVB at $317.9m in our base case and $417.6m in our bull case, which equate to $0.60 per share and $0.79 per share, after accounting for estimated future dilution.

The key assumptions driving our DCF valuation are outlined below:

### Capital requirement assumptions

We assume a further $40m is raised in the next 24 months as part of a strategic investment and partnership, although we assume the company goes on to commercialise its products in its own right. Although the company may not need to raise a full $40m, especially not in the short-term considering the company has raised $9.9m in an Institutional Placement and Entitlement Offer) our modelling shows *some* capital would need to be raised (at least $15m) in the next couple of years to avoid the company being in a negative cash flow position, barring an unexpectedly fast market penetration and cost control in the face of such penetration.

### Revenue model

We model 3 revenue sources for the company: Devices sold, service pricing and SaaS revenues.

**HiRise devices sold.** We start with a cost of US$410,000 and assume 3% annual cost inflation, as well as an A$1=US$0.66 exchange rate. We assume 15 devices sold in FY25, followed by 23 in FY26, 32 in FY27 and 41 in FY28. Thereafter, growth slows but by FY34, we forecast 69 devices sold and a total of 499 active devices, which only ~3% of the company's potential penetration. We have looked at the market as a whole and not broken it down into individual segments (in other words distinguished between hospitals and independent practices).

**Service pricing.** We track the cumulative number of devices across the life of the model. We assume a servicing price of US$30,000 for each of these devices and once again 3% annual cost inflation and a A$1=US$0.66 exchange rate. By FY34, we reach $57.4m in device revenue and $29.6m in service revenue.

**SaaS revenues (BMD).** We only model revenues from FY27 and this is a function of reports per day and working days. We use the company's estimation of US$90 per report and use 262 days (all weekdays in a year).

## Other assumptions

**Business expenses and margins**. We use a 45% gross margin throughout the life of our model, sticking with the company's result in FY23. We model most other expenses (except D&A) using a cost inflation assumption of 10%. Depreciation and amortisation is modelled as a percentage of the opening book, equating to an average of 3% of sales throughout the life of our model.

We assume NPAT profitability in FY28, with a narrow $1.9m profit. Thereafter we assume gradual margin growth to 23%. We use a 21% corporate tax assumption, which is the rate in the USA.

**Discount rate**. We use an 11.13% WACC. We assume a 77-23% weight of debt equity as we model to be the case in FY25. The cost of debt is 4% pre-tax and the cost of equity is 14.5%. The latter figure is derived from a 4% risk free rate of return, a 7% equity premium and a 1.5x beta.

**Terminal growth**. We assume a 2% terminal growth rate beyond the initial 10-year life of our model, given that HiRise or BMD will not have market exclusivity.

## Base and Bull Case Differences

**Revenue model**. We model faster revenue growth in our bull case, starting with 20 devices in FY25, 32 in FY26, 45 in FY27 and 58 in FY28. By FY34, we assume 98 devices sold and 696 devices deployed all up. The market penetration in this case is ~4%. This leads to $81.7m in device revenue and $41.3m in service revenue, using the same cost and reports per day assumptions as in our base case.

**Margins**. We use the same cost of sales assumption (45% of sales) but 10% cost inflation growth for most other expenses. We use the same PPE and Intangible assumptions in our bull case as in our base case. Profitability is reached 1 year earlier, in FY27, with a 5% margin. Margins grow over time, reaching 37% by FY34, as opposed to 29% in our base case.

Figure 11 shows our valuation summary for CurveBeam AI and the upside potential of the stock while Figure 12 shows the sensitivity of our valuation to various WACCs.

**Figure 11: DCF calculation**

| Valuation (A$m) | Base Case | Bull case |
|---|---:|---:|
| Present Value of FCF | 48.6 | 146.6 |
| Present Value of Terminal Value | 305.9 | 307.3 |
| **Enterprise Value (A$ m)** | **354.6** | **454.2** |
| Net (debt) cash (FY25) | (36.6) | (36.6) |
| **Equity value (A$ m)** | **317.6** | **417.6** |
| Shares outstanding (millions) (FY25) | 529.5 | 529.5 |
| **Implied price (A$ cents)** | **0.60** | **0.79** |
| Current price (A$ cents) | 0.235 | 0.235 |
| Upside (%) | 155.3% | 236.2% |

*Source: Pitt Street Research*

**Figure 12: Sensitivity analysis of DCF calculation (base case)**

| | | WACC | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | 9.6% | 10.1% | 10.6% | 11.13% | 11.6% | 12.1% | 12.6% |
| Terminal Rate | 0.5% | 0.66 | 0.61 | 0.56 | 0.51 | 0.47 | 0.43 | 0.40 |
| | 1.0% | 0.71 | 0.65 | 0.59 | 0.54 | 0.50 | 0.46 | 0.42 |
| | 1.5% | 0.75 | 0.69 | 0.62 | 0.57 | 0.52 | 0.48 | 0.44 |
| | 2.00% | 0.80 | 0.73 | 0.66 | **0.60** | 0.55 | 0.50 | 0.46 |
| | 2.5% | 0.87 | 0.78 | 0.70 | 0.64 | 0.58 | 0.53 | 0.49 |
| | 3.0% | 0.93 | 0.83 | 0.75 | 0.68 | 0.62 | 0.56 | 0.51 |
| | 3.5% | 1.01 | 0.90 | 0.81 | 0.72 | 0.66 | 0.60 | 0.54 |

*Source: Pitt Street Research*

**We foresee CurveBeam AI being re-rated** to our valuation range driven by the following factors:

- The company developing an enhanced version of HiRise that is expected to be FDA approved by the end of CY24 under an accelerated model. This will enable scans of larger patients' hips and knees, to meet key landmarks and specifications required for robotic surgery planning. This in direct response to feedback from orthopaedic practices that need scans to meet these benchmarks, and consequently cannot commit to HiRise until they do.

- Regulatory approval for BMD. Approval for BMD is planned in mid-CY25, following submission in the second half of CY24.

- Company revenues increasing through introduction of BMD. Revenue from BMD will be SaaS-based and recurring.

## Risks

We see the following key risks to our investment thesis:

– **Regulatory risk.** The company's ability to commercialise its product is contingent on regulators maintaining approval where it already exists (including meeting ongoing regulatory compliance requirements) and giving approval to new products. A failure to give new products approval, or even a withdrawal of approval, could be catastrophic to its future ambitions.

– **Commercial risk**. There is the risk that the company may fail to execute its commercial objectives for a variety of reasons including (but not limited to):

i)       the failure to find commercial partners,

ii)      supply chain issues,

iii)     lack of acceptance by the market,

iv)     competition from other imaging providers (most pertinently from Planmed) and other diagnostic methods (such as blood testing) that could potentially be cheaper and more accurate; and

v)      failure to secure reimbursement for end users of the products and their medical providers from third-party healthcare payer organisations.

vi)     Loss of. or modified reimbursement coverage, under policy by US Medicare and private insurers

– **Key personnel risk**. There is the risk that the company may lose key personnel and be unable to replace them and/or their contribution to the business.

– **Capital risk**. There is the risk that the company may need future capital raisings. There is no guarantee that the company will be able to raise such capital, let alone on favourable terms. Even if successful, this would be dilutive to existing shareholders.

## Glossary

**2D (Two Dimensional)** – In the context of imaging, 2D images are flat and linear, without any depth, only having the dimensions of length and width.

**3D (Three Dimensional)** – 3D images have depth in addition to length and width, thus making three dimensions.

**Bone Fragility** – Where the bones have low mass and/or deteriorating in the microarchitecture. Patients with this conditions have increased risk of bone fracture.

**Bone Mineral Density (BMD)** – A test of calcium and other minerals in the bones. The more of these minerals there are in the bone, the denser the bones are, and thus less likely to fracture.

**Computerised Tomography (CT)** – A diagnostic imaging exam using X-Ray technology to produce 3D images of the inside of the body.

**Cone-based Imaging** – Where a cone-shaped source of radiation is directed through a target.

**Digital volumetric tomography (DVT)** – A specific type of cone beam tomography that ensures high quality 3D images.

**Dual-Energy X-Ray Absorptiometry (DEXA)** – A method of X-Ray imagine where two X-Ray beams, with different energy levels, are used and Bone Mineral Density (BMD) is measured.

**Fragility** – Where bones are vulnerable to fractures due to lower bone mass and microarchitectural deterioration of bone tissue.

**Gesetzliche Krankenversicherung** – Germany's statutory health insurance

**Hairline (fracture)** – A small crack or severe bruise in the bone, so-called because of its small size. They are often unable to be identified by conventional X-rays.

**Osteoarthritis** – A degenerative joint disease where tissues in the joint break down over time.

**Osteoporosis** – A bone disease where bone mineral density and bone mass decreases.

**Ostopenia** – A loss of bone density in general terms.

**Patient specific instrumentation (PSI)** - a modern technique in knee replacements where specific moulds are used as cutting guides during the surgery, with those moulds created through pre-operative scans.

**Software as a Service (SaaS)** – A business model where a service is delivered through centrally hosted software via the Cloud, paid for via a subscription plan.

**Structural Fragility Score (SFS)** – A measure of the deterioration of cortical and trabecular bone in an individual.

**Weight Bearing** – Where a joint is 'bearing weight', such as standing in the context of ankles and feet.

**X-Ray** – In general terms, a form of electromagnetic radiation that can pass through objects in the body. This technology is used to generate images of tissues and structures inside the body.

## Appendix I - Comparable companies

We have considered companies providing Health Care Equipment, specifically companies providing Imaging Equipment and/or Services (Figure 13). We considered both ASX-listed and foreign-listed companies. Further details on CVB's peers are outlined below.

**Figure 13: CurveBeam AI's peers**

| Company | Location | Code | Market Cap (A$m) | Website |
|---|---|---|---|---|
| *Australian-Listed* | | | | |
| Resonance Health | Perth, Western Australia | ASX:RHT | 28.6 | https://www.resonancehealth.com/ |
| Imricor Medical Systems | Minneapolis, Minnesota | ASX:IMR | 133.8 | https://imricor.com/ |
| Imagion BioSystems | San Diego, California | ASX:IBX | 1.3 | https://imagionbiosystems.com/ |
| Pro Medicus | Melbourne, Victoria | ASX:PME | 13,420 | https://www.promed.com.au/ |
| 4D Medical | Melbourne, Victoria | ASX:4DX | 182.7 | https://4dmedical.com/ |
| CurveBeam AI | Melbourne, Victoria | ASX:CVB | 80.7 | https://curvebeamai.com/ |
| | | | | |
| *Foreign-Listed* | | | | |
| Hyperfine | Guilford, Connecticut | NDQ:HYPR | 124.1 | https://hyperfine.io/ |
| ClearPoint Neuro | Solana Beach, California | NDQ:CLPT | 372.7 | https://www.clearpointneuro.com/ |
| NeuroOne Medical Technologies | Minneapolis, Minnesota | NDQ:NMTC | 36.5 | https://nmtc1.com/ |
| Fonar Corporation | Melville, New York State | NDQ:FONR | 164.8 | https://www.fonar.com/ |
| Vivos | Richland, Washington State | OTCPK:RDGL | 74.6 | https://vivos.com/ |
| Armcoma AB | Växjö, Sweden | OM:ARCOMA | 30.4 | https://www.armcoa.com/vendor |

*Source: Pitt Street Research*

### ASX-listed

**Resonance Health (ASX:RHT)** offers FerriScan, a non-invasive MRI based system for quantifying liver iron concentration (LIC); FerriSmart, an artificial intelligence (AI) assisted device for the automated real-time assessment of LIC; HepaFat-AI, an AI-trained device for the automated real-time multi-metric measurement of liver-fat; CardiacT2, a dual analysis service with FerriScan for assessing heart iron loading; HepaFat-Scan, a non-invasive MRI-based solution for the assessment of liver-fat in liver tissue; and LiverSmart, a non-invasive MRI-based multi-parametric device combining FerriSmart and HepaFat-AI into a consolidated report. Resonance Health was incorporated in 1987 and is headquartered in the Perth suburb of Burswood.

**Imricor Medical Systems (ASX:IMR)** designs, manufactures, sells, and distributes magnetic resonance imaging (MRI) compatible products for cardiac catheter ablation procedures in the United States. The company's principal product includes the Advantage-MR EP Recorder/Stimulator system, an EP recording system and cardiac stimulator. Its products also include Vision-MR Ablation Catheter, which is used as an indication for treating type I atrial flutter; and Vision-MR Dispersive Electrode that is used to minimize eddy currents induced on the conductive pads during MR scanning. It also performs contract research, as well as licenses its intellectual property for use in implantable devices. Imricor Medical Systems was incorporated in 2006 and is headquartered in southern Minneapolis, Minnesota.

**Imagion BioSystems (ASX:IBX)** provides medical imaging technologies using magnetic resonance. It has activities in nanotechnology; biotechnology; cancer diagnostics; and superparamagnetic relaxometry. The company develops MagSense, which is in Phase I clinical trials for the treatment of HER2 breast cancers, as well as in preclinical stage to treat prostate, ovarian, brain, and pancreatic cancer. It also develops PrecisionMRX, an iron oxide nanoparticle to detect cancer. Imagion Biosystems is based in San Diego, California.

**Pro Medicus (ASX:PME)** offers Visage, a proprietary medical software that provides radiologists and clinicians with visualization capability for viewing 2-D, 3-D, and 4-D medical images, as well as picture archive and communication system (PACS)/digital imaging software; and integration products. In addition, the company offers Visage Ease Pro, a mobile application that provides users the ability to interpret various diagnostic imaging studies stored on a Visage 7 server. Pro Medicus was founded in 1983, listed in 2000 and is headquartered in Melbourne, Australia. Including Pro Medicus as a comparable company may seem controversial because it is an A$13bn market cap company as of July 2024. However, it can give an indication of how high-margin a Saas-based radiology model can be.

**4D Medical (ASX:4DX)** operates as a medical technology company in Australia and the United States. It commercializes XV Technology, a four-dimensional lung imaging technology. The company also offers software as a service delivery model; XV lungs ventilation analysis software; Permetium, a preclinical imaging system which quantify regional changes in pulmonary function; and AccuVent 200, a small animal ventilator. The company was incorporated in 2012 and is based in Melbourne, Australia.

### Foreign listed

**Hyperfine (NDQ:HYPR)** is a medical device company, provides magnetic resonance imaging (MRI) products in the United States. The company offers Swoop Portable MR imaging system, which offers portable brain neuroimaging; and support and technical assistance services. It serves ICU, comprehensive, and primary stroke accredited facilities through direct sales and distributors. Hyperfine was founded in 2014 and is based in Guilford, Connecticut.

**ClearPoint Neuro (NDQ:CLPT)** operates as a medical device company primarily in the United States. It develops and commercializes platforms for performing minimally invasive surgical procedures in the brain under magnetic resonance imaging guided interventions. The company offers ClearPoint, an integrated system for the insertion of deep brain stimulation electrodes, biopsy needles, and laser catheters, as well as the infusion of pharmaceuticals into the brain. ClearPoint Neuro was incorporated in 1998 and is headquartered in Solana Beach, California.

**NeuroOne Medical Technologies (NDQ:NMTC)** a developmental stage company, provides solutions for EEG recording, brain stimulation and ablation solutions for patients suffering from epilepsy, Parkinson's disease, dystonia, essential tremors, and chronic pain due to failed back surgeries and other related neurological disorders. It also fucuses on applications for other areas, such as depression, mood disorders, pain, incontinence, high blood pressure, and artificial intelligence. It has a strategic partnership with RBC Medical Innovations to develop a radio frequency ablation generator. The company was incorporated in 2009 and is based in Minneapolis, Minnesota.

**Fonar Corporation (NDQ:FONR)** together with its subsidiaries, engages in the research, development, production, and marketing of magnetic resonance imaging (MRI) scanners for the detection and diagnosis of human diseases in the United States. It provides Upright MRI scanner that allows patients to be scanned in weight-bearing conditions, such as standing, sitting, bending, or lying down. It owns and operates diagnostic imaging facilities in Florida; and manages MRI scanning facilities. The company markets its scanners to private diagnostic imaging centers and hospital outpatient imaging facilities. FONAR Corporation was founded in 1970 and is based in Melville, New York State.

**Vivos (OTCPK:RDGL)** is a radiation oncology medical device company, develops brachytherapy devices for the treatment of non-resectable tumors in the United States. It develops yttrium-90 based RadioGel device, an injectable particle-gel for brachytherapy radiation treatment of cancerous tumors in people and animals; and IsoPet for the treatment of solid tumors in animals. Vivos was incorporated in 1994 and is headquartered in Richland, Washington State.

**Armcoma (OM:ARCOMA)** develops, produces, and provides radiology solutions worldwide. It offers digital x-ray systems for radiographic applications, as well as for use in general, eneral, muscle/skeleton, thoratic, pediatric, and trauma/resus clinics. The company sells its products through OEM partners. Arcoma was incorporated in 1990 and is based in Växjö, Sweden.

## Appendix II – Current Capital Structure

| Class | Number | % |
|---|---|---|
| Current Ordinary Shares on Issue | 320,138,492 | 79% |
| Phase 1 Placement and ANREO^ | 44,119,954 | 11% |
| Phase 2 Placement | 11,111,111 | 3% |
| **Total Ordinary Shares** | **375,369,557** | **92%** |
| Contingent Shares | 2,457,005 | 1% |
| Options | 29,091,428 | 7% |
| Rights | 591,939 | 0% |
| **Total Diluted Shares** | **407,509,929** | **100%** |

*Source: Company*

*^ Accelerated Non-Renounceable Entitlement Offer*

*Placement shares are subject to shareholder approval.*

## Appendix III – Shareholder Registry

| Shareholders | % of Shares |
|---|---|
| Arun Singh | 12.5% |
| Firetrail Investments | 10.3% |
| Ilwella | 8.2% |
| Karst Peak Capital | 6.8% |
| Greg Brown | 5.4% |
| Non-Executive Directors & other Key Managers | 3.1% |
| Other Pre-IPO Holders | 37.4% |
| Other | 16.3% |
| **Total** | **100.0%** |

*Source: Company*

## Appendix IV – Shares under escrow

| Holders of escrowed shares | No. of shares | % of Total |
|---|---|---|
| Directors | 110,936,757 | 35% |
| Other related parties & promoters | 26,993,764 | 8% |
| Key Managers | 3,897,833 | 1% |
| Others | 5,350,821 | 2% |
| Total shares escrowed | 147,179,175 | 46% |

*Source: Company IPO prospectus section 11.11*

*^ Excludes 641,300 shares owned by Key Management and 32,904,054 shares owned by other investors set to exit escrow in July 2024. All of the 147,179,175 shares barring 1,449,723 shares are set to end escrow 24 months from CurveBeam AI's official quotation on the ASX. The previously mentioned 1,449,723 shares will exit escrow 12 months from the official quotation*

## Appendix V – Analysts' Qualifications

Stuart Roberts, lead analyst on this report, has been an equities analyst since 2002.

– Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).

– Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research speciality at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.

– After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.

– In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.

– Since 2018, Stuart has led Pitt Street Research's Resources Sector franchise, spearheading research on both mining and energy companies.

Nick Sundich is an equities research analyst at Pitt Street Research.

– Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018. He has also completed the CFA Investment Foundations program.

– He joined Pitt Street Research in January 2022. Previously he worked for over three years as a financial journalist at Stockhead.

– While at university, he worked for a handful of corporate advisory firms