CurveBeam AI

ASX: CVB

23 August 2023

CurveBeam AI commences trading on ASX and provides business update

Highlights

- CurveBeam AI lists on the ASX today under ticker code 'CVB' after raising A$25m at A$0.48 per share under its IPO.
- CurveBeam AI is releasing its Appendix 4E to ASX today and has achieved A$11.48m pro forma revenue (unaudited) in FY23, driven by sales of HiRise™. This represents ~55% growth on the prior year with a US sales team of three.
- CurveBeam AI expects its co-marketing and distribution agreement with Stryker Corporation's (NYSE: SYK) Foot and Ankle (F&A) division for the US territory, which launched with the Stryker FLEX financing option in May 2023, to drive sales growth going forward through Stryker's expanded market reach and financing options.
- Since 1 July 2023, Stryker has taken orders for two HiRise™ devices, representing a total of three devices booked or sold year to date by Stryker for calendar year 2023.
- Notably the Company sold and installed a HiRise™ system at the Hospital for Special Surgery (HSS) located in New York in June 2023, a globally recognised orthopaedic specialty centre.
- The company as of the end of FY23 had 40 HiRise placed globally in hospitals and orthopaedic practices. With the two sales from Stryker so far this FY, and one HiRise sold by the company (Duke University), as of today there are globally 43 HiRise systems either placed or to be placed.
- CurveBeam AI and Stryker continue to work collaboratively to drive sales of the HiRise™ device to hospitals and group orthopaedic practices. The potential addressable market for the HiRise™ device in the US alone is A$10b.
- In addition to targeting sales growth in the US, the Company has recently established a German subsidiary, CurveBeam AI GmbH, to launch direct sales into Germany.
- CurveBeam AI is progressing the development of a CT bone mineral density (BMD) analysis and reporting software module. Subject to regulatory clearance, the BMD module is targeting to be available to HiRise™ customers as a SaaS product in late FY25 and has the potential to generate future revenues of between A$150-200k per device per annum at a 90%+ gross margin.
- CurveBeam AI has developed an AI diagnostic tool to assess bone fragility and fracture risk called OssView®. In a clinical trial of 2,000 women, OssView® significantly outperformed BMD which is the current gold standard diagnostic (p=0.005). OssView® at the wrist has received Breakthrough Device Designation from the FDA.
- CurveBeam AI has recently published the world's first application of a deep learning AI (DLAI) algorithm, called OssView® 2, to aid in determining fracture risk using images derived from high resolution peripheral quantitative CT (HR-pQCT) scans of the wrist.

Melbourne, Australia & Hatfield, Pennsylvania: CurveBeam AI Limited (ASX: CVB, "CurveBeam AI" or the "Company"), a fully integrated developer and manufacturer of point-of-care specialised medical imaging (CT) equipment and supporting AI enabled SaaS-based clinical assessment solutions, commences trading on the Australian Securities Exchange (ASX) today following

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completion of a fully-underwritten public offer to raise A$25m, that was well supported by new and existing institutional investors.

The Company's flagship product is the HiRise™ CT scanner, which has the combined ability to perform weight bearing CT (WBCT) scans of the lower extremity (with a patient standing in a normal, weight bearing pose) as well as traditional non-weight bearing CT scans of the upper and lower extremities. CurveBeam AI's weight bearing CT devices have several advantages including being quicker, lower radiation dose than traditional multi-detector CT, and a more accurate diagnosis due to the unique alignment data that can be derived from the scan being performed under a standing load.[1] The HiRise™ is self-shielded, plugs into a standard power supply and only requires one day of training to operate, making it significantly cheaper to purchase, install and operate than a traditional CT device. The HiRise™ also represents an attractive commercial proposition for surgical centres with the centres targeting and often receiving payment from payors on a per scan basis.

Including first and second generation WBCT devices, a total of 170 devices have been placed by the Company worldwide to date, including placements at well recognised US medical institutions such as Mayo Clinic, HSS, Penn, Duke and UCLA. The Company is reporting A$11.48m pro forma revenue (unaudited) in FY23, which includes revenue from 16 HiRise™ devices (refer to the Appendix 4E which is being released today). HiRise™ has FDA clearance, TGA approval and CE Mark to sell the device into the US, Australia and the European Union, respectively. The Company is also developing a range of AI clinical assessment modules for aiding in surgical planning and bone health assessment. All modules are still subject to regulatory clearance. The CT Bone Mineral Density (BMD) module is expected to be commercially available in the US in late FY25 (assuming FDA clearance is obtained in FY25) and the existing US reimbursement (CPT code and coverage) for BMD testing with CT scans, should be available for BMD scans on HiRise™.

CurveBeam AI has more than 70 employees across its corporate headquarters in Melbourne, Australia and its operational headquarters in Hatfield, Pennsylvania, USA.

"*We believe this Company holds the potential of advancing care in orthopaedics and bone health around the world, and as we reach this critical juncture of an IPO, the vision is shared by a range of institutional investors,*" said CurveBeam AI CEO and Managing Director, Greg Brown. "*Such is our belief in the Company, senior management have combined invested ~A$1.25m into the IPO, bringing the total cash invested by senior managers in the Company to over A$20m. We have 'first to market', proprietary technologies servicing a point of care weight bearing CT market estimated at approximately A$10b in the US. We are eager to execute on our business plan to help ensure the issues of bone fragility (osteoporosis) and osteoarthritis are better managed under the one care giver (orthopaedic surgeons) with total joint replacements. Succeeding in this goal should deliver value back to our supportive existing shareholders and the new shareholders we are welcoming as part of this IPO.*"

Sales and Distribution

CurveBeam AI's business model is to sell its CT devices using both its internal sales team, together with distributor agreements with larger medical device vendors that specialise in servicing orthopaedic surgeons and hospitals.

CurveBeam AI is party to a co-marketing and distribution agreement with Stryker Corporation's (NYSE: SYK) Foot and Ankle (F&A) division for the US territory, which launched with the Stryker FLEX financing option in May 2023. Stryker provides significant reach into CurveBeam AI's target customers, with a ~500 strong salesforce and 40 regional specialists. A key challenge for any medical device company is access to their target customer, in this case the orthopaedic surgeons,

where the Company can leverage the existing deep relationships that Stryker has as a market leader in orthopaedics.

Stryker has multiple incentives to sell HiRise™ devices in addition to the direct monetary benefit. Stryker has a full array of high margin implant choices to fit the patient's specific needs which require CT images. Having the HiRise™ installed in a surgeon's office, with automatic uploads of WBCT datasets to the designated Stryker portal reduces a barrier to adoption of these products. The Company understands that Stryker plans to place HiRise™ devices through its FLEX financing program which allows an orthopaedic practice to pay for the lease of a HiRise™ device through the purchase of other Stryker products. FLEX financing packages enables Stryker to sign up orthopaedic practices on multi-year contracts with minimum purchase requirements for its products, thus gaining market share.

Since 1 July 2023, the agreement with Stryker has taken orders for two HiRise™ devices, representing a total of three units ordered or placed in calendar year 2023 (since the Flex financing launch in May 2023). The Company also recently sold and installed a HiRise™ system at the Hospital for Special Surgery (HSS) in New York City, a globally recognised orthopaedic specialty centre. Stryker has an advanced pipeline of opportunities in the US which is expected to accelerate the Company's revenue growth in FY24 and beyond.

CurveBeam AI recently established a German subsidiary to facilitate direct sales of the HiRise™ devices in the German market. The Company is currently building its sales support infrastructure and expects to see direct German sales in FY24. Germany has ~4,300 potential weight bearing CT installation sites for HiRise™ device sales. Reimbursement and private insurance is available in Germany for scans using the Company's CT devices.

Manufacturing

CurveBeam AI manufactures and assembles its devices at its operational headquarters in Hatfield, Pennsylvania, USA. Over the past year, the Company invested heavily in its manufacturing and supply chain capabilities and has access to inventory to support the anticipated growth in sales volumes over the next 12 months and beyond.

The Company is also developing improvements to the HiRise™ platform, including a stronger X-Ray source. This will enable higher resolution imaging of the hip and knee joints required for key surgical robotic systems such as the Stryker robotic knee and hip replacement system called Mako. The enhanced capabilities are expected to be available from Q3 FY24 and will allow HiRise™ scans to be used routinely for all lower limb patient-specific joint replacement planning and instrumentation. This HiRise™ system upgrade is also critical for offering the AI SaaS based CT BMD module on the HiRise™ for knee and hip replacements.

Cloud-based AI diagnostic modules

The Company is developing a range of cloud-based AI modules to assist doctors in diagnosis and surgical planning. The most advanced module with pre-existing reimbursement in the US is for CT BMD on the HiRise™ scanner.

The CT BMD analysis and reporting software module is under-development and the Company targets filing with the FDA for a 510(k) clearance in FY24. The Company will make the BMD assessment capability available on the new enhanced HiRise™ device to new and existing customers in the US. This module has the potential to generate future revenues in the US of between A$150-200k per device per annum at a 90%+ gross margin.

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Other modules on the HiRise™ scanner include CubeVue AutoMetrics™ which aims to reduce 16 hours of pre surgical planning to a scan and report available in 15 minutes. The Company is targeting a filing with the FDA for Autometrics™ in FY24.

OssView® on CurveBeam AI's InReach™ device

While BMD is the current gold standard for osteoporosis diagnosis with established reimbursement, it is an imperfect diagnostic tool. A key challenge in the diagnosis of bone fragility is that osteoporosis as defined by BMD fails to predict the majority of fragility fractures. Up to ~80% of women who experience a fragility fracture have osteopenia or normal BMD[2]. The current method for assessing BMD is through a DEXA machine which has low energy x-rays that only measures the surface density of bone. To overcome this shortcoming, CurveBeam AI has developed the InReach™ HRpQCT imaging equipment, a high resolution peripheral quantitative CT (HR-pQCT) device, for imaging of the distal radius. On this device, the Company has developed an AI-based assessment of the bone micro-architecture, called OssView®, which is used to aid a clinician to better assess fracture risk.

In a clinical trial of ~2,000 women, OssView® predicted over 70% of fractures whereas BMD predicted ~30% (p=0.0005)[2]. In FY23, the FDA designated OssView® as a Breakthrough Device Designation. The Company is targeting FDA clearance of OssView® with the InReach™ HRpQCT, of the wrist, in FY24 and then plans to pursue economic validation in the capitated healthcare networks in the US.

The Company, showing its leadership in this field, recently published a new DLAI algorithm (OssView® 2). This publication in eLife found that the DLAI algorithm developed by CurveBeam AI predicted fractures significantly better than BMD and BMD plus FRAX, especially in women 65 years and older[3].

IPO

The Company's IPO comprised of 52.08m shares to raise A$25m at a price of A$0.48 per share, giving the Company an indicative market capitalisation of A$153.7m upon listing. Proceeds from the IPO are to be used for enhancing sales and marketing, continued R&D, new product innovation, and further clinical trials.

Bell Potter Securities and Lodge Corporate were JLMs to the Offer, which was fully underwritten by Bell Potter Securities.

Release approved by the Board of Directors.

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[1] Martinus Richter, Francois Lintz, Cesar de Cesar Netto, Alexej Barg, Arne Burssens, Results of more than 11,000 scans with weightbearing CT — Impact on costs, radiation exposure, and procedure time, Foot and Ankle Surgery,Volume 26, Issue 5,2020,Pages 518-522, ISSN 1268-7731, https://doi.org/10.1016/j.fas.2019.05.019. (https://www.sciencedirect.com/science/article/pii/S1268773119300967)

[2] Chapurlat R, Bui M, Sornay-Rendu E, Zebaze R, Delmas PD, Liew D, Lespessailles E, Seeman E. (2020) Deterioration of Cortical and Trabecular Microstructure Identifies Women With Osteopenia or Normal Bone Mineral Density at Imminent and Long-Term Risk for Fragility Fracture: A Prospective Study. J Bone Miner Res. May;35(5):833-844. doi: 10.1002/jbmr.3924.

[3] Chapurlat Roland, Ferrari Serge, Li Xiaoxu, Peng Yu, Xu Min, Bui Min, Sornay-Rendu Elisabeth, lespessailles Eric, Biver Emmanuel, Seeman Ego (2023) Deep Learning Using High-Resolution Images of Forearm Predicts Fracture eLife 12:RP87990

About CurveBeam AI Limited

CurveBeam AI Limited (ABN 32 140 706 618) (ASX:CVB) develops, manufactures and sells specialised medical imaging (CT) scanners, coupled with AI SaaS-based clinical assessment solutions, to support medical practitioners in the management of musculoskeletal conditions. The Company's flagship CT scanner, HiRise™, performs weight bearing CT scans as well as traditional non weight bearing CT scans, providing a range of advantages over the use of traditional CT or MRI devices. CurveBeam AI has more than 70 employees with its corporate office, AI and IP functions located in Melbourne, VIC, Australia and global operations headquarters in Hatfield, Pennsylvania, USA.

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

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