ASX: CVB

15 September 2026

CurveBeam AI receives FDA 510(k) Clearance for CT-based Bone Mineral Density (BMD) technology

- **FDA 510(k) clearance received for CurveBeam AI's CT based BMD technology.**
- **Clearance establishes an FDA cleared foundation for future broader BMD SaaS applications across CurveBeam AI's CT portfolio;**
- **CurveBeam AI will now pursue FDA clearance to extend the technology to BMD measurement to HiRise™, and SaaS revenue launch.**
- **Longer-term opportunity to integrate quantitative BMD data into advanced and robotic-assisted orthopaedic surgical planning workflows**

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, supported by a range of AI-enabled SaaS-based clinical assessment solutions, is pleased to announce it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for its CT-based Bone Mineral Density (BMD) technology using multidetector CT (MDCT) supine (lying-down) scans.

The clearance represents an important regulatory milestone in CurveBeam AI's strategy to expand its advanced CT imaging capabilities into quantitative bone-health assessment, and over time develop a broader CT-based platform that can deliver anatomical, alignment and bone-quality information from a single examination generating additional revenues through a SaaS model once the clearance on HiRise™ is achieved.

The next stage of CurveBeam AI's BMD regulatory strategy is to extend the cleared BMD technology to weight bearing, standing CT BMD measurement on the Company's HiRise™ platform. HiRise™ is designed to provide weight bearing CT imaging of the lower extremity, providing the potential to combine assessment of the patient's anatomy, alignment and bone quality within a single standing examination. The ability to assess BMD using a standing CT examination could provide an important additional clinical capability for orthopaedic applications, particularly where understanding bone quality in the weight bearing environment is relevant to clinical decision-making.

Importantly, integrating BMD into the CT examination has the potential to provide surgeons with additional quantitative information without requiring the patient to undergo a separate imaging examination. This could support a more efficient practice workflow, with relevant anatomical and bone-health information available from the same imaging pathway used for orthopaedic assessment and surgical planning.

Greg Brown, CEO and Managing Director of CurveBeam AI, said: "This is a significant milestone for CurveBeam AI, being our first clearance of the two necessary steps to take our SaaS based bone health products to market. Achieving our first FDA 510(k) clearance for CT-based BMD establishes an important regulatory foundation for the Company and demonstrates our ability to bring quantitative bone health capabilities through the FDA pathway. Our next objective is to take

Telephone: +61 3 9620 0250
Email: info@curvebeamai.com
Website: curvebeamai.com

Corporate Office
Level 10, 10 Queen Street
Melbourne, Victoria, 3000, Australia

Global Operations Headquarters
2800 Bronze Dr., Suite 110
Hatfield, PA 19440 USA

this capability to the HiRise™ platform and pursue clearance for weight bearing CT BMD. This is particularly exciting because it aligns quantitative bone health assessment with the weight bearing imaging environment that is central to the HiRise™ proposition.

Potential to streamline the orthopaedic imaging and surgical planning workflow

The Company believes this clearance represents a valuable addition to its existing regulatory and intellectual property portfolio and strengthens the long-term potential of its CT imaging platforms.

Longer-term, CurveBeam AI believes quantitative BMD information could ultimately become an additional data layer within the broader digital orthopaedic workflow. CT examinations are increasingly used to generate patient-specific three-dimensional anatomical models for advanced surgical planning, including robotic-assisted orthopaedic procedures. Subject to appropriate regulatory clearances and clinical validation, deriving quantitative BMD information from the same CT dataset could provide surgeons and planning systems with additional information alongside patient anatomy and alignment.

Access to conventional bone mineral density (BMD) assessment can involve significant delays. A U.S. study of more than 10,000 DXA examinations found that the mean time from the initial order to completion of the DXA examination increased from 79.1 days before the COVID-19 pandemic to 88.8 days during the pandemic ($p<0.001$), highlighting the potential for delays in access to conventional bone density assessment. [1]

This evidence illustrates the potential value of integrating BMD assessment into existing CT imaging pathways. CurveBeam AI's cleared BMD technology has the potential to provide quantitative bone density assessment from CT imaging that is already being acquired for patients undergoing orthopaedic evaluation, including patients being prepared for total joint replacement. For surgeons and orthopaedic practices, this could support a more integrated "one visit, one scan" model, in which a single CT examination can potentially provide anatomical, alignment and bone health information without requiring a separate DXA appointment.

The potential benefit extends beyond clinical assessment. The same CT dataset used to create patient specific three-dimensional anatomy for advanced surgical planning and robotic-assisted procedures could potentially provide an additional quantitative bone quality data layer. This could allow future surgical planning workflows to consider not only the patient's anatomy and alignment, but also quantitative information relating to bone quality, subject to regulatory clearance and clinical validation. This has the potential to make the CT examination a more valuable component of the digital surgical workflow, rather than simply an imaging step prior to surgery.

Next Steps

CurveBeam AI will progress regulatory planning for a CT BMD 510(k) submission for HiRise™, including assessment of the appropriate regulatory pathway, clinical evidence requirements and validation activities. The Company will also continue to evaluate the potential integration of quantitative bone quality information into broader CT-based orthopaedic workflows, including advanced three-dimensional and robotic surgical planning applications, subject to appropriate regulatory clearance and clinical validation. The Company will provide further updates as the regulatory program progresses.

[1] Hisatomi L, et al. (2022), "Impact of COVID-19 Pandemic on Osteoporosis Screening using Dual-Energy X-ray Absorptiometry," Orthopedics and Rheumatology Open Access Journal, 20(5), DOI: 10.19080/OROAJ.2022.20.556048.

Release has been authorised for release by the Board.

Telephone: +61 3 9620 0250
Email: info@curvebeamai.com
Website: curvebeamai.com

Corporate Office
Level 10, 10 Queen Street
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About CurveBeam AI Limited

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

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

Investor / media enquiries

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