

ASX: CVB

15 July 2024

FDA clearance received for Enhanced HiRise™

Melbourne, Australia & Hatfield, Pennsylvania: CurveBeam AI Limited (ASX: CVB “CurveBeam AI” or the “Company”), a developer of point-of-care specialised medical imaging (CT) equipment and AI-enabled SaaS-based clinical assessment solutions, is pleased to announce its Enhanced HiRise™ scanner has received 510(k) clearance from the United States Food and Drug Administration (FDA).

CurveBeam AI received notice of the clearance on Friday, 12 July 2024, US time.

With this clearance, the Enhanced HiRise™ scanner can now be used in routine medical practice settings, allowing the final validation steps to be run on patients to ensure compatibility with custom knee and hip procedures, including robotic surgical systems. It also permits the Company to execute on its commercial launch and expansion plans for the Enhanced HiRise™ platform in the US market.

Greg Brown, CEO & Managing Director of CurveBeam AI, commented, "We are both excited and pleased to receive the FDA 510(k) clearance for our Enhanced HiRise™ platform. This is an important milestone that allows us to plan both the commercial launch of the Enhanced HiRise™ and validation of custom protocols for personalised knee and hip procedures, including robotic systems. This critical step permits knee and hip patients to be imaged on the HiRise™ in a routine setting. We are targeting this quarter to have multiple sites utilising the Enhanced HiRise™ for custom robotic surgeries."

CurveBeam AI's HiRise™ platform is continuing to gain traction in the market due to its unique capabilities and advanced technological features. The Enhanced HiRise™ CT scanner offers both weight-bearing and non-weight-bearing CT scans, providing critical data for orthopaedic and musculoskeletal diagnostics and for both manual or robotic assisted surgical planning. This technology aids in a surgeon's visual clinical assessment and treatment plan, targeting better patient outcomes.

Release approved by the Board of Directors.

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>

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