

ASX: CVB

13 October 2026

CurveBeam AI Achieves NMPA Approval for HiRise in China, Unlocking Future Commercial Sales and Further Equity Investment

- **HiRise™ weight bearing CT system receives NMPA approval, a major milestone in CurveBeam AI's strategic expansion into China and an important step towards commercialisation in one of the world's largest medical device markets.**
- **Approval achieved on the early end of expectations, advancing the regulatory and commercial objectives established under CVB's 10-year strategic agreements with Shandong WeiYing Intelligent Medical Technology Co., Ltd.**
- **Contracted A\$1 million equity investment milestone triggered at A\$0.405 per share, strengthening CVB's capital position and reinforcing alignment with its Chinese partner.**
- **Commercial sales can now commence in China, enabling the partners to progress market launch activities, customer engagement and distribution of HiRise™.**
- **The milestone builds on the partnership's broader future objectives of local China-based manufacturing, supply chain optimisation and long-term royalty income from the Chinese market.**

Melbourne, Australia & Hatfield, Pennsylvania: CurveBeam AI Limited (ASX: CVB) ("**CVB**", "**CurveBeam AI**" or the "**Company**"), a developer of point-of-care (PoC) specialised medical imaging (CT) equipment and AI enabled SaaS based clinical assessment solutions, is pleased to announce that its HiRise™ weight bearing CT ("WBCT") system has received approval from China's National Medical Products Administration ("NMPA"), China's national medical products regulator.

The approval represents a major milestone in the execution of CVB's China market strategy and enables the Company and its strategic Chinese partner, Shandong WeiYing Intelligent Medical Technology Co., Ltd. ("WeiYing" or the "Partner"), to progress commercial sales of HiRise™ in China. Importantly, the approval has been achieved on the early end of timeline expectations, advancing the commercialisation timetable under the strategic collaboration announced in October 2025.

In October 2025, CVB executed definitive 10-year agreements with WeiYing, a joint venture between Shandong Weigao Haixing Medical Device Co. (Wego), Ltd. and other Chinese commercialisation partners and investors. The agreements established a framework for the exclusive distribution, marketing and local manufacture of CVB's WBCT systems and associated AI technologies across China, Hong Kong, Macau and Taiwan, subject to the applicable regulatory approvals. The partnership combines CVB's proprietary imaging technology with the Partner's established medical device industry relationships, distribution capabilities, manufacturing infrastructure and local regulatory expertise. NMPA approval of HiRise™ represents a critical step in translating this strategic agreement into commercial activity. With this regulatory milestone

achieved, the parties can advance the next phase of the collaboration, focusing on market development, customer engagement and the commencement of sales in China.

Further A\$1 million equity investment milestone

Under the Share Subscription Agreement announced in October 2025, the Partner committed to an equity investment of up to A\$10 million in CVB, linked to specified regulatory, commercial and product development milestones. The Company confirms that the HiRise™ NMPA approval triggers a further A\$1 million equity investment under the agreements. The shares are to be issued at A\$0.405 per share, consistent with the agreed subscription price.

This investment milestone reinforces the alignment between CVB and its Chinese partner, with the Partner's equity participation in CVB linked to the advancement of the collaboration and the commercialisation of CVB's technology. The original agreement provides for an investment of A\$4 million associated with execution of the licence agreements (received and announced in February), with the remaining investment linked to the achievement of specified milestones. The market will be advised in due course of the precise timing of the placement.

Significant commercial opportunity

China represents a substantial long-term opportunity for CVB's specialised medical imaging technology. The strategic partnership was established to accelerate access to this market while creating a platform for future local China-based manufacturing, improved supply chain economics and the expansion of CVB's global commercial footprint.

HiRise™ provides three-dimensional weight bearing CT imaging of the lower extremities, enabling clinicians to assess musculoskeletal anatomy under physiological loading. The technology is designed to support orthopaedic assessment and surgical planning by providing information that may not be apparent from conventional non-weight bearing imaging alone.

With NMPA approval now secured, the Company and its Partner can focus on converting the regulatory achievement into commercial adoption. The collaboration also provides a pathway towards local manufacturing in China, with the potential to improve cost competitiveness, strengthen the supply chain and support broader international market access over time.

CurveBeam AI CEO Greg Brown said: "Receiving NMPA approval for HiRise™ is a major milestone and is a reflection on the dedication of our international team, whose commitment and determination have driven this outcome while simultaneously delivering FDA 510(k) clearance for our MDCT based Bone Mineral Density (BMD) technology.

"When we executed our definitive China agreements in October last year, we established a long-term strategic partnership to accelerate our entry into China, supported by an established orthopaedic medical device group and a committed local commercialisation platform. Securing approval on the early end of our expected timeline reflects the strength of this partnership and the considerable work involved in navigating the Chinese regulatory process. I particularly want to thank our global team, who have worked tirelessly across time zones, often putting in long hours and weekends to keep both regulatory programs moving forward. Their collaboration, persistence and commitment have been exceptional.

"NMPA approval moves us beyond regulatory preparation and into commercialisation. We can now work with our Partner to commence sales, build customer relationships and establish HiRise™ in China. This pivotal growth opportunity for CVB will be backed by HiRise™ sales, local manufacturing and supply chain optimisation."

Next steps

Following NMPA approval, CVB and Wego Orthopedics will focus on progressing commercial launch activities, developing the distribution pipeline and supporting the introduction of HiRise™ to the Chinese market. The parties will also continue to progress the broader strategic collaboration, including local manufacturing and the development of future generation imaging products and associated AI solutions, in accordance with the executed agreements.

Release approved by the Board of Directors.

About CurveBeam AI Limited

CurveBeam AI Limited (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>

About Shandong WeiYing Intelligent Medical Technology Co., Ltd.

Shandong WeiYing Intelligent Medical Technology Co., Ltd. is a newly established Chinese medical-technology company located in the Torch Hi-Tech Industrial Development Zone, Weihai, Shandong Province. The company is a joint venture between Shandong Weigao Haixing Medical Device Co., Ltd and other partners.

About Shandong Weigao Haixing Medical Device Co., Ltd

Shandong Weigao Haixing Medical Device Co., Ltd is a subsidiary of Shandong Weigao Orthopaedic Materials Co., Ltd. (“WEGO Orthopaedics”). WEGO Orthopaedics is a leading Chinese medical device company specialising in the research, development, manufacture, and sale of orthopaedic medical devices. Its core product portfolio includes orthopaedic implant systems and surgical instruments used in trauma, spine, joint replacement, and sports medicine procedures.

WEGO Orthopaedics is recognised as one of China’s most comprehensive and competitive orthopaedic implant manufacturers, holding the largest domestic market share among orthopaedic device suppliers. The company has established a fully integrated R&D and manufacturing system, equipped with internationally advanced facilities and modern project management capabilities.

Through continuous innovation and product iteration, WEGO Orthopaedics has developed a broad and diversified product line that meets the full spectrum of clinical needs in orthopaedic surgery. The company is a subsidiary of the WEGO Group, one of China’s largest and most diversified healthcare conglomerates.

Forward-Looking Statements

This announcement contains certain forward-looking statements, including statements of intent, belief or current expectations with respect to the Company’s business and operations, market conditions, results of operations and financial condition. Forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements to differ materially from those expressed or implied in such statements.

Readers are cautioned not to place undue reliance on these forward-looking statements. Except as required by law, CVB undertakes no obligation to update or revise any forward-looking statements to reflect any change in expectations or events, conditions or circumstances on which such statements are based.

Investor / media enquiries

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

For personal use only