



CapsoVision Announces 510(k) Submission for the Addition of AI-Assisted Reading Module in CapsoCam Plus®

December 29, 2025

Company Preparing to Commence Commercialization Following U.S. FDA 510(k) Clearance

SARATOGA, Calif., Dec. 29, 2025 (GLOBE NEWSWIRE) -- CapsoVision, Inc. (NASDAQ: CV), a commercial-stage medical technology company developing advanced imaging and AI-enabled capsule endoscopy solutions, today announced submission of its 510(k) application to the Food and Drug Administration (FDA) for its proprietary AI-assisted module for CapsoCam Plus®. The addition of this reading tool will improve the detection of clinically significant pathology, as well as reduce clinician review time. The Company intends for U.S. commercialization activities to commence after the FDA clearance.

CapsoVision's CapsoCam Plus capsule endoscopy system is intended for visualization of the small bowel mucosa to detect abnormalities of the small bowel in adults and children aged two years and older. The Company believes that it is a more advanced capsule endoscopy solution compared to competitor systems, both in how it captures and presents images of the GI tract and the clinical workflow and patient experience that it enables.

"This submission marks an important milestone in our commitment to customers and patients towards advancing a best-in-class solution that integrates advanced imaging with AI-powered interpretation for small bowel diagnostics," said Johnny Wang, President and Chief Executive Officer. "We believe we are the only capsule endoscopy company with in-house AI core competency, and the scale and quality of our growing image data trove create a powerful foundation for training AI models and uncovering new clinical insights that will set our platform apart from competitive options. Combined with our fully cloud-based architecture—which eliminates the need for on-site servers, reduces cost and downtime, and removes the burden of IT maintenance—we are delivering an AI-enabled diagnostic platform designed to bring efficiency, accuracy, and accessibility to GI practices of all sizes."

About CapsoVision

CapsoVision is a commercial-stage medical technology company focused on developing advanced imaging and AI-enabled solutions to transform the detection and diagnosis of gastrointestinal diseases. Its flagship product, CapsoCam Plus®, is a wire-free, panoramic capsule endoscope that enables high-resolution visualization of the small bowel and supports cloud-based or direct capsule video retrieval. The Company's next pipeline product, CapsoCam Colon™ with enhanced AI, is designed to enable non-invasive colon imaging and polyp detection. With a proprietary platform targeted to expand across multiple GI indications, including esophageal and pancreatic disorders, CapsoVision is advancing a new era in capsule-based diagnostics. For more information on CapsoVision, please visit www.capsovision.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In this context, forward-looking statements mean statements related to future events, which may impact our expected future business and financial performance, and often contain words such as "expected", "anticipates", "intends", "plans", "believes", "potential", "will", "should", "could", "would" or "may" and other words of similar meaning. Examples of these forward-looking statements include, but are not limited to, statements concerning possible or assumed future results of operations, including the timing and receipt of regulatory approvals, the Company's plans, strategies and timing for its pipeline development, and the success of the Company's plans and strategies. These forward-looking statements are based on the Company's current expectations and inherently involve significant risks and uncertainties, including those beyond the Company's control. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, market conditions and the failure to receive regulatory clearance. These and other risks and uncertainties are described more fully in the Company's filings with the Securities and Exchange Commission ("SEC"), including the "Risk Factors" section of the Company's prospectus filed on July 3, 2025 with the SEC, as part of the Company's Registration Statement on Form S-1 (File No. 333-287148), and the Company's most recent Form 10-Q. Forward-looking statements speak only as of the date of this press release, and the Company undertakes no obligation to update or revise these statements, except as required by law.

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