CapsoVision Submits Breakthrough Device Designation Application to FDA for Pancreatic Cancer Screening Capsule

November 10, 2025

Non-invasive capsule endoscopy system aims to enable earlier detection of pancreatic ductal adenocarcinoma - among the most fatal cancers worldwide

SARATOGA, Calif., Nov. 10, 2025 (GLOBE NEWSWIRE) -- CapsoVision, Inc. (NASDAQ: CV), a commercial-stage medical technology company developing advanced imaging and AI-enabled capsule endoscopy solutions, today announced that it has submitted an application to the U.S. Food and Drug Administration (FDA) on November 6, 2025 requesting Breakthrough Device Designation (BDD) to accelerate development of the Company's CapsoCam UGI capsule endoscopy system for use in early-stage pancreatic cancer detection.

This submission represents an important milestone in CapsoVision's mission to expand its capsule-based diagnostics platform beyond the small bowel and address some of the most challenging diseases in gastroenterology. Pancreatic ductal adenocarcinoma — the most common form of pancreatic cancer — is among the deadliest cancers worldwide, with a five-yea survival rate of only 8%, largely because it is diagnosed at advanced stages that cannot be treated. Currently, no early screening tools are recommended to identify the disease at a treatable stage in the general population.

CapsoVision is pursuing the potential use of its CapsoCam UGI endoscopy to identify pancreatic disease at an earlier stage. The device's unique panoramic imaging capability enables clear visualization of the duodenal papilla, a small bowel landmark that controls release of digestive fluids. Changes in the papilla's appearance can be associated with pancreatic abnormalities and may serve as an early indicator of disease.

Unlike traditional endoscopic or imaging procedures, CapsoCam UGI is completely non-invasive. Patients simply swallow a pill-sized camera, eliminating the need for sedation, intubation, or recovery time, while enabling physicians to review detailed images through a secure, cloud-based system.

The FDA's Breakthrough Devices Program is designed to expedite the development and review of technologies that may offer more effective diagnosis or treatment for life-threatening conditions where no adequate alternatives exist. If granted, the designation would allow CapsoVision to work closely with the FDA to accelerate development and shape upcoming clinical studies, leading the regulatory review process.

Pancreatic Cancer Screenings

Pancreatic cancer remains one of the most lethal malignancies, with a five-year survival rate of only 10%[1], a figure that has seen little improvement in decades. It is now the third leading cause of cancer-related death in the United States[2], despite accounting for just over 3% of all cancer cases. Approximately 80% of diagnoses occur at advanced stages[3] when the disease is already unresectable or metastatic, leaving limited options for curative treatment. Existing diagnostic methods including CT, MRI, and endoscopic ultrasound are invasive, costly, and lack the sensitivity needed to detect small or early-stage lesions[4].

Early detection can improve survival more than fourteen-fold[5], yet no non-invasive screening method for the general population is currently recommended. This underscores an urgent global need for innovative, patient-friendly diagnostic technologies that can visualize pancreatic abnormalities earlier, before symptoms emerge and while curative treatment is still possible.

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. Specifically, the Company’s proposed capsule endoscopy solution may not meet the eligibility requirements for the Breakthrough Device Designation and, even if a Breakthrough Device Designation is received, it may not receive the FDA authorization required to market the proposed capsule endoscopy solution. 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.

Investor Relations Contact

Leigh Salvo
New Street Investor Relations
Investors@CapsoVision.com

Media Contact

Leslie Strickler and Paul Spicer
Être Communications
leslies@etrecommunications.com | (804) 240-0807
pauls@etrecommunications.com | (804) 503-9231

Sources

1. SEER Cancer Statistics Review, 2025. *National Cancer Institute.* https://seer.cancer.gov/statfacts/html/pancreas.html

2. Rawla P, Sunkara T, Gaduputi V. *Epidemiology of pancreatic cancer: global trends, etiology and risk factors. World Journal of Oncology.* 2019;10(1):10.

3. MD Anderson Cancer Center. *Pancreatic Cancer Overview.* Accessed July 2025. https://www.mdanderson.org/cancer-types/pancreatic-cancer.html

4. Olakowski M, Bułdak Ł. *Current status of inherited pancreatic cancer. Hereditary Cancer in Clinical Practice.* 2022;20(1):26.

5. SEER Statistics Network Explorer. *U.S. Cancer Statistics.* https://seer.cancer.gov/statistics-network/explorer