

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 25, 2026

CapsoVision, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-42705
(Commission
File Number)

20-3369494
(IRS Employer
Identification Number)

18805 Cox Avenue, Suite 250
Saratoga, California
(Address of Principal Executive Offices)

95070
(Zip Code)

Registrant's telephone number, including area code: (408)-624-1488

n/a
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
common stock, \$0.001 par value per share	CV	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On September 28, 2026, the Company announced that AI Highlights™, its AI-assisted reading feature for the CapsoCam Plus® system, received clearance from the U.S. Food and Drug Administration on September 25, 2026. The press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) The following exhibits are being filed herewith:

Exhibit No.	Description
99.1	Press Release issued on September 28, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CAPSOVISION, INC.

Date: September 28, 2026

By: /s/ Kang-Huai (Johnny) Wang

Name: Kang-Huai (Johnny) Wang

Title President and Chief Executive Officer



CapsoVision Announces FDA Clearance of AI Highlights for CapsoCam Plus®

AI-assisted reading tool designed to aid physician review of small bowel capsule endoscopy studies performed due to suspected bleeding using the CapsoCam Plus® system

SARATOGA, Calif., September 28, 2026 -- CapsoVision, Inc. (NASDAQ: CV), a commercial-stage medical technology company developing advanced imaging and AI-enabled capsule endoscopy solutions, today announced that AI Highlights™, its AI-assisted reading tool for the CapsoCam Plus system, received clearance from the U.S. Food and Drug Administration (FDA) on September 25, 2026.

AI Highlights is designed to support physicians in the review of small bowel capsule endoscopy studies collected from adult and pediatric patients (over two years of age) in whom the study was performed due to suspected small bowel bleeding, specifically to reduce the time taken to review capsule endoscopy images. It does so through recognizing and marking images containing suspected abnormal lesions, which are highlighted and prioritized for physician review. The feature integrates with CapsoView®, CapsoVision's video processing and review software, and supports workflows connected to the Company's CapsoCloud® platform. During video processing, the AI algorithm analyzes frames captured by the CapsoCam Plus capsule. AI-processed studies can then support physician review within connected CapsoView or CapsoCloud workflows, depending on workflow configuration.

"FDA clearance of AI Highlights represents an important milestone in the continued evolution of the CapsoVision platform and our commitment to bringing integrated, AI-assisted technologies to physicians in the United States," said Johnny Wang, President and Chief Executive Officer of CapsoVision. "Following the international launch of AI Highlights earlier this year, including in the European Union under the Medical Device Regulation, we are pleased to reach this important regulatory milestone in the United States. We believe AI-assisted review tools may help support physician efficiency and may help improve reading performance as capsule endoscopy adoption continues to expand."

Integrated within the CapsoVision ecosystem, AI Highlights works across the connected CapsoCloud workflow to support capsule endoscopy review without the need for a separate AI platform. Where and when available, CapsoCloud enables organizations to securely access AI-processed videos for remote physician review, collaboration, and case management.

The AI Highlights reading tool that was reviewed and cleared by the FDA represents a part of comprehensive updates to the CapsoView and CapsoCloud software. AI Highlights is intended to be used by trained healthcare professionals and is not intended to replace gastroenterologists' diagnostic interpretation or, where applicable, histopathological sampling. Please refer to the product's Instructions for Use for complete information regarding indications, contraindications, warnings, precautions, and limitations.

About CapsoVision

CapsoVision is a commercial-stage medical technology company focused on developing advanced imaging and AI-enabled solutions to transform the detection and screening 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 review. 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,” “anticipate(s),” “intend(s),” “plan(s),” “believe(s),” “potential,” “will,” “should,” “could,” “would,” “may,” “continue,” “remain,” “target(ed),” “expand”, or “improve” 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 and financial position, including the Company’s expectations regarding the Company’s product and clinical development efforts, the timing and receipt of regulatory submissions and approvals, the Company’s plans, strategies and timing for its pipeline development the Company’s expectations regarding the potential benefits of AI-assisted review tools to support physician efficiency and reading performance, the Company’s expectations regarding continued expansion of capsule endoscopy adoption, 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 (including competition in the capsule endoscopy market), the Company’s financial condition and the availability of cash and financing, and the success of the Company’s product and clinical development efforts. 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 most recent Form 10-K and 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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