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): November 12, 2026

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

Delaware	001-42705	20-3369494
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

18805 Cox Avenue, Suite 250 Saratoga, California	95070
(Address of Principal Executive Offices)	(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 2.02. Results of Operations and Financial Condition.

On November 12, 2026, the Company issued a press release announcing its financial results for the fiscal quarter ended September 30, 2026. A copy of the press release, dated November 12, 2026, is furnished hereto as Exhibit 99.1 and is incorporated herein by reference.

The foregoing information in this Item 2.02 (including the exhibit hereto) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

The following exhibits are being filed herewith:

Exhibit No.	Description
99.1	Press Release of CapsoVision, Inc, dated November 12, 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: November 12, 2026

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

Name: Kang-Huai (Johnny) Wang

Title Director, President and Chief Executive Officer

Exhibit 99.1

CapsoVision Reports Third Quarter 2026 Financial Results

SARATOGA, Calif., November 12, 2026 - CapsoVision, Inc. (NASDAQ: CV), a commercial-stage medical technology company developing advanced imaging and AI-enabled capsule endoscopy solutions, today reported financial results and provided a business update for its third quarter ended September 30, 2026.

Recent Highlights

- Reported third quarter 2026 revenue of $3.6 million, compared with $3.5 million in the third quarter 2025.
- CapsoCam Plus® used by more than 184,000 patients worldwide as of September 30, 2026, compared with 151,000 a year earlier.
- Received FDA clearance for AI Highlights™, the Company's AI-assisted reading tool for CapsoCam Plus®, on September 25, 2026, followed by its U.S. commercial launch on November 2, 2026. Available for both adults and pediatric patients aged two and older, AI Highlights supports physician review through both local computer and cloud-based platforms. The Company expects the addition of AI Highlights to accelerate CapsoCam Plus sales growth, with the full commercial impact anticipated in 2027.
- Completed enrollment and clinical data collection for the second-generation CapsoCam Colon™ study, including physician review of capsule videos both with and without AI assistance. FDA 510(k) submission remains on track for year-end 2026.
- Continued expanding the clinical footprint of the CapsoCam UGI study for pancreatic cancer detection. Building on two active community-based clinical sites, the Company has executed a clinical trial agreement with a third site and is in various stages of contracting and feasibility discussions with more than a dozen larger medical centers with expertise in pancreatic ductal adenocarcinoma (PDAC), which the Company expects will help accelerate patient enrollment.
- Completed an $18 million registered direct offering with existing shareholders in September 2026, generating approximately $17.8 million in net proceeds.
- Raised approximately $1.7 million in net proceeds through the at-the-market offering program during the third quarter of 2026.
- Appointed David S. Shields, M.D., to the Board of Directors effective July 1, 2026.

Management Commentary

"The FDA clearance and subsequent U.S. launch of AI Highlights marks an important step forward for CapsoVision," said Johnny Wang, President and Chief Executive Officer. "Our four-camera, 360-degree panoramic capsule already provides physicians with a differentiated view of the small bowel. By combining that imaging capability with AI-assisted review, we believe we can reduce reading time, improve detection accuracy compared with manual review, and give physicians an additional level of diagnostic confidence. We believe the combination of panoramic imaging and FDA-cleared AI-assisted review, approved for use in patients two years and older is a meaningful differentiator for CapsoCam Plus.

At the same time, completing enrollment in our colon clinical study brings us closer to our planned FDA submission by year end, which we believe represents a substantially larger market opportunity. With the support of our existing shareholders through our recent financing, we are focused on translating these milestones into broader adoption and long-term growth," concluded Wang.

Third Quarter 2026 Financial Results

Total revenue was $3.6 million compared to $3.5 million in the third quarter of 2025. Average selling price was stable year over year. The Company expects the addition of AI Highlights, launched on November 2, 2026, following FDA clearance, to accelerate CapsoCam Plus sales growth, with the full commercial impact anticipated in 2027.

Gross profit was $1.8 million, compared with $1.9 million in the third quarter of 2025. Gross margin was 49%, compared to 54% in the third quarter of 2025. The decline primarily reflected higher material costs associated with increased flash memory prices, a one-time inventory obsolescence charge, and higher stock-based compensation expense.

Operating expenses decreased to $9.1 million, from $9.9 million in the third quarter of 2025, reflecting continued expense management while supporting clinical and development programs, including the CapsoCam Colon pivotal study. With the study now complete, the Company expects related clinical expenses to decline while it continues advancing its development pipeline.

Net loss was $7.3 million, or $0.15 per share, compared with a net loss of $7.9 million, or $0.17 per share, in the third quarter of 2025.

Cash and cash equivalents totaled $21.8 million as of September 30, 2026. During September, the Company completed an $18 million registered direct offering with existing shareholders, generating approximately $17.8 million in net proceeds. The Company also sold 276,446 shares through its at-the-market offering program during the quarter for approximately $1.7 million in net proceeds.

Conference Call and Webcast

CapsoVision will host a conference call today, November 12, 2026, at 4:30 p.m. ET to discuss its third quarter financial results. Individuals interested in listening to the conference call may do so by dialing (800) 715-9871 for domestic callers or (646) 307-1963 for international callers and referencing conference ID 2841803, or from the webcast link on the Events page in the investor relations section of the company's website at www.capsovision.com.

To access the replay, please register via the webcast link on the Events page. The webcast will be available for one year following the completion of the call.

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”, “positioned”, “on track”, “anticipate(s)”, “intend(s)”, “plan(s)”, “believe(s)”, “potential”, “will”, “should”, “could”, “would”, “may”, “continue”, “remain”, “advancing”, “approach(ing)”, “planned”, “look forward”, or “target(ed)” 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 sales growth of CapsoCam Plus® and the timing thereof, the Company’s expectations regarding clinical and other operating expenses, 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 (including the commercialization, physician adoption

and anticipated benefits of AI Highlights™, the continued development and anticipated 510(k) submission for CapsoCam Colon™, and the market opportunity for CapsoCam Colon™, the clinical study for CapsoCam® UGI in pancreatic cancer detection) 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, including from competitors with FDA-cleared AI products), the Company's financial condition and the availability of cash and financing (including through the Company's at-the-market equity offering program), the success of the Company's product and clinical development efforts, the failure to receive regulatory clearance or approval, changes in U.S. trade policies, tariffs or other government regulations that could increase the Company's costs or affect the Company's supply chain, and the failure to adapt the Company's products for new indications. 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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CAPSOVISION, INC.
CONDENSED BALANCE SHEETS (UNAUDITED)
(in thousands, except par value and share amounts)

	September 30, 2026	December 31, 2025
ASSETS		
Current Assets		
Cash and cash equivalents	$ 21,757	$ 10,112
Accounts receivable, net	2,456	2,498
Inventory	4,747	2,987
Prepaid expenses and other current assets	2,086	1,072
Total current assets	**31,046**	**16,669**
Property and equipment, net	508	611
Operating lease right-of-use assets	747	843
Other long-term assets	451	41
TOTAL ASSETS	**$ 32,752**	**$ 18,164**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 1,102	$ 1,143
Accrued expenses and other current liabilities	4,355	2,697
Deferred revenue	146	177
Operating lease liabilities – current	521	410
Total current liabilities	**6,124**	**4,427**
Operating lease liabilities – long-term	259	477
Total liabilities	**6,383**	**4,904**
Commitments and contingencies - Note 8		
Stockholders' Equity		
Preferred stock, $0.001 par value: 10,000,000 shares authorized and none issued and outstanding as of September 30, 2026; 10,000,000 shares authorized and none issued and outstanding as of December 31, 2025	—	—
Common stock, $0.001 par value: 300,000,000 shares authorized as of September 30, 2026; 53,569,896 and 46,865,051 issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	54	47
Additional paid-in capital	203,833	168,878
Accumulated deficit	(177,518)	(155,665)
Total stockholders' equity	**26,369**	**13,260**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 32,752**	**$ 18,164**

CAPSOVISION, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)

(in thousands, except share and per-share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Net revenue	**$ 3,568**	**$ 3,538**	**$ 10,003**	**$ 9,636**
Costs of revenue	**1,804**	**1,624**	**5,039**	**4,417**
Gross profit	**1,764**	**1,914** —	**4,964**	**5,219**
OPERATING EXPENSES				
Selling and marketing	2,060	1,773	6,087	5,581
Research and development	4,803	6,090	14,547	12,589
General and administrative	2,285	2,070	6,387	5,101
Total operating expenses	**9,148**	**9,933**	**27,021**	**23,271**
Operating loss	**(7,384)**	**(8,019)**	**(22,057)**	**(18,052)**
NON-OPERATING INCOME				
Interest income, net	46	132	187	175
Other non-operating income (expense), net	(1)	(34)	17	(44)
Total non-operating income, net	**45**	**98**	**204**	**131**
Loss before income taxes	**(7,339)**	**(7,921)**	**(21,853)**	**(17,921)**
Provision for income taxes	—	—	—	—
Net loss and comprehensive loss	**$ (7,339)**	**$ (7,921)**	**$ (21,853)**	**$ (17,921)**
Net loss per share – basic and diluted	**$ (0.15)**	**$ (0.17)**	**$ (0.44)**	**$ (1.05)**
Weighted average common shares outstanding – basic and diluted	**50,568,141**	**46,217,127**	**49,332,254**	**17,049,671**

CAPSOVISION, INC.

CONDENSED STATEMENTS OF CASH FLOWS (UNAUDITED)

(in thousands)

	Nine Months Ended September 30,	
	2026	**2025**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (21,853)	$ (17,921)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	173	161
Loss on disposal of property and equipment	—	1
Amortization of operating lease right-of-use assets	307	260
Unrealized foreign exchange losses (gains)	57	(170)
Stock in lieu of debt repayment	—	31
Stock-based compensation	1,863	629
Bad debt expense	10	11
Changes in operating assets and liabilities:		
Accounts receivable	10	151
Inventory	(1,760)	(558)
Prepaid expenses and other current assets	(1,014)	(303)
Other long-term assets	(410)	—
Accounts payable	(203)	596
Accrued expenses and other current liabilities	1,658	2,220
Deferred revenue	(31)	(26)
Operating lease liabilities	(318)	(260)
Net cash used in operating activities	**$ (21,511)**	**$ (15,178)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(70)	(82)
Net cash used in investing activities	**$ (70)**	**$ (82)**
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from IPO, net of commissions	—	26,557
Payment of IPO offering costs	—	(3,184)
Repayment of promissory note	—	(1,000)
Proceeds from Private Placement	14,000	—
Payment of Private Placement issuance costs	(601)	—
Proceeds from ATM Program, net of issuance costs	1,710	—
Proceeds from Securities Purchase Agreement	18,000	—
Payment of constructive dividend	(12)	—
Proceeds from promissory note issuance	—	1,000
Proceeds from exercises of options on common stock and warrants	164	216
Net cash provided by financing activities	**$ 33,261**	**$ 23,589**
Net increase in cash and cash equivalents	11,680	8,329
Effect of exchange rate changes on cash and cash equivalents	(35)	139
Cash and cash equivalents at beginning of period	**10,112**	**9,319**
Cash and cash equivalents at end of period	**$ 21,757**	**$ 17,787**

CAPSOVISION, INC.

CONDENSED STATEMENTS OF CASH FLOWS (UNAUDITED)

(in thousands)

SUPPLEMENTAL CASH FLOW DISCLOSURES		
Cash paid for income taxes	$ 10	$ 7
Cash paid for interest	—	15
NON-CASH FINANCING AND INVESTING ACTIVITIES		
Obtaining a right-of-use asset in exchange for a lease liability	211	—
Underwriters warrants issued in connection with the IPO	—	519
Conversion of convertible preferred stock into common stock upon initial public offering	—	143,625
Securities Purchase Agreement issuance costs in accounts payable	162	—