

CapsoVision - The First AI Commercial Bet

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Company: CapsoVision, Inc. (NASDAQ: CV; SEC CIK 0001378325)

Case convention: The choices below are constructed for teaching; they are not disclosed board proposals. No program-level budgets, feature economics or investment returns were public by the cutoff.

A clearance, three demands on a small balance sheet

On September 28, CapsoVision announced that the FDA had cleared AI Highlights for use with its CapsoCam Plus capsule endoscopy system. The clearance was granted three days earlier. The tool identifies and marks images containing suspected abnormalities so trained professionals can prioritize review of small-bowel capsule studies performed because of suspected bleeding in adults and children over age two. The physician remains responsible for diagnostic interpretation; the release did not report clinical performance results or show that the software changed patient outcomes. [P02]

The clearance arrived alongside two other development priorities. CapsoVision had said that 801 patients were enrolled in the pivotal arm for second-generation CapsoCam Colon and targeted a Q4 2026 510(k) submission. It had also started an upper-GI (UGI) study, with three patients enrolled by the August filing; management discussed up to 140 patients and further study work before a possible later FDA resubmission. [P01]

CapsoVision is a small commercial-stage medical-technology company. Its Q2 2026 revenue was \$3.6 million, up 10% year over year, as capsule units sold rose 13% and average selling price fell about 3% amid competitive pricing. First-half revenue was \$6.4 million, up 6%. These results describe the existing product business, not AI Highlights economics: the U.S. clearance came after quarter-end. [P01]

CapsoVision was entering an AI-enabled capsule-reading category that already included Deep Capsule AI, cleared by the FDA in March 2026. The competitor's device and retrospective study do not establish CapsoVision's performance or adoption and are not a like-for-like benchmark. [P04]

Your assignment: Recommend how CapsoVision should sequence management attention and incremental discretionary spending across AI Highlights commercialization, Colon submission readiness and the UGI study, while protecting liquidity and required work. State what evidence should release or limit the next commitment. These are constructed alternatives; no public source described a board decision, program budgets, customer adoption cohorts, product margins or paybacks. Do not presume the September offering's estimated proceeds translate into a new disclosed cash balance.

Three constructed approaches

1. **AI-first, staged rollout.** Concentrate near-term commercial effort on the newly cleared feature, but release expansion in stages against proposed evidence on site activation, eligible case volume, clinician use, workflow time, support burden and repeat use. Protect critical-path work on Colon and existing obligations.
2. **Colon-first readiness.** Protect the stated Q4 510(k) submission target and keep AI commercialization focused on current channels while gathering early adoption evidence. This preserves a near-term pipeline milestone but risks underinvesting in the newly cleared feature.
3. **Liquidity-first policy.** Set a student-proposed minimum liquidity reserve and cap discretionary commitments regardless of regulatory progress. Slow one or more expansion activities if the downside cash forecast breaches the reserve. The reserve and forecast horizon are teaching assumptions, not company guidance.

Required regulatory, quality, customer-support and existing contractual obligations are not optional in any route. The company did not disclose which incremental commitments could be stopped or their cost to complete.

Evidence and constraints

At June 30, CapsoVision reported \$9.1 million of cash and cash equivalents. It used \$14.5 million in operating cash during the first half of 2026 and reported a \$14.5 million net loss. Its 10-Q said substantial doubt existed about its ability to continue as a going concern within one year, that additional capital would likely be needed before year-end for operations and planned studies, and that financing was not assured; it might scale back plans. [P01]

In September, CapsoVision sold 3,163,444 shares at \$5.69 in a registered direct offering. Its prospectus estimated approximately \$18.0 million gross and \$17.8 million net proceeds. Transaction counsel reported the offering closed September 18. No later cash balance or revised runway was disclosed by October 2, so the June 30 reported cash remains the latest public balance-sheet snapshot. The separate \$100 million at-the-market (ATM) facility permits possible future share sales; the company is not obligated to sell, and the ceiling is not committed funding. [P01, P03, P06]

Exhibit 1. Selected operating and liquidity evidence

USD millions unless noted; reported periods end June 30.

Measure	Q2 / June 30, 2026	Comparator	What it says-and does not say
Revenue	\$3.6	\$3.3 Q2 2025	+10% year over year; before U.S. AI Highlights clearance
Capsule units sold	+13%	year over year	Unit growth did not translate one-for-one to revenue
Average selling price	~3% lower	year over year	Company cited competitive pricing
Gross margin	51%	55% Q2 2025	Existing portfolio measure, not AI feature margin

Measure	Q2 / June 30, 2026	Comparator	What it says-and does not say
Cash and equivalents	\$9.077	\$10.112 Dec. 31, 2025	Latest reported cash balance; not post-offering cash
H1 operating cash used	\$14.469	\$9.512 H1 2025	Historical cash-flow measure; not a forecast
H1 net loss	\$14.514	-	GAAP earnings measure, not identical to cash use
Sep. registered direct	\$18.0 gross; ~\$17.8 estimated net	3.163m shares at \$5.69	Closed Sep. 18 per transaction counsel; no updated cash statement
ATM capacity	Up to \$100	-	Potential future sales; no obligation to sell, not committed proceeds

Sources: P01 (Q2 10-Q, financial statements and MD&A), P03 (424B5), P06 (transaction-counsel close notice). Rounded; the \$100 million ATM is separate from the completed registered direct offering.

Exhibit 2. Development paths at cutoff

Program	Public status by cutoff	What remains unknown
CapsoCam Plus / AI Highlights	FDA clearance Sep. 25; announced Sep. 28. Narrow use: suspected small-bowel bleeding studies in patients older than two. Marks suspect images for clinician review. [P02]	U.S. adoption, use rates, performance, price, reimbursement, customer economics, support costs and realized workflow savings
CapsoCam Colon Gen 2	801 patients enrolled in pivotal arm; management targeted Q4 2026 510(k) submission. [P01]	Remaining submission cost, review timeline, clearance probability, capacity needs, launch economics
UGI	Study underway; three patients enrolled by Aug. 13 filing; up to 140 planned. FDA had not granted requested Breakthrough Device designation. Company said more work and site expansion were needed before possible resubmission. [P01]	Incremental cost, trial timing, evidence threshold and commercial path

The Q2 filing's planned clearance timing for AI Highlights was superseded by the September announcement. The public IR notice announced an on-demand H.C. Wainwright presentation beginning September 11, but the linked current corporate deck has no visible version date and cannot be confirmed as that conference deck; no dated transcript was located. Its older pre-clearance forecast is not evidence of post-clearance execution. [P05]

Questions for discussion

1. Which work should be protected in all cases, and which spending or management bandwidth is genuinely discretionary?

2. Which of the three constructed approaches would you choose? What is the strongest argument against it?
3. What data and milestones would you require before increasing investment in AI Highlights? How would you keep patient-safety and physician-oversight measures in the scorecard?
4. How should the Colon and UGI priorities change if financing is delayed or the initial AI rollout shows low site activation?
5. What monthly cash forecast and program data would you request before setting a reserve or authorizing larger commitments?

Sources

- P01.** CapsoVision, Q2 2026 Form 10-Q, accession 0001378325-26-000036, [SEC filing](#).
- P02.** CapsoVision, “CapsoVision Announces FDA Clearance of AI Highlights for CapsoCam Plus,” Sep. 28, 2026, [SEC Exhibit 99.1](#).
- P03.** CapsoVision, Sep. 17 registered direct offering prospectus, accession 0001628280-26-062680, [SEC filing](#).
- P04.** FDA, Deep Capsule AI 510(k) decision summary K250655, [PDF](#).
- P05.** CapsoVision, Sep. 3 investor conference notice, [issuer release](#).
- P06.** O’Melveny, transaction counsel, Sep. 22, 2026, [offering close notice](#).

Information cutoff: October 2, 2026, 4:00 p.m. ET. Additional source locators and limits: research source register and evidence extraction.