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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2026

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____to _____

Commission file number 001-42705

CAPSOVISION, INC.
(Exact name of registrant as specified in its charter)

Delaware	**20-3369494**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
18805 Cox Avenue, Suite 250 Saratoga, CA	**95070**
(Address of Principal Executive Offices)	(Zip Code)

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

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

Title of each class	Trading Symbol(s)	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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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.

☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ☐ No ☒

As of November 11, 2026, the registrant had 53,609,719 shares of common stock, $0.001 par value per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements in this Quarterly Report on Form 10-Q constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We base these forward-looking statements on our expectations and projections about future events, which we derive from the information currently available to us. Such forward-looking statements relate to future events or our future performance, including: our financial performance and projections; our growth in revenue and earnings; and our business prospects and opportunities. You can identify forward-looking statements by those that are not historical in nature, particularly those that use terminology such as “may,” “should,” “expects,” “anticipates,” “contemplates,” “estimates,” “believes,” “plans,” “projected,” “predicts,” “potential,” or “hopes” or the negative of these or similar terms. In evaluating these forward-looking statements, you should consider various factors, including: our ability to change the direction of the Company; our ability to keep pace with new technology and changing market needs; and the competitive environment of our business. These and other factors may cause our actual results to differ materially from any forward-looking statement. Forward-looking statements are only predictions. The forward-looking events discussed in this Quarterly Report on Form 10-Q may not occur, and actual events and results may differ materially and are subject to risks, uncertainties and assumptions about us. We are not obligated to publicly update or revise any forward-looking statement, whether as a result of uncertainties and assumptions. The forward-looking events discussed in this Quarterly Report on Form 10-Q might not occur.

While we believe we have identified material risks, these risks and uncertainties are not exhaustive. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties, and other factors described in the section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. New risks and uncertainties emerge from time to time, and it is not possible to predict all risks and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy or completeness of any of these forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. We are under no duty to update any of these forward-looking statements after the date of this Quarterly Report on Form 10-Q to conform our prior statements to actual results or revised expectations, and we do not intend to do so.

Forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the acceptance of our products by patients and doctors;
- our expectations regarding the potential market size for our current CapsoCam Plus capsule and CapsoCam Colon (once FDA cleared) and those markets that we may pursue;
- our plans to increase small bowel capsule sales following 510(k) clearance for pediatric use and telehealth supervision and related products currently under development, including our capsule delivery device and patency capsule;
- our expected timing for submission of 510(k) application for our second-generation of CapsoCam Colon capsule;
- our expected receipt of and related timing for FDA 510(k) clearance of our CapsoCam Colon capsule and related sales;
- our expected timing and enrollment size of our study of CapsoCam UGI system and our expected resubmission of the Breakthrough Device Designation application following the study;

- our plans and efforts to expand into new indications in terms of new GI pathologies and expanded patient populations;
- our plans and efforts to introduce enhancements and improvements to our products and technologies, including the AI capabilities incorporated into our products , and the commercialization of AI Highlights™ following its FDA clearance;
- our commercialization capabilities and strategies, including our plans to increase revenues and sales capabilities in and outside the United States (the "U.S.");
- the implementation of our strategic plan for our business and products and technology;
- our relationships with, and capabilities of, our assembly manufacturers and component suppliers;
- the impact of U.S. trade policies and tariffs on our costs, gross margin and supply chain;
- the protection of our intellectual property (including our AI capabilities) including through patents and trade secret protections;
- the expected performance of our products;
- our ability to manage our growth;
- the anticipated use of net proceeds from our equity financings, including sales under our at-the-market offering program;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") or smaller reporting company under U.S. securities laws;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing, and our ability to obtain additional capital, including through sales under our at-the-market offering program;
- our ability to continue as a going concern; and
- our future financial performance.

We caution you not to place undue reliance on the forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q in the case of forward-looking statements contained in this Quarterly Report on Form 10-Q.

Item 1. Financial Statements

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**

The accompanying notes are an integral part of these condensed financial statements.

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**

The accompanying notes are an integral part of these condensed financial statements.

CAPSOVISION, INC.
CONDENSED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) (UNAUDITED)
(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock				
	Shares	Amount	Shares	Par Value	Additional Paid-in-Capital	Accumulated Deficit	Total Stockholders' Equity
December 31, 2025	**—**	**$ —**	**46,865,051**	**$ 47**	**$ 168,878**	**$ (155,665)**	**$ 13,260**
Issuance of common stock upon Private Placement, net of issuance cost	—	—	2,867,089	3	13,617	—	13,620
Issuance of common stock upon exercises of stock options	—	—	106,727	—	39	—	39
Stock-based compensation	—	—	—	—	334	—	334
Net loss	—	—	—	—	—	(7,033)	(7,033)
March 31, 2026	**—**	**$ —**	**49,838,867**	**$ 50**	**$ 182,868**	**$ (162,698)**	**$ 20,220**
Private Placement issuance cost	—	—	—	—	(220)	—	(220)
Constructive Dividend	—	—	—	—	(12)	—	(12)
Issuance of common stock upon exercises of stock options	—	—	181,149	—	82	—	82
Issuance of common stock upon vesting of restricted stock units	—	—	12,132	—	—	—	—
Stock-based compensation	—	—	—	—	577	—	577
Net loss	—	—	—	—	—	(7,481)	(7,481)
June 30, 2026	**—**	**$ —**	**50,032,148**	**$ 50**	**$ 183,295**	**$ (170,179)**	**$ 13,166**
Issuance of common stock via ATM, net of issuance cost	—	—	276,446	1	1,709	—	1,710

The accompanying notes are an integral part of these condensed financial statements.

CAPSOVISION, INC.
CONDENSED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) (CONTINUED)
(in thousands, except share amounts)

Issuance of common stock via Securities Purchase Agreement, net of issuance cost	—	—	3,163,444	3	17,835	—	17,838
Issuance of common stock upon exercises of stock options	—	—	97,858	—	43	—	43
Stock-based compensation	—	—	0	0	952	—	952
Net loss	—	—	—	—	—	(7,339)	(7,339)
September 30, 2026	**—**	**—**	**53,569,896**	**54**	**203,833**	**(177,518)**	**26,369**

	Convertible Preferred Stock		Common Stock				
	Shares	**Amount**	**Shares**	**Par Value**	**Additional Paid-in-Capital**	**Accumulated Deficit**	**Total Stockholders' Deficit**
December 31, 2024	**38,665,583**	**$ 143,625**	**2,090,945**	**$ 2**	**$ 838**	**$ (130,350)**	**$ (129,510)**
Issuance of common stock upon exercises of stock options	—	—	87,549	—	34	—	34
Stock-based compensation	—	—	—	—	152	—	152
Net loss	—	—	—	—	—	(5,375)	(5,375)
March 31, 2025	**38,665,583**	**$ 143,625**	**2,178,494**	**$ 2**	**$ 1,024**	**$ (135,725)**	**$ (134,699)**
Issuance of common stock upon exercises of stock options	—	—	265,674	—	95	—	95
Issuance of common stock upon exercises of warrants	—	—	15,015	—	73	—	73
Stock-based compensation	—	—	—	—	170	—	170
Net loss	—	—	—	—	—	(4,625)	(4,625)
June 30, 2025	**38,665,583**	**$ 143,625**	**2,459,183**	**$ 2**	**$ 1,362**	**$ (140,350)**	**$ (138,986)**

The accompanying notes are an integral part of these condensed financial statements.

CAPSOVISION, INC.
CONDENSED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) (CONTINUED)
(in thousands, except share amounts)

Conversion of all convertible preferred stock to common stock - initial public offering	(38,665,583)	(143,625)	38,665,583	39	143,586	—	143,625
Issuance of common stock in initial public offering, net of issuance costs	—	—	5,629,978	6	22,848	—	22,854
Issuance of Underwriters Warrants	—	—	—	—	519	—	519
Issuance of common stock upon promissory note repayment	—	—	7,508	—	31	—	31
Reverse stock split rounddown and cash in lieu payment	—	—	-108	—	(1)	—	(1)
Issuance of common stock upon exercises of stock options	—	—	36,757	—	14	—	14
Stock-based compensation	—	—	—	—	307	—	307
Net loss	—	—	—	—	—	(7,921)	(7,921)
September 30, 2025	**—**	**$ —**	**46,798,901**	**$ 47**	**$ 168,666**	**$ (148,271)**	**$ 20,442**

The accompanying notes are an integral part of these condensed financial statements.

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**

The accompanying notes are an integral part of these condensed financial statements.

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	—

The accompanying notes are an integral part of these condensed financial statements.

1. DESCRIPTION OF BUSINESS AND ORGANIZATIONAL STRUCTURE

CapsoVision, Inc. (“CapsoVision” or the “Company”), a commercial stage medical technology enterprise, that innovates, manufactures, and markets endoscopic video imaging devices focused on internal imaging of the gastrointestinal (“GI”) system. Internal GI imaging facilitates earlier detection of colorectal cancer and other diseases, enabling more timely and effective treatment regimens for patients. The Company is based in Saratoga, California. Its customers include, in the U.S., gastrointestinal medical practices, clinics, and hospitals; outside of the U.S., the Company sells to distributor customers who resell products.

Since its 2005 formation, the Company’s organizational structure has comprised a single Delaware corporation with a branch office in Taiwan, Republic of China, the location of certain suppliers and Company personnel.

The Company’s core technology platform is an orally ingestible capsule including multiple cameras facilitating 360 degree imaging, light-emitting diodes for measurement, onboard memory storage, and battery life permitting recording and onboard storage of video images. This platform obviates the need for external data transmission or for a patient to remain in a medical facility throughout the digestive cycle. The Company’s products consist of (i) the on-market CapsoCam Plus®, directed at the small intestines, and (ii) the in-development CapsoCam Colon directed at the large intestines (colon). Stored video imagery is downloaded from capsules with a data access device, CapsoAccess® and enabling software, CapsoView®. This video access solution permits on-site, on-demand video download and viewing by customers. The Company operates the CapsoCloud® cloud-based software-as-a-service ecosystem as an off-premise video access and download solution. Using CapsoCloud®, retrieved capsules are sent by customers to a centralized processing center for video downloading; patient video content is then made available via web portal or dedicated app access for customers to view, download, and generate patient reports. The Company’s services also include video reading; pursuant to this offering, physician customers may purchase a video reading and generation of patient report carried out by a second physician.

CapsoCam Plus® was cleared by the U.S. Food and Drug Administration ("FDA") in 2016 and has since been approved in various other countries. CapsoCam Colon completed the second arm of our pivotal clinical study with planned submission for regulatory clearance, starting with the FDA, and we anticipate filing with the FDA in the fourth quarter of 2026. The Company is subject to risks and uncertainties common to life sciences companies including, but not limited to, risks associated with the success of research and development, risks associated with contract manufacturing, competition from other companies, protection of intellectual property and the risk of litigation related thereto, compliance with government regulations, and the ability to secure additional capital to fund operations and research and development. Current and future programs, including for products focused on other areas of the GI system, will require significant research and development efforts, extensive clinical testing, and submissions for regulatory approval prior to commercialization.

Private Placement

On March 16, 2026, the Company entered into a Securities Purchase Agreement (the “Securities Purchase Agreement”) with selected accredited investors (the “Investors”), for the purposes of raising approximately $14 million in aggregate gross proceeds for the Company (the “Private Placement”). Pursuant to the terms of the Securities Purchase Agreement, the Company agreed to issue and sell to the Investors in the Private Placement an aggregate of 2,867,089 shares (the “Shares”) of common stock of the Company, par value $0.001 per share (the “Common Stock”), at $4.883 per Share. The closing of the Private Placement occurred on March 16, 2026. The Company intends to use the net proceeds from the Private Placement for general corporate purposes, including sales and marketing, research and development activities, general and administrative matters, working capital and capital expenditures.

In connection with the Private Placement, the Company entered into a registration rights agreement, dated March 16, 2026 (the “Registration Rights Agreement”), with the Investors, pursuant to which, among other things, the Company will (i) prepare and file with the Securities and Exchange Commission (the “SEC”) a registration statement to register for resale the Shares within 90 days after the closing of the Private Placement, and (ii) use

commercially reasonable efforts to have such registration statement declared effective as soon as reasonably practicable following the filing thereof with the SEC. The Registration Rights Agreement contains customary terms and conditions for a transaction of this type. On April 22, 2026, the SEC declared effective the registration of the Shares sold in the Private Placement.

Shelf Registration and 2026 At-the-Market (ATM) Agreement with Cantor

On August 13, 2026, the Company filed with the SEC a universal Shelf Registration Statement on Form S-3 (File No. 333-298315) (the “2026 Shelf Registration Statement”). The 2026 Shelf Registration Statement initially provides the Company with the ability to offer up to $250 million of securities, including common stock, preferred stock, warrants, rights and units. The 2026 Shelf Registration Statement was declared effective by the SEC on August 21, 2026. Pursuant to the 2026 Shelf Registration Statement, the Company may offer additional securities from time to time and through one or more methods of distribution, subject to market conditions and its capital needs.

On August 13, 2026, the Company entered into a Controlled Equity Offering^{SM} Sales Agreement (the “2026 ATM Agreement”) with Cantor Fitzgerald & Co. (“Cantor”) with respect to an at-the-market offering program under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, having an aggregate offering price of up to $100 million through Cantor as its “sales agent” (the “Agent”).

September 2026 Securities Purchase Agreement

On September 17, 2026, the Company entered into a securities purchase agreement (the "September 2026 Securities Purchase Agreement") with certain existing investors (the "Purchasers"), providing for the issuance and sale of its common stock, in a registered direct offering (the "Registered Direct Offering"), under the prospectus supplement to the 2026 Shelf Registration Statement for the purpose of raising approximately $18 million in aggregate gross proceeds for the Company. The Company offered 3,163,444 shares of the Company's common stock, par value $0.001 per share, at a purchase price of $5.69 per share, representing a discount of approximately 5% to the last reported sale price of the Common Stock on The Nasdaq Capital Market on September 16, 2026. The Registered Direct Offering closed on September 18, 2026.

The offering was made without an underwriter or a placement agent and did not result in paying any underwriting fees or commissions. Each of the Purchasers is an existing stockholder of the Company. Two of the Purchasers are Related Parties with more than 5% ownership of the Company's outstanding common stock as described in Note 14. RELATED PARTIES.

The Company intends to use the net proceeds from the sale of common stock offered under this prospectus supplement for general corporate purposes, including sales and marketing, research and development activities, general and administrative matters, and working capital.

2. GOING CONCERN

The Company has incurred operating losses and negative cash flows from operations since its inception. Since the launch of CapsoCam Plus® in 2016, the Company has been able to fund increasing portions of its operating expenses from sales. However, the Company has continued to incur operating losses, net losses, and negative operating cash flows. The Company expects to continue to experience similar circumstances until existing and future products’ sales yield further growth in revenues, achievement of break-even, and realization of future operating income, net income, and positive operating cash flows. As of September 30, 2026, the Company had cash and cash equivalents of $21,757. For the nine months ended September 30, 2026, the Company had an operating loss of $22,057, a net loss and comprehensive loss of $21,853, and net cash used in operating activities of $21,511. The Company, having evaluated the extant facts and circumstances, concluded that the facts and circumstances raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date of issuance of these financial statements. While the Company raised approximately $14 million

in the gross proceeds resulting from the Private Placement in the first quarter of 2026, and approximately $18 million in gross proceeds through the Securities Purchase Agreement in the Registered Direct Offering and approximately $1.8 million in gross proceeds through the 2026 ATM Agreement in the third quarter of 2026, as described in Note 1. DESCRIPTION OF BUSINESS AND ORGANIZATIONAL STRUCTURE and further discussed in Note 9. COMMON STOCK, it is not probable that these funds are sufficient to fund expenditures necessary to achieve sales growth and innovation objectives. The Company intends to pursue additional capital raising activities, but there is no certainty as to such capital raising activities occurring at all, or occurring with sufficient timing or magnitude, sufficient to alleviate such substantial doubt.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

These unaudited interim condensed financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and pursuant to the rules and regulations of the United States Securities and Exchange Commission ("SEC"). Any reference in these notes as it concerns U.S. GAAP is meant to refer to authoritative pronouncements as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) issued by the Financial Accounting Standards Board (“FASB”).

These unaudited interim condensed financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to effect fair presentation of financial position as of September 30, 2026, the results of operations for the three and nine months ended September 30, 2026 and 2025, and cash flows for the nine months ended September 30, 2026 and 2025. The condensed balance sheet at December 31, 2025 was derived from the audited annual financial statements but does not contain all of the footnote disclosures from the audited annual financial statements. These interim financial results are not necessarily indicative of results expected for the full fiscal year or for any subsequent interim period and should be read in conjunction with the audited annual financial statements.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business.

Reporting Entity

The Company’s organizational structure reflects a single incorporated entity, CapsoVision, Inc. This single entity has a foreign branch and physical presence in Taiwan, Republic of China, which is an extension of the U.S. corporation.

Private Placement Issuance Costs

The Company accounts for costs directly attributable to the issuance of equity securities in a private placement as a reduction to the gross proceeds received from the offering, in accordance with ASC 340-10 and ASC 505-10. These costs typically include legal, accounting, advisory, and other professional fees, as well as regulatory and filing fees, that are incremental and would not have been incurred absent the private placement transaction.

Issuance costs are initially recorded as deferred assets within prepaid expenses and other current assets on the balance sheet until the closing of the private placement. Upon closing, the total amount of issuance costs incurred is reclassified as a reduction to additional paid-in capital (APIC) within stockholders’ equity. This treatment ensures that the net proceeds from the private placement reflect the actual funds available to the Company after all directly related costs.

The Company's legal and advisory cost directly attributable to the Private Placement and other incremental costs associated with the SEC registration of shares issued as a result of the Private Placement totaling approximately $600 are qualified as issuance costs and recorded to stockholders' equity as a reduction to the gross proceeds from the offering in the period when they are incurred.

Equity Financing Costs

The Company capitalizes qualifying direct incremental third-party costs incurred in connection with establishing 2026 Shelf Registration Statement.

Deferred shelf registration costs are presented as other current and long-term assets and are allocated to future equity offerings via 2026 ATM Agreement. Upon completion of an equity offering, the allocated deferred costs are recognized as a reduction of Additional Paid-in Capital. As of September 30, 2026, the current and long-term balance of deferred shelf registration cost was $87, and $362, respectively. During the three months ended September 30, 2026 the Company allocated $8 deferred shelf registration cost and recognized as a reduction of Additional Paid-in Capital.

Costs incurred solely to maintain the effectiveness of an existing 2026 Shelf Registration Statement are recognized in operating expenses as incurred. Maintenance expenses in relation to the 2026 Shelf Registration Statement were nil for all periods presented. Management evaluates deferred shelf registration costs for recoverability at each reporting date and whenever events or changes in circumstances indicate that future utilization of the registration statement may no longer be probable. If management concludes that future utilization is no longer probable, any remaining deferred balance is recognized in earnings.

Reverse Stock Split

On July 2, 2025, the Company amended and restated its amended and restated certificate of incorporation to effect a 1-for-3.33 reverse stock split of the Company's common stock, which automatically resulted in reciprocal adjustments (reductions) to the conversion ratios of each of the Company's series of convertible preferred stock (the "Reverse Stock Split"). The par values per share of the common and convertible preferred stock were not adjusted as a result of the Reverse Stock Split. All amounts for issued and outstanding common stock, convertible preferred stock, options to purchase common stock, warrants on common stock, and reserves related to common stock, as well as related per-share amounts, contained in the financial statements have been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented. No fractional shares were issued as a result of the reverse stock split.

Foreign Currency

The reporting currency for the financial statements of the Company is the United States Dollar. The functional currency of the U.S. corporation, and its foreign branch which is an extension of the U.S. corporation, is the U.S. Dollar. The assets, liabilities, and expenses of the Company’s foreign branch recorded in local currency are remeasured into the U.S. Dollar each period, with associated gains and losses included in operating expenses (as a component of general and administrative expenses). Monetary assets and liabilities denominated in currencies other than the functional currency are translated at exchange rates in effect at the balance sheet date with associated gains and losses included in operating expenses (as a component of general and administrative expenses). For the three months ended September 30, 2026 and 2025, the Company recorded $(48) and $20, respectively, and for nine months ended September 30, 2026 and 2025, the Company recorded $(63) and $191, respectively, of net foreign exchange (losses) gains as components of general and administrative expenses.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the making and usage of estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and the

related disclosure of contingent assets and liabilities, if any. The Company bases its estimates on historical experience when available and on other assumptions that management believes are reasonable under the circumstances. The Company seeks to moderate the influence of subjectivity and estimation uncertainty through reliance on useful information from market participants and peers wherever possible. Estimates and assumptions affect various financial statement amounts and their related disclosures, including, but not limited to, the recognition of revenue, underwriters' warrants valuation, stock based compensation, research and development expenses, income tax-related amounts, lease-related amounts, and allowances for credit losses. Actual results could materially differ from estimates.

Segments

The Company is organized as, and managed as, one operating (and reportable) segment. Its chief operating decision maker is its Chief Executive Officer.

Fair Value Measurements

Where required, certain assets and liabilities are carried at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. A framework is used for measuring fair value utilizing a three-tier hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the three levels of the hierarchy:

- Level 1 - defined as observable inputs, such as quoted prices unadjusted in active markets for identical assets or liabilities
- Level 2 - defined as inputs other than quoted prices included in Level 1 that are either directly or indirectly observable
- Level 3 - defined as significant unobservable inputs for which little or no market data exists, therefore necessitating entity-specific assumptions

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. An asset or liability’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value.

The carrying amounts of the Company’s financial assets (which include cash and accounts receivable) and liabilities (which include accounts payable) approximate fair value due to their insensitivity to interest rates and/or close proximity to maturity and qualify as Level 1 measurements.

Concentration Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of demand deposits at well-known financial institutions and accounts receivable. At times, the Company’s cash deposits may exceed U.S. Federal deposit insurance limits.

The Company's sales to customers are typically originated with trade credit terms and receivables are uncollateralized, with limited exceptions for prepayments required for certain customers or credit card sales. The Company historically has experienced insignificant levels of bad debt; allowances for credit losses on accounts receivable were insignificant for all periods presented.

The Company’s concentration risk related to revenues relates primarily to its product revenues being derived from a single product and a single international distributor (Customer A in a table below). No US customer represented

more then 10% of the Company's revenue as of three and nine months ended September 30, 2026 and more then 10% of the Company's net accounts receivable balances as of September 30, 2026 and December 31, 2025.

The following table summarizes the information about the Company’s concentration of customers:

	Customer A
Revenues, customer concentration risk	
Three Months Ended September 30, 2026	11 %
Nine Months Ended September 30, 2026	11 %
Three Months Ended September 30, 2025	10 %
Nine Months Ended September 30, 2025	10 %
Accounts receivable, customer concentration risk	
As of September 30, 2026	23 %
As of December 31, 2025	22 %

The Company’s supply concentration risk relates primarily to its materials procurement and contract manufacturing being substantially concentrated with vendors located in Asia.

Comprehensive Income (Loss)

Comprehensive income (loss) comprises net income (loss) and other comprehensive income (loss), which is defined as all changes in stockholders’ equity (deficit) other than net income (loss) and those resulting from investments by and distributions to stockholders. Historically, and for all periods presented, there are no differences between net loss and comprehensive loss.

Revenue Recognition

Revenue is recognized in accordance with ASC 606, *Revenue from Contracts with Customers*. The core principle is that an entity should recognize revenue to depict the transfer of control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The Company recognizes revenue using a five-step model resulting in revenue being recognized as performance obligations within a contract are satisfied. The steps within that model include: (i) identifying the existence of a contract with a customer; (ii) identifying the performance obligations within the contract; (iii) determining the contract’s transaction price; (iv) allocating the transaction price to the contract’s performance obligations; and (v) recognizing revenue as the contract’s performance obligations are satisfied. Judgment is required to apply the model and make certain estimates and assumptions about the Company’s contracts with its customers, including, among others, the nature and extent of its performance obligations, its transaction price amounts and any allocations thereof (including estimates of standalone selling prices), the events which constitute satisfaction of its performance obligations, and when control of any promised goods or services is transferred to customers. The guidance also requires certain incremental costs incurred to obtain or fulfill a contract to be deferred and amortized on a systematic basis consistent with the transfer of goods or services to a customer.

The Company generates (i) product revenue from the sale of capsule medical devices, (ii) service revenue from the provision of reading services for videos, and (iii) product or service revenue depending on which video delivery option is utilized by the customer to download and view capsule videos. The customer’s delivery options include (1) a capsule data reading device shipped to the customer which works together with downloadable software installed locally on a customer’s computer (classified as product revenue), or (2) a software-as-a-service offering which involves the customer mailing capsule devices to an off-site Company-operated facility which

processes uploads of video content to a cloud platform the customer can access via a web browser or a smart device application in order to view videos and generate reports (classified as service revenue).

The Company's contracts with customers contain fixed consideration reflecting prices negotiated with customers and immaterial variable consideration. For contracts with variable consideration, the Company uses the most likely amount method to estimate the transaction price. Variable consideration is constrained to the extent that it is deemed probable that a significant reversal of the amount of revenue recognized will not occur. Where products or services are not sold separately or experience a range of selling prices, the Company estimates standalone selling prices using a cost-plus-expected margin approach and utilizes the resultant standalone selling prices to allocate transaction prices at transaction inception on a relative standalone selling price basis. The Company recognizes revenue for its product and reading service performance obligations at a point in time, that being when the performance obligations are satisfied and control is transferred to the customer (generally upon shipment for products, or conveyance of final deliverable for services). For the software-as-a-service video delivery offering performance obligation, the associated revenue is recognized over time, typically less than one fiscal quarter, representing the estimate of the typical period of time in which customers derive utility from the cloud-based service.

The Company does not have any significant financing components as payment is received at or shortly after sale. Standard trade credit terms are typically 30 to 60 days from invoice date. Costs incurred to obtain or fulfill a contract are expensed as incurred when the amortization period is less than one year, which is the case for the Company. The Company considers all shipping and handling to be fulfillment activities and not a separate performance obligation. Shipping and handling costs are recorded as costs of revenue. The Company has elected an accounting policy to exclude sales taxes and other similar taxes from the measurement of the transaction price.

The Company has certain U.S. customers characterized as group purchasing organizations that function as procurement agents for their underlying medical practice, clinic, or hospital members; these group purchasing organizations typically charge the Company percentage-based fees in exchange for the right to do business with the group purchasing organization. Such fees, which do not provide a distinct separate benefit to the Company, are recorded as reductions to revenue in the same period as the recognition of the related revenue.

The Company's products are sold with the same limited quality assurance warranties offered to all customers; the Company typically does not allow returns of products, except for cases of damage or defect, whereby products would be replaced. Actual product returns have historically been immaterial given the one-time-use nature of capsule devices; estimated product returns (periodically adjusted to reflect actual experience), if warranted, are accounted for as reductions to revenue with offsets to a product return liability included within accrued expenses and other current liabilities in the balance sheet.

Contract Assets and Contract Liabilities; Accounts Receivable and Related Allowance

The Company records contract assets when it has completed performance obligations prior to receiving consideration from the customer and where such amounts are unbilled; where billed, amounts are reflected as trade accounts receivable. The Company promptly invoices its accounts receivable; therefore, the Company's contract assets were zero for all periods presented.

Contract liabilities, portrayed as deferred revenue, reflect (i) obligations to provide goods for which the Company has already received consideration (generally arising from up-front payments received) and (ii) performance obligations to provide services which are not yet satisfied in the context of a particular contract (principally consisting of video delivery obligations related to the Company's off-premise cloud-based video delivery offering).

Trade accounts receivable are recorded at invoiced amounts and do not bear interest. The Company grants trade credit to most of its customers in the normal course of business and generally does not require collateral. An allowance for credit losses arises subsequent to the origination of a sale for estimated uncollectible receivables based on the Company's assessment of the collectability of customer accounts. A provision (or a reversal of the

allowance) is recorded as a component of general and administrative expenses. In determining the amount of the allowance, the Company considers aging of accounts, historical credit losses, customer-specific information, the current economic environment, supportable forecasts, and other relevant factors. Uncollectible receivables are written off against the allowance when all attempts to collect have been exhausted. Allowances for credit losses were insignificant for all periods presented.

Costs of Revenue

Costs of revenue include materials, direct labor, and manufacturing overhead costs related to sold products, as well as certain period costs such as non-allocated overhead, scrap, and outbound freight costs, fees paid to physicians for providing reading services, and the costs of operating the Company's cloud-based software-as-a-service offering for video delivery such as shipping costs, processing costs, and data storage costs. Shipping and handling costs directly related to bringing products to their final point of sale are included in costs of revenue and were $36 and $28 for the three months ended September 30, 2026 and 2025, respectively, and $104 and $71 for the nine months ended September 30, 2026 and 2025, respectively.

Selling, General and Administrative Expenses

Selling and marketing expenses include costs directly attributable to actively marketing the Company's products and services using both direct employees and outside contractors or vendors. These costs include, but are not limited to, salaries, bonuses, benefits, stock-based compensation, sales commissions, travel costs and expense reimbursements, and the costs of sponsoring programs, events, and conferences. Advertising costs were nil for all periods presented.

General and administrative expenses consist primarily of salaries, bonuses, benefits, and stock-based compensation related to the Company's executive, administrative, finance, human resources, and other supporting functions. Also included are professional fees for legal services, consulting services, tax matters and audits, information technology, office expenses, rent, insurance, and foreign exchange gains (losses).

Research and Development Expenses (including Clinical Trial Expenses)

Research and development ("R&D") costs are expensed as incurred in accordance with ASC 730, *Research and Development*. Research and development expenses include costs directly attributable to the conduct of research and development programs, including salaries, bonuses, benefits, and stock-based compensation for employees focused on research and development or clinical trials, costs of independent contractors and outside vendors, costs of supplies consumed in or product inventory utilized in clinical trials, and the costs of clinical trial activities as charged within the negotiated budgets by trial sites or vendors responsible for multiple trial sites.

The Company capitalizes prepayments for goods or services, including trial device inventory, that will be used, consumed, or rendered for future research and development activities and recognizes expense as the related goods are delivered or services are performed. The Company also records expenses and accruals for estimated costs of research and development activities, including third party services for clinical trials. The Company bases its estimates on information available at the time. Costs for certain clinical trial activities are recognized based on the pattern of performance of the individual arrangements, which may differ from the pattern of billings incurred, and are reflected in the balance sheet as prepaid expenses or as accrued expenses. The Company recognizes R&D expenses for non-recurring engineering services from outside vendors calculated as an estimated percentage of completion based on management's estimated total effort for the programs.

For the three months ended September 30, 2026 and 2025, the Company incurred $1,643 and $2,350, respectively, and for the nine months ended September 30, 2026 and 2025, the Company incurred $5,649 and $4,102, respectively, of expenses related to ongoing clinical trial activities which are included within research and development expenses.

Net Loss Per Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period without consideration of potentially dilutive securities. Diluted net loss per share reflects the potential dilution that could occur if options or warrants on common stock were exercised or convertible preferred stock shares were converted into common stock. Diluted net loss per share is the same as basic net loss per common share since the effect of the potentially dilutive securities are anti-dilutive. Potential dilutive common share equivalents consist of incremental common shares issuable upon exercise of vested stock options, common stock warrants, and the Company's various series of convertible preferred stock. Upon completion of the IPO in July 2025, all outstanding shares of preferred stock were converted into shares of Company's common stock (after giving effect to the 1-for-3.33 reverse stock split). Subsequent to the conversion, only common stock remains outstanding. Accordingly, the two-class method is no longer applicable for periods after the IPO.

Cash and cash equivalents

Cash and cash equivalents comprises demand deposits in the form of checking accounts and money market accounts (which may be deposited into and withdrawn at will with no restrictions as to investment or redemption) and includes cash balances denominated in the Euro and New Taiwan Dollar, for which fluctuations in exchange rates result in gains or losses reported within operating expenses as a component of general and administrative expenses.

Inventory

Inventories, consisting of materials, direct labor and manufacturing overhead, are subdivided into raw materials, work in process, and finished goods and are stated at the lower of cost (average cost) or net realizable value.

The Company evaluates inventories as to (i) net realizable value and (ii) circumstances or indicators of loss, damage, insufficient time to expiry (determined by battery life), excess quantities, or obsolescence and provisions accordingly via direct charges against the carrying value of inventory.

Long-Lived Assets

Property and equipment is recorded at historical cost, less accumulated depreciation. The Company capitalizes major improvements and expenses repairs and maintenance as incurred. Depreciation is recorded using the straight-line method based on the estimated useful lives of the depreciable property or, for leasehold improvements, the remaining term of the lease, whichever is shorter. Useful lives are as follows;

Asset Class	Estimated Useful Life
Machinery & equipment	5 years
Computer equipment and office equipment	3 to 5 years
Purchased software	3 to 5 years
Leasehold improvements	Shorter of remaining lease term or useful life

Upon disposal (retirement or sale) of property and equipment, as applicable, the cost and related accumulated depreciation are removed and any resulting gain or loss is reflected within operating expenses. Such amounts were insignificant for all periods presented.

Long-lived assets are evaluated for impairment as warranted by triggering events related to changes in facts and circumstances. There have historically been no impairments and there were none for all periods presented.

Leases

The Company has operating leases for office and storage space in California and office space in Taiwan, Republic of China. The Company determines if an arrangement is a lease at inception and classifies its leases at commencement. Operating leases are presented as right-of-use (“ROU”) assets and the corresponding lease liabilities are depicted in operating lease liabilities, current and operating lease liabilities, non-current in the balance sheet. ROU assets represent the right to use an underlying asset, and lease liabilities represent the obligation for lease payments in exchange for the ability to use the asset for the duration of the lease term.

ROU assets and lease liabilities are recognized at commencement date and determined using the present value of the future minimum lease payments over the lease term. The Company utilizes an incremental borrowing rate when assessing lease classification and measuring lease liabilities. The estimated incremental borrowing rate considers credit rating practices applied by well known statistical rating organizations to borrowers, Company-specific factors, and the actual lease term at commencement date. The lease term may include options to extend when it is reasonably certain that the Company will exercise that option. The Company recognizes operating lease expense on a straight-line basis over a lease's term.

The Company has lease agreements which contain both lease and non-lease components, which it has elected to account for as a single lease component. Variable lease payments that are not dependent on an index or rate are not included in lease measurements and are accounted for as incurred.

Stock-Based Compensation

The Company accounts for employee and nonemployee equity compensation awards in accordance with ASC 718, *Compensation - Stock Compensation* (“ASC 718”). In accordance therewith, the Company accounts for stock-based compensation for awards granted to nonemployees in a similar fashion to stock-based compensation awards to employees. ASC 718 requires the recognition of stock-based compensation expense, using a fair-value based method, for costs related to all stock-based compensation awards.

Stock-based compensation awards issued under the Company’s 2005 Stock Plan (the “2005 Plan”) and the Company’s 2025 Equity Incentive Plan (the “2025 Plan”) take the form of stock options (non-qualified or incentive stock options), restricted stock or restricted stock units (the "RSUs"). The 2025 Plan also provides for the grant of stock appreciation rights, stock bonuses, stock units and other forms of awards including cash awards to the Company’s officers, directors, employees, consultants and advisors. The Black-Scholes option-pricing model is used to determine the fair value of options; application of the model requires judgment to develop assumptions input into the model, some of which are more subjective, including: (i) the fair value of the underlying common stock on the date of grant; (ii) the expected term of the award; (iii) the expected volatility of the underlying common stock; (iv) the risk-free interest rate; and (v) expected dividends. Income and market approaches to valuation are judgmentally weighted and combined to determine a composite value representing the fair value of the underlying common stock. In estimating the fair value of the underlying common stock prior to IPO, the Company utilized a third party professional valuation firm whose analyses supported management's concluded estimate. Post IPO the fair value of the underlying common stock is based on the Company’s closing stock price on the date of grant. An expected volatility assumption is based on stock price volatility of a peer group of comparable public companies over a similar expected term. The risk-free rate is based on U.S. Treasury yields in effect at the time of grant for periods corresponding with the expected term; no dividends are assumed.

The Company’s employee and nonemployee stock-based compensation awards granted on or before September 30, 2026 contain only service conditions for vesting. The Company recognizes stock-based compensation cost as a component of the related functional expense (costs of revenue or category of operating expenses) on a straight-line basis over the requisite service period, which is explicitly stated in the case of awards issued to employees and implicitly understood to be the period over which services are provided for nonemployees. The Company recognizes forfeitures as they occur and reverses any previously recognized compensation cost associated with pre-vesting forfeitures.

Stock-based compensation awards in the form of the restricted stock units (the "RSUs") are issued to the Directors of CapsoVision, Inc., who are not employed by the Company ("Non-Employee Directors"). These RSUs are issued in lieu of annual cash compensation (annual base retainer). Each RSU granted to the Non-Employee Directors represents a right to receive one share of the Company common stock when the RSU vests. The Company estimates compensation cost based on the grant date fair value and recognizes the expense on a graded vesting basis over the vesting period of the award. Please, see Note 10. STOCK-BASED COMPENSATION for details.

Warrants

In connection with the IPO, offering costs related to legal, accounting, and underwriting costs were net with the proceeds and recorded as a reduction in additional paid in capital, in the stockholders' equity section of the balance sheet. The Company also issued Underwriters Warrants (as defined in Note 9. COMMON STOCK) for services provided during the IPO to purchase 168,898 shares of common stock. The Underwriters Warrants are accounted for as equity instruments and are included in the Stockholders' Equity section of the balance sheet. The fair value of the Underwriters Warrants has been estimated using the Black-Scholes option pricing model.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740, *Income Taxes* ("ASC 740"), which requires that the asset and liability method be used. Deferred tax assets and liabilities are determined based on the differences between financial reporting (book basis) and the tax reporting (tax basis) amounts of assets and liabilities; these pre-tax differences are measured and reflected after-tax using the enacted tax rates and law that will be in effect when the differences are expected to reverse.

ASC 740 requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some or all of the deferred tax assets will not be realized. The Company evaluates the realizability of its deferred tax assets at least annually and more frequently as warranted by changes in facts and circumstances and adjusts the amount of the valuation allowance accordingly. Factors considered include the presence of reversing taxable temporary differences as a source of taxable income, forecasts of future taxable income, and available tax planning strategies that could be implemented and are both prudent and feasible. The Company has recorded a full valuation allowance with respect to all of its deferred tax assets based upon the significant negative evidence presented by its accumulated deficit position, its operating losses and negative operating cash flows, and the uncertainty associated with the timing and amount of future profits and therefore taxable income that enable realization. In future periods, if the Company generates book income and taxable income, changes in judgment may reduce or eliminate the valuation allowance.

The Company accounts for uncertain tax positions in accordance with a two-step model. Firstly, a recognition threshold must be met; a tax benefit from an uncertain tax position may only be recognized if the tax position would, more likely than not, be sustained by the taxing authority assuming an examination and the application of typical practices and precedents. Secondly, a measurement rule is applied; the amount of tax benefit that can be recognized is the portion that is greater than 50% likely of being realized upon a settlement. The determination as to whether a tax benefit will, more likely than not, be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances, without consideration of detection risk. As of September 30, 2026 and 2025 the Company's uncertain tax positions were principally related to the non-recognition of a portion of Federal and U.S. state research and development tax credits. The Company recognizes any interest and penalties associated with its income tax positions in the provision for income taxes.

Accounting Pronouncements Issued and Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses* ("ASU 2024-03"). The new guidance requires more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation, amortization, and depletion) included in certain

expense captions presented on the face of the statement of operations. ASU is effective for public business entities for annual periods beginning after December 15, 2026, and for quarters in the years beginning after December 15, 2027; early adoption is permitted. The new guidance may be applied either (1) prospectively to financial statements issued for reporting periods after the effective date or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact ASU 2024-03 will have on its disclosures.

In September 2025, the FASB issued ASU 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software*, which amends certain aspects of the accounting for and disclosure of internal-use software costs. The amendments are effective for all entities for annual reporting periods beginning after December 15, 2027, and interim reporting periods within those annual reporting periods. Early adoption is permitted and the amendments should be applied either prospectively to financial statements issued for reporting periods after the effective date, retrospectively to any or all prior periods presented in the financial statements, or through a modified prospective transition approach which is based on the status of the project and whether software costs were capitalized before the date of adoption. The Company is currently evaluating the impact ASU 2025-06 will have on its disclosures.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements,* which provides clarity about current interim disclosure requirements and adds a disclosure principle that requires entities to disclose events since the end of the last annual reporting period that have a material impact on the entity. The amendments are effective for interim reporting periods within annual reporting periods beginning after December 15, 2027, for public business entities and for interim reporting periods within annual reporting periods beginning after December 15, 2028, for entities other than public business entities. Early adoption is permitted for all entities. The amendments in this Update can be applied either (1) prospectively or (2) retrospectively to any or all prior periods presented in the financial statements. At the same time, the FASB issued ASU 2025-12 - *Codification Improvements*. The amendments are effective for all entities for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual reporting periods. Early adoption is permitted in both interim and annual reporting periods in which financial statements have not yet been issued or made available for issuance. If an entity adopts the amendments in this Update in an interim period, it must adopt them as of the beginning of the annual reporting period that includes that interim reporting period. An entity may elect to early adopt the amendments on an issue-by-issue basis. The Company is currently evaluating the impact ASU 2025-11 and ASU 2025-12 will have on its disclosures.

4. FAIR VALUE MEASUREMENTS

The Company’s demand deposit accounts include money market demand deposits which constitute cash, given the lack of investment restrictions or redemption conditions and the ability to immediately withdraw funds. The carrying amounts of the Company’s financial assets (which include cash and accounts receivable) and liabilities (which include accounts payable) approximate fair value due to their insensitivity to interest rates and/or close proximity to their maturities and qualify as Level 1 measurements. There were no transfers between Level 1, 2 or 3 during any periods presented.

5. BALANCE SHEET COMPONENTS

Inventory

Inventory comprised the following amounts:

	September 30, 2026	December 31, 2025
Finished goods	$ 251	$ 107
Work in process	2,025	994

Raw materials	2,471	1,886
Inventory	**$ 4,747**	**$ 2,987**

For the three and nine months ended September 30, 2026 and September 30, 2025, there were no provisions to write down inventories.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets comprised the following amounts:

	September 30, 2026	December 31, 2025
Prepayment for insurance	$ 582	$ 324
Advance payments for inventory purchases	840	300
Deferred Shelf Registration Costs	87	—
Other	577	448
Prepaid expenses and other current assets	**$ 2,086**	**$ 1,072**

Property and Equipment, Net

Property and equipment comprised the following amounts:

	September 30, 2026	December 31, 2025
Machinery and equipment	$ 998	$ 928
Computer equipment, office equipment, and purchased software	101	101
Leasehold improvements	157	157
Accumulated depreciation and amortization	(748)	(575)
Property and equipment, net	**$ 508**	**$ 611**

Depreciation and amortization expenses of $58 and $54 for the three months ended September 30, 2026 and 2025, respectively, and $173 and $161 for the nine months ended September 30, 2026 and 2025, respectively, were recorded within costs of revenue and components of operating expenses.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities comprised the following:

	September 30, 2026	December 31, 2025
Accrued compensation	$ 646	$ 568
Accrued clinical trial expenses	9	83
Accrued R&D expenses	3,399	1,448
Accrued sales taxes	62	79
Other	239	519
Accrued expenses and other current liabilities	**$ 4,355**	**$ 2,697**

6. REVENUE AND DEFERRED REVENUE

Total revenue disaggregated by geographic source, type of customer, and products or services was as follows.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	2026	2025
United States (medical practice, clinic, and hospital customers):				
Products (capsules and capsule reading devices)	$ 2,463	$ 2,515	$ 6,738	$ 6,784
Services (cloud-based video delivery and reading services)	252	234	718	666
Outside United States (distributor customers):				
Products (capsules and capsule reading devices)	853	789	2,547	2,186
Total revenue	**$ 3,568**	**$ 3,538**	**$ 10,003**	**$ 9,636**

For the three months ended September 30, 2026 and 2025, U.S. service revenues included (i) $170 and $169, respectively, from the Company's cloud-based software-as-a-service video delivery offering (recognized over time commencing with the shipment of capsules) and (ii) $82 and $65, respectively, of revenue from the provision of video reading to customers (recognized at a point in time upon provision of deliverables).

For the nine months ended September 30, 2026 and 2025, U.S. service revenues included (i) $488 and $455, respectively, from the Company's cloud-based software-as-a-service video delivery offering (recognized over time commencing with the shipment of capsules) and (ii) $230 and $211, respectively, of revenue from the provision of video reading to customers (recognized at a point in time upon provision of deliverables).

Product revenues outside the United States are attributable to individual foreign countries based upon shipment destination. The Company's distributor customers outside the United States typically serve the countries in which they are domiciled (and may distribute to adjacent countries or territories). Outside the United States, for the three and nine months ended September 30, 2026, product revenues included $381 and $1,100 attributable to France, respectively, and $153 and $565 attributable to Germany, respectively, with the balance attributable to other countries; for the three and nine months ended September 30, 2025 product revenues included $369 and $991 attributable to France, respectively, and $153 and $441 attributable to Germany, respectively, with the balance attributable to other countries.

Deferred revenue (contract liabilities, all of which are current in nature) consists of upfront purchases by customers related to the cloud-based software-as-a-service video delivery offering and prepaid video reading services. Deferred revenue represents the excess of amounts invoiced over amounts recognized as revenues. For each component of deferred revenue, the recognition of deferrals as revenue occurred within three months.

The Company's deferred revenue balance was $146, $177 and $132 as of September 30, 2026, December 31, 2025 and December 31, 2024, respectively. During the nine months ended September 30, 2026, the Company recognized $177 of revenue that was included in deferred revenue as of December 31, 2025. During the nine months ended September 30, 2025, the Company recognized $132 of revenue that was included in deferred revenue as of December 31, 2024.

Fees paid to group purchasing organizations and recorded as reductions to revenue were $8 and $33 for the three months ended September 30, 2026 and 2025, respectively.

Fees paid to group purchasing organizations and recorded as reductions to revenue were $27 and $78 for the nine months ended September 30, 2026 and 2025, respectively.

7. LEASES

The Company has operating leases for office and manufacturing space in California and office space in Taiwan, Republic of China, with remaining lease terms ranging from under one year to approximately 2 years, 9 months as of September 30, 2026.

In July 2026, the Company entered into two lease agreements for its California facility. The facilities are approximately 2,548 square feet. The lease term is for 3 years and expires on June 30, 2029. Based on the present value of the lease payments, the Company recognized an operating lease asset and liability for operating leases of $211 on July 01, 2026.

Leases with an initial term of twelve months or less are not accounted for in the balance sheet; these are limited to minor leases in Taiwan, which are excluded from amounts presented in the following tables. The operating leases include certain variable payments related to operating expenses, which are billed by the landlord, as is customary with these types of charges for office space.

The Company's existing leases contain escalation clauses and renewal options. The Company has evaluated several factors in assessing whether it is reasonably certain that the Company will exercise a contractual renewal option. For leases with renewal options that are reasonably certain to be exercised, the Company includes the renewal term in the total lease term used in deriving the right-of-use asset and lease liability. The Company's main office lease includes a renewal option of three years, which was excluded after evaluation of those factors.

Amounts comprising total lease expense, reflected in general and administrative expenses and costs of revenue, were as follows.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating lease expense	$ 139	$ 118	$ 376	$ 355
Short-term lease expense	6	10	27	28
Total lease expense	**$ 145**	**$ 128**	**$ 403**	**$ 383**

Lease-related amounts reflected in the balance sheet and data related thereto were as follows.

	September 30, 2026	December 31, 2025
Operating lease right-of-use assets	**$ 747**	**$ 843**
Operating lease liabilities - current	$ 521	$ 410
Operating lease liabilities – long-term	259	477
Total operating lease liabilities	**$ 780**	**$ 887**
Weighted average remaining lease term	1.6 years	2.0 years
Weighted average discount rate	11.9%	11.8%

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Cash payments related to operating leases	$ 142	$ 118	$ 386	$ 355

Future minimum lease payments under non-cancellable leases are as follows as of September 30, 2026.

2026	$	142
2027		585
2028		85
2029		43
2030 and thereafter		—
Total minimum lease payments	**$**	**855**
Less: interest		(75)
Total operating lease liabilities	**$**	**780**

8. COMMITMENTS AND CONTINGENCIES

Purchase Commitments

The Company, post-acquisition of raw materials, relies significantly upon third-party contract manufacturers located in Taiwan. Management believes that supply risks related to dependence on fewer key suppliers or contract manufacturers, and political risk, can potentially be hedged with the use of more than one supplier and a readiness to quickly adjust the supply chain (and geographic sourcing within Asia). Purchase commitments to raw materials suppliers were $1.0 million as of September 30, 2026.

On July 15, 2025, the Company entered into a development agreement with Canon Inc., a Japanese corporation, for the development of complementary metal-oxide-semiconductor (“CMOS”) image sensor samples to allow the Company to evaluate functionality and performance, conduct clinical evaluation of capsule endoscopies that incorporate Canon image sensors and obtain FDA 510(k) clearance thereof. Under the Agreement, the Company agreed to pay Canon a fee of approximately $4.1 million for Canon’s development efforts, which is comprised of (a) an initial fee of $1.0 million that was paid in cash on July 31, 2025 upon the Agreement’s effectiveness, and (b) following delivery of a specified number of CMOS image sensors meeting agreed specifications within the required timeframe, a remaining development fee of approximately $3.1 million. Additionally, due to the changes in the development scope by the end of fiscal year 2025, Canon and the Company agreed to increase the development fee by $1.0 million and executed an amendment to the original development agreement in March 2026. For the three and nine months ended September 30, 2026, we recognized $292 and $1,232, respectively, in R&D expenses for Canon development effort. The outstanding balance due to Canon was $2.6 million and included in Accrued Expenses and Other Current Liabilities in the balance sheet as of September 30, 2026. The outstanding purchase commitment for this agreement as of September 30, 2026 is $1.5 million.

Litigation and Legal Matters

The Company may be the subject of adverse litigation as a defendant, arbitration, claims, or proceedings related to things such as intellectual property infringement or disputes, commercial contract breaches or disputes, employment matters, or other matters in the ordinary course of business. Such matters are subject to many uncertainties and outcomes may be unpredictable. Such matters may be fully or partially mitigated by the effect of insurance coverage in place or counter-party indemnitors. The Company provides for liabilities via a charge to operating expenses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company is not a party to any material litigation, arbitration, claims or proceedings and therefore did not have any contingency-related liabilities as of September 30, 2026 and December 31, 2025.

9. COMMON STOCK

September 2026 Securities Purchase Agreement

On September 17, 2026, the Company entered into the September 2026 Securities Purchase Agreement as described in Note 1. DESCRIPTION OF BUSINESS AND ORGANIZATIONAL STRUCTURE, pursuant to which it issued and sold 3,163,444 shares of the Company's common stock at a purchase price of $5.69 per share for an aggregate amount of gross proceeds of $18 million. The net proceeds resulted in $17.8 million after deducting offering expenses of $162.

Each of the Purchasers is an existing stockholder of the Company. Two of the Purchasers are related persons as disclosed in Note 14. RELATED PARTIES. All Purchasers purchased shares at the same price and on the same material terms. The Company plans to use the net proceeds from the sale of common stock offered under this prospectus supplement for general corporate purposes, including sales and marketing, research and development activities, general and administrative matters, and working capital.

2026 At-The-Market (ATM) Offering Agreement

On August 13, 2026, the Company entered into the 2026 ATM Agreement, with Cantor, which established an at-the-market equity program pursuant to which we may offer and sell shares of our common stock from time to time as set forth in the 2026 ATM Agreement. From the inception of the ATM Offering through September 30, 2026, the Company sold 276,446 shares of its common stock for aggregate net proceeds of approximately $1,709 net of $49 of placement fee paid to Cantor and $8 allocated deferred shelf registration cost.

Private Placement

On March 16, 2026, the Company closed the Private Placement as described in Note 1. DESCRIPTION OF BUSINESS AND ORGANIZATIONAL STRUCTURE and issued and sold 2,867,089 shares of common stock at $4.883 per share.

IPO

On July 3, 2025, the Company completed its initial public offering ("IPO") of 5,500,000 shares of its common stock at a price to the public of $5.00 per share.

The Company granted to the IPO underwriters an overallotment option (the “Over-Allotment Option”) to purchase up to an additional 825,000 shares of Common Stock, which is equal to 15% of the number of shares of Common Stock sold in the IPO. Under the Over-Allotment Option the underwriters had the right to exercise this option, in whole or in part, for our common stock, any time during the 30-day period from the date of the closing of the IPO. On July 18, 2025, a total of 129,978 shares of common stock were issued in connection with the partial exercise by the IPO underwriters of their Over-Allotment Option at a price to the public of $5.00 per share (the "Over-allotment Exercise").

Common Stock Warrants

In connection with the IPO share issuances, the Company issued to the IPO underwriters warrants to purchase an aggregate of 168,898 shares of Common Stock (including 3,898 shares of Common Stock issued in connection with the Over-allotment Exercise (the "Over-allotment Exercise Underwriters' Warrants"), collectively referred to as the “Underwriters' Warrants”). The Underwriters' Warrants are exercisable at a per share exercise price equal to $6.25 and are exercisable at any time and from time to time, in whole or in part, for a term of five years commencing from the first day of the seventh month after July 3, 2025 (the “Original Closing Date”), and terminating on July 1, 2030.

All of the Underwriters’ Warrants were outstanding as of September 30, 2026. The warrants were classified as equity and the fair value of $519 is reflected as additional paid-in capital. The Black-Scholes option-pricing model was used to estimate the fair value of the warrants with the following assumptions:

	Initial Placement Underwriters' Warrants	Over-allotment Exercise Underwriters' Warrants
Risk-free interest rate	3.94 %	3.96 %
Expected term	5 years	4.96 years
Volatility of common stock	78.83 %	78.94 %
Expected dividend rate	— %	— %

The fair value of the underlying common stock for the valuation of the Initial Placement Underwriters' Warrants was equal to the IPO price of $5.00 per share as of July 1, 2025, when the Company's registration statement related to the IPO was declared effective. The fair value of the underlying common stock for the valuation of the Over-allotment Exercise Underwriters' Warrants is based on the Company's closing stock price on July 18, 2025.

Common Stock

Pursuant to the Company's certificate of incorporation, as amended and restated, for its $0.001 par value common stock, the Company had 300,000,000 authorized shares at September 30, 2026 and December 31, 2025, and had 53,569,896 and 46,865,051 issued and outstanding shares, as of September 30, 2026 and December 31, 2025, respectively.

Authorized common stock was reserved for future issuance as follows, including pursuant to outstanding equity awards and future equity awards under the 2005 Plan and the 2025 Plan.

	September 30, 2026	December 31, 2025
Exercises of stock options under 2005 Plan	1,237,701	1,627,097
Exercises of stock options under 2025 Plan	2,438,402	348,551
Restricted Stock Units under 2025 Plan	11,825	—
Exercises of warrants	168,898	168,898
Reserved for future grants under 2025 Plan	3,599,125	3,838,331
Total reserved shares of common stock	**7,455,951**	**5,982,877**

10. STOCK-BASED COMPENSATION

2025 Stock Plan

The 2025 Plan, which was adopted by the Company's Board of Directors in May 2025 and approved by the Company's stockholders in June 2025, became effective upon the consummation of the IPO. Upon the effectiveness of the 2025 Plan, the 2005 Plan was terminated and no further grants may be made under the 2005 Plan. The Company's 2025 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, stock bonuses, restricted stock, stock units and other forms of awards including cash awards to its officers, directors, employees, consultants and advisors of the Company.

A total of 4,204,204 shares of the Company's common stock were initially authorized for issuance with respect to awards granted under the 2025 Plan. Shares subject to outstanding awards granted under the 2005 Plan that are not paid, delivered or exercised before they expire or are canceled or terminated will be available for award grants under the 2025 Plan. In addition, per the terms of the 2025 Plan, the share limit will automatically increase on the first trading day in January of each year (commencing with 2026) by an amount equal to (1) 4% of the total number of shares of our common stock that are issued and outstanding on the last trading day in December in the prior year, or (2) a lesser number as determined by the Company's Board of Directors. Any shares subject to awards granted under the 2025 Plan that are not paid, delivered or exercised before they expire or are canceled

or terminated, fail to vest, as well as shares used to pay the purchase or exercise price of awards or related tax withholding obligations, will become available for new award grants under the 2025 Plan. As of September 30, 2026, a total of 3,599,125 shares is available for award purposes under the 2025 Plan, including automatic increase on January 2, 2026 for 1,874,602 shares.

Amended and Restated 2005 Stock Plan

Pursuant to the 2005 Plan, the Company granted equity-based incentive awards prior to the IPO to the Company's employees, directors, and consultants. The 2005 Plan permitted the grant of stock options (either Incentive Stock Options ("ISO" – employees only) or Non-Qualified Stock Options ("NQSO")) and restricted stock awards ("RSA"); only ISOs and NQSOs were outstanding during the periods presented. Upon the effectiveness of the 2025 Plan, the 2005 Plan was terminated and no new awards were granted under the 2005 Plan after the IPO, and there were no shares of common stock available for new award grants as of September 30, 2026 under the 2005 Plan.

Options granted to employees and non-employees contain only service vesting conditions, with typical grants vesting over a four-year period (vesting 25% on the first anniversary of the award and 1/48th each month thereafter) but may be granted with different vesting profiles, including options that are vested-at-grant (immediate vesting) and that are subject to different vesting schedules. Options granted to employees and non-employees expire no more than 10 years from the date of grant.

Stock Options

Stock option activity for the nine months ended September 30, 2026 was as follows.

	Options on Common Stock	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding (vested and expected to vest) as of December 31, 2025	**1,975,648**	**$ 1.74**	**7.47**	**$ 17,869**
Granted	2,100,158	6.64		
Exercised	(385,734)	0.42		2,328
Forfeited, canceled, or expired	(13,969)	5.24		
Outstanding (vested and expected to vest) as of September 30, 2026	**3,676,103**	**$ 4.66**	**8.66**	**$ 7,920**
Exercisable as of September 30, 2026	**755,667**	**$ 0.77**	**6.17**	**$ 4,303**

The aggregate intrinsic values are calculated as the differences between the exercise prices of the underlying options and the fair value of the Company's common stock for options that were in the money. The Company had 2,920,436 unvested stock options outstanding as of September 30, 2026.

During the nine months ended September 30, 2026 and 2025, 385,734 and 389,980 stock options were exercised and satisfied with newly-issued shares, resulting in cash proceeds of $164 and $143, respectively.

The following table summarizes the weighted-average assumptions used in the Black-Scholes option pricing model for stock options granted during the three and nine months ended September 30, 2026 and 2025.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Risk-free interest rate	4.37 %	3.70 %	4.20 %	3.81 %
Expected term	6.08 years	6.08 years	6.01 years	6.02 years
Volatility of common stock	75.8 %	80.2 %	76.2 %	78.8 %
Expected dividend rate	— %	— %	— %	— %
Fair value per share of common stock	$7.04	$4.33	$6.64	$2.78

In estimating the fair value of the underlying common stock prior to IPO, the Company utilized a third party valuation firm whose analyses supported management's concluded estimate. Post IPO the fair value of the underlying common stock is based on the Company’s closing stock price on the date of grant.

Restricted Stock Units

The Company grants restricted stock units (RSUs) to its Non-Employee Directors utilizing a fair market value (FMV) per share of the Company's common stock on the grant date. These RSUs are scheduled to vest as to 50% of the RSUs on June 30, 2026 and as to the remaining 50% of the RSUs on December 31, 2026 subject to the Non-Employee Director's continued service on the Board through such vesting date.

The following table summarizes the activity for restricted stock units ("RSUs") during the nine months ended September 30, 2026:

	Restricted Stock Units	Weighted Average Grant Date Fair Value per Share
Outstanding (expected to vest) as of December 31, 2025	—	
Granted	25,980	$ 6.35
Vested	(12,132)	
Forfeited, canceled, or expired	(2,023)	
Outstanding (expected to vest) as of September 30, 2026	11,825	

For the three and nine months ended September 30, 2026, the Company recorded $38 and $113, respectively, in stock-based compensation related to RSUs. The total fair value of RSUs vested during the nine months ended September 30, 2026 was approximately $92.

As of September 30, 2026, unrecognized stock-based compensation expense related to RSUs was $38 and expected to be recognized over a weighted-average period of three months.

Stock-Based Compensation Expense

Stock-based compensation, measured at the grant date, is recognized ratably over the requisite service period, using the straight-line method of expense attribution. Forfeitures are accounted for as a reduction in expense in the period in which they occur; no compensation cost is recorded for awards that do not vest. The Company

recognized total stock-based compensation expense for employees and non-employees as components of the statement of operations and comprehensive loss as follows.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Costs of revenue	$ 54	$ 1	$ 90	$ 6
Selling and marketing	116	3	161	17
Research and development	283	47	520	148
General and administrative	498	256	1,092	458
Total stock-based compensation expense	**$ 952**	**$ 307**	**$ 1,863**	**$ 629**

11. SEGMENTS

The Company has one operating (and reportable) segment known as the Capsule Endoscopy Segment; its chief operating decision maker is its Chief Executive Officer. The composition of this segment reflects the Company's focus on capsule endoscope medical devices addressing different areas within the GI tract. Refer to Note 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES and Note 6. REVENUE AND DEFERRED REVENUE for descriptions of products and services. Segment accounting policies are the same as those described therein. The chief operating decision maker assesses performance for the Capsule Endoscopy Segment and decides how to allocate resources based upon net income (loss) as reported in the statement of operations and comprehensive loss; also considered is operating income (loss), measured on the same basis as in the statement of operations and comprehensive loss. Net income (loss) and operating income (loss) are used in the process of evaluating expenses and determining where to prioritize resources.

Segment assets are identical to those reported in the balance sheet as total assets. Segment revenue and cost of revenue are identical to that reported in the statement of operations and comprehensive loss; significant segment expenses are identical to those identified in the statement of operations and comprehensive loss under the line items for selling and marketing expenses, research and development expenses, and general and administrative expenses. Other segment items are represented by non-operating income (expense), net (which includes insignificant interest income) and the provision for income taxes as reported in the statement of operations and comprehensive loss. Segment depreciation expense and capital expenditures are identical to amounts in the statement of cash flows.

12. INCOME TAXES

The provision for income taxes for the nine months ended September 30, 2026 and 2025 was not material. The Company continues to incur operating losses. The Company had an approximately zero effective tax rate for each of the nine months ended September 30, 2026 and 2025, respectively. The effective tax rates differ significantly from the U.S. statutory tax rate, primarily due to the Company's maintenance of a full valuation allowance against its net deferred tax assets in all periods presented.

13. NET LOSS PER SHARE

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Numerator:				
Net loss – basic and diluted	$ (7,339)	$ (7,921)	$ (21,853)	$ (17,921)
Denominator:				
Weighted-average number of shares of common stock outstanding – basic and diluted	50,568,141	46,217,127	49,332,254	17,049,671
Net loss per share – basic and diluted	**$ (0.15)**	**$ (0.17)**	**$ (0.44)**	**$ (1.05)**

Basic net loss per share is the same as diluted net loss per share as the inclusion of potential common shares outstanding would have been anti-dilutive. The Company's convertible preferred stock Series constitute participating securities; however, as a result of the net loss position, they are excluded from the calculation of basic net loss per share.

Potentially dilutive securities that were not included in the preceding calculations because they would be anti-dilutive were as follows.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Convertible preferred stock (all series)	—	420,278	—	25,777,055
Warrants on common stock	168,898	164,591	168,898	64,431
Options on common stock	3,728,846	1,709,776	3,728,847	1,796,755
Restricted Stock Units	11,825	3,013	13,186	1,015
Total	**3,909,569**	**2,297,658**	**3,910,931**	**27,639,256**

14. RELATED PARTIES

On February 12, 2026 the Company signed a consulting agreement with Wen-Hung Tsai, one of the Company's shareholders and a former member of the Company's Board of Directors (until February 26, 2024). Per the consulting agreement Mr. Wen-Hung Tsai will provide strategic advice, help with industrial affiliation and partnerships, as well as work on the supply chain establishment for new products. As compensation for his services, the Company granted to Mr. Wen-Hung Tsai on February 12, 2026 an option to purchase 250,000 shares of the Company's Common Stock under the Company’s 2025 Equity Incentive Plan. Eighty percent (80%) of the option grant is scheduled to vest and become exercisable on February 12, 2027. The remaining portion of the option grant is scheduled to vest and become exercisable in three (3) equal monthly installments on the same day of each successive calendar month following February 12, 2027. For the three and nine months ended September 30, 2026, the Company recorded $159 and $398, respectively, stock based compensation expenses associated with this award as a component of general and administrative expenses.

On March 16, 2026, the Company closed the Private Placement as described in Note 1. DESCRIPTION OF BUSINESS AND ORGANIZATIONAL STRUCTURE and issued and sold to the Investors in the Private Placement 2,867,089 shares of common stock at $4.883 per share. Three out of four participating Investors were the Company's shareholders at the time of this transaction and invested $13.5 million in 2,764,693 Company's shares through the Private Placement.

On September 17, 2026, the Company entered into a securities purchase agreement as described in Note 1. DESCRIPTION OF BUSINESS AND ORGANIZATIONAL STRUCTURE, pursuant to which issued and sold to the Purchasers 3,163,444 shares of the Company's common stock at a purchase price of $5.69 per share for an aggregate amount of gross proceeds of $18.0 million. Each of the Purchasers is an existing stockholder of the Company. Two of the Purchasers are related persons as each beneficially owns more than 5% of the Company's outstanding Common Stock. Star One Global Capital Limited, which is wholly owned by Ching-Hang Shen, purchased 878,734 shares for an aggregate purchase price of approximately $5.0 million. Eliyahou Harari purchased 1,757,469 shares for an aggregate purchase price of approximately $10.0 million. An additional existing stockholder who beneficially owns less than 5% of the Company's outstanding Common Stock purchased the remaining 527,241 shares for an aggregate purchase price of approximately $3.0 million. All Purchasers purchased shares at the same price and on the same material terms.

For the three and nine months ended September 30, 2026, the Company's other material transactions with related parties related to certain R&D expenses ($287 and $789 for the three and nine months ended September 30, 2026, respectively) for non-recurring engineering services with an R&D and manufacturing services vendor that holds an insignificant percentage of the Company's capital stock. The outstanding balance for the non-recurring services was included in Accrued Expenses and Other Current Liabilities in the condensed balance sheet as of September 30, 2026. There were no amounts due from related parties at September 30, 2026. There were no amounts due from or to related parties at December 31, 2025.

15. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through the date these financial statements were issued and has determined that no events or transactions have occurred subsequent to September 30, 2026 that would require recognition or disclosure in these condensed financial statements.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and the related notes and the discussion under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2025. In addition to historical financial information, the following discussion contains forward looking statements that reflect our plans, estimates, and beliefs that involve significant risks and uncertainties. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to those differences include those discussed below and elsewhere in this Quarterly Report on Form 10-Q, particularly in "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements."

Overview

We are a global medical technology company that develops advanced imaging and AI technologies, deployed in our capsule endoscopy solutions to identify abnormalities of the GI tract for diagnostic and screening purposes. Our capsule endoscope system, currently comprising the CapsoCam Plus single-use capsule and the CapsoCloud and CapsoView software, provides 360 degree panoramic visualization of the small-bowel mucosa to investigate abnormalities such as obscure GI bleeding and Crohn's disease, while our AI assisted pathology detection tools detect and highlight suspected abnormalities for a clinician, reducing their time to review the video and making capsule endoscopy more financially attractive to their practice. Our cloud-based solution enables medical professionals to access their patients' videos and review those videos anytime, anywhere, 24/7, without a need to have an on-site server and maintain it, while accumulating an immense data trove on the cloud storage for AI training.

We were founded in 2005 and are headquartered in Saratoga, California. We sell our small bowel capsule system to our provider customers (i.e., primarily gastroenterologists practicing in clinics and/or hospitals) both internationally and in the U.S. through our global sales and marketing team. In the U.S., we sell to customers directly. Internationally we sell both directly and through qualified exclusive distributors in specified regions. Our largest international shipping destinations in the nine months ended September 30, 2026 include France, Germany, and Colombia. As of September 30, 2026, our CapsoCam Plus has been used in over 184,000 patients. We currently manufacture and intend to continue manufacturing our CapsoCam capsules included in our GI-tract capsule endoscopy solution (including CapsoCam Colon capsules). To assist us in manufacturing our GI-tract capsule endoscopy products, we rely on component suppliers and assembly manufacturers based in Asia (particularly Taiwan and Japan).

As part of our effort to expand and grow our revenues beyond small-bowel-related revenues, we are developing our next pipeline capsule endoscope product, CapsoCam Colon. Our CapsoCam Colon capsule (i) leverages CapsoCam Plus's existing capsule design with its panoramic view and (ii) incorporates both our self-developed AI to automatically detect polyps and a polyp-size measurement tool enabled by a 3D sensor in the capsule (polyp size being highly correlated with a polyp's risk of becoming cancer).

In the second quarter of 2025 we filed our 510(k) submission to the U.S. Food and Drug Administration (the "FDA") for our initial CapsoCam Colon capsule endoscopy solution (the "First-Generation Product"). We received responses from the FDA in September 2025. During our meeting with the FDA in December 2025, the FDA raised inquiries on topics including panoramic image processing methodology, and the proposed study design, sample size and primary endpoint for an extended study. Based on our communications with the FDA, we have decided not to further pursue the submission and approval for the First-Generation Product, and to prioritize our resources for the development of our second-generation of CapsoCam Colon capsule (the "Second-Generation Product"), which features improved imaging quality and increased field of review with use of AI and better lens. We also expanded a second arm pivotal study to enroll approximately 800 patients at up to 20 sites in the U.S. in preparation for submitting a new 510(k) application for the Second-Generation Product. As of the date of this Quarterly Report, we have completed the second arm pivotal study with 801 patients enrolled. We currently

expect to submit the 510(k) application for the Second-Generation Product in the fourth quarter of 2026, subject to any further requests from the FDA.

Since we continue to invest in AI to improve our existing products, we completed a clinical study to demonstrate the benefits of our incorporation of AI technology into CapsoCam Plus, our existing product for the small bowel. We submitted the related 510(k) application to the FDA in December 2025. In response to the FDA's feedback, we submitted a proposal to the FDA in April 2026. As further requested by the FDA, we conducted further demographic analysis of the study data and submitted the analysis to the FDA at the end of August 2026. AI Highlights™, our AI-assisted reading feature for the CapsoCam Plus® system, received clearance from the FDA on September 25, 2026. Its commercialization began in the US on November 2, 2026. We also made the initial EU submission in January 2026 and submitted the related technical documents in July 2026. We commercialized in EU in August 2026. Because of the shorter reading time needed by doctors and improved accuracy, the Company expects the addition of AI Highlights to accelerate CapsoCap Plus sales growth, with the commercial impact anticipated in 2027.

Longer term, we believe our CapsoCam family of products, incorporating our panoramic imaging solution, can be adapted to address new GI medical indications. Potential new medical indications include esophageal medical conditions (such as esophageal varices) and pancreatic cancer. In connection with our efforts to address pancreatic cancer, we submitted an FDA "Breakthrough Device Designation" application for our capsule endoscopy solution on November 6, 2025. A response from FDA in January 2026 determined that the CapsoCam UGI does allow for visualization of the papilla and its abnormalities, for both pre-cancerous and cancerous lesions. Due to the fact that the device does not specifically define diagnostic criteria, the application was not approved. Following the FDA's response, we initiated a study for early pancreatic cancer detection using the CapsoCam UGI system in May 2026. This study will build on established scientific literature and engage leading opinion leaders, including leadership of leading societies in the pancreatobiliary field, to define malignancy diagnosis criteria with the device. This study is expected to enroll up to 140 patients using the CapsoCam UGI system. As of the date of this Quarterly Report, three patients have been enrolled in this study. The study continues and we are working on expanding a number of clinical sites participating in the study. Building on two active community-based clinical sites, we have executed a clinical trial agreement with a third site and are in various stages of contracting and feasibility discussions with more than a dozen larger medical centers with expertise in pancreatic ductal adenocarcinoma (PDAC), which we expect will help to accelerate patient enrollment. We expect to resubmit the Breakthrough Device Designation application following the study, when additional data is available. The breakthrough designation is a part of the on-going project, potentially supplementing the regulatory pathway and approval for early pancreas cancer detection. However, additional research and studies to collect data may delay our anticipated timeline for obtaining the regulatory clearance (including obtaining the Breakthrough Device Designation) and may increase our research and development costs.

As of September 30, 2026, we had an accumulated deficit of $177.5 million. To date, we have funded our operations primarily through proceeds from the sale of shares of our convertible preferred stock, IPO, the private placement of our common stock that closed in March 2026 (the "Private Placement"), the registered direct offering of our common stock that closed in September 2026 (the "September 2026 Securities Purchase Agreement") and sales of our common stock under our at-the-market offering program established in August 2026 (the "ATM Program") and cash generated from the sale of CapsoCam capsules and the use of CapsoCloud or CapsoView, CapsoCloud data access, and capsule video reading service.

Our mission is to transform lives through innovative medical solutions that improve the health of patients around the world. When used in this Quarterly Report on Form 10-Q, the terms "we," "us," "our" and "the Company" mean CapsoVision.

Our Business Model

Key Factors Affecting Our Results of Operations and Performance

We believe there are several important factors that have impacted and that we expect will impact our operating performance and results of operations for the foreseeable future. These factors include:

Success in further penetrating the small bowel capsule endoscopy market. Until commercialization of our CapsoCam Colon capsule (targeted for within one quarter after FDA clearance is provided), to grow our revenues (and, in turn, reduce our expected losses and negative cash flows), we intend to grow our small-bowel-related revenues by, among other things: (i) retaining and growing our customer base; (ii) cost-effectively increasing the size and effectiveness of our U.S. and international sales teams and our customer-support function; (iii) pursuing the pediatric market (with children comprising a significant portion of the Crohn's disease patient population); (iv) introducing complementary products such as our (a) capsule delivery device with full commercialization expected in the first quarter of 2027, and (b) patency capsule (for verifying whether a capsule endoscope can pass through the bowel without retention prior to an exam) with the FDA 510(k) application submitted in July 2026, for which we received questions from the FDA in September 2026 and expect clearance in the first quarter of 2027; (v) facilitating increased telemedicine adoption following FDA clearance in December 2024 of remote ingestion of our CapsoCam Plus, allowing patients to ingest our capsules in the comfort of their own homes with remote provider supervision; and (vi) following related FDA 510(k) clearance in September 2026, commercializing our updated CapsoCam Plus which incorporates our AI assisted pathology detection technology.

Success in our clinical development efforts and managing related costs. Prior FDA, EU and other regulatory clearances are required (as applicable) to, among other things, (i) commercialize our GI-tract capsule endoscopy solution (including newly developed capsules or major hardware or software enhancements and improvements to a previously approved capsule or related product), (ii) target a new or expanded indicated patient population for our solution or (iii) target new medical conditions. These clearances must be supported by satisfactory clinical study data, among other things. By their nature, clinical development and related expenses often require significant upfront investment in terms of time and cost before revenue generation is ensured. Consequently, to generate or achieve and maintain revenue, we must effectively manage our planned clinical development efforts in terms of successful results and time and costs expended. In particular, our clinical study expenses may fluctuate significantly due to numerous factors, including the nature of a clinical study and relatedly, the study's protocols, size in terms of patients and clinical sites and duration and the ability to timely enroll sufficient qualified patients (which may be impacted by competing clinical trials). We may also be required to conduct additional clinical trials or other testing of any of our products beyond those that are contemplated or if we experience significant delays in enrollment in any clinical trials, we could incur significant additional costs and the clinical development timeline for our products may be delayed.

Success in our research and development efforts. We plan to continue investing in research and development to build upon and expand our GI-tract capsule endoscopy solution. Our research and development initiatives are focused on introducing new capsule products and enhancements and improvements to existing products, aimed at increasing the value provided by our GI-tract capsule endoscopy solution to patients and providers. We plan to appropriately modify our combined CapsoCam capsule and CapsoCloud and/or CapsoView solution to address new GI indications, for which we have begun and/or expect to soon begin the technical validation process for several additional indications and clinical-use cases beyond the small bowel.

Success in further developing our AI product features. We plan to continue investing to (i) improve the pathology-detection and classification accuracy and the scope of our AI algorithms and (ii) apply AI, including large language models, to streamline the diagnostic and medical-report-generation processes, which in turn improves the efficiency and effectiveness of our healthcare provider customers. Our CapsoCloud platform in the ordinary course collects patient videos and physician diagnostic reports that, with patient consent, we can utilize as a dataset for training and validating our AI algorithms. This ever-expanding patient pathology dataset is unique among capsule endoscopy companies, and together with our in-house team of AI experts, provides a competitive advantage. Ongoing investment is required to apply expert labels to the accumulated image data and to modify,

train, and test the algorithms on this labeled data to expand applications beyond the current horizon. AI Highlights, our AI-assisted reading tool for the CapsoCam Plus system which is available for both adults and pediatric patients aged two and older, is now commercialized in EU and the US, integrates with our CapsoView software and CapsoCloud platform and is designed to reduce the time physicians spend reviewing small bowel capsule endoscopy studies performed for suspected small bowel bleeding by recognizing, marking and prioritizing images containing suspected abnormal lesions for physician review.

Components of our Results of Operations

Revenue

We generate (i) product revenue from the sale of CapsoCam capsules, (ii) service revenue from the provision of reading services for videos, and (iii) product or service revenue depending on which video delivery option is utilized by the customer to download and view capsule videos (CapsoCloud or CapsoView). The customer's delivery options include (1) CapsoCam capsules shipped to the customer which works together with downloadable software (CapsoView) installed locally on a customer's computer (classified as product revenue), or (2) a software-as-a-service offering which involves the customer mailing capsule devices to an off-site Company-operated facility which processes uploads of video content to a cloud platform (CapsoCloud) the customer can access via a web browser or a smart device application in order to view videos and generate reports (classified as service revenue). We recognize revenue for our product and reading service performance obligations at a point in time, that being when the performance obligations are satisfied and control is transferred to the customer (generally upon shipment for products, or conveyance of final deliverable for services). For the software-as-a-service video delivery offering performance obligation, the associated revenue is recognized over time, typically less than one fiscal quarter, representing the estimate of the typical period of time in which customers derive utility from the cloud-based service.

Fees paid to group purchasing organizations (GPOs) that act as procurement agents for their underlying medical practice, clinic, or hospital members are deducted from revenue in the period the related revenue is recognized.

Our revenue fluctuates primarily based on the number of CapsoCam capsules sold.

Costs of Revenue

We currently manufacture and intend to continue manufacturing our CapsoCam capsules included in our GI-tract capsule endoscopy solution. To assist us in doing so, we rely on component suppliers and assembly manufacturers based in Asia (particularly Taiwan and Japan).

Costs of revenue include materials, direct labor, and manufacturing overhead costs related to sold products, as well as certain period costs such as non-allocated overhead, scrap, and outbound freight costs, fees paid to physicians for providing reading services, and the costs of operating CapsoCloud as a software-as-a-service offering for video delivery of capsule videos such as shipping costs, processing costs, and data storage costs. All shipping and handling costs directly related to bringing products to their final point of sale are included in costs of revenue. As we expand our product offerings, acquire new customers and existing customers increase their use of our CapsoCam solutions, we expect that our costs of revenue will continue to increase in absolute terms in line with increased revenues.

Beginning in early 2025, the U.S. government announced changes to its trade policies, including increasing tariffs on imports. Such changes could pose a risk to our business that could adversely affect our revenue, cost of revenue, gross profit, and gross margin. We will continue to evaluate the potential impact of tariffs on our business and results of operations and mitigating actions we might consider implementing.

Gross Profit and Gross Margin

We calculate gross profit as revenue less costs of revenue. Gross margin represents gross profit as a percentage of revenue. We expect gross profit and gross margin to change and be affected by various factors going forward, including selling prices, product costs, customer mix and production volumes as well as product mix once sale of CapsoCam Colon capsules begin with CapsoCam Colon capsules expected to have a higher sales price and related costs of revenue as compared to CapsoCam Plus, given the additional optics and other features incorporated into the capsule.

Due to the potential increase in costs of revenue, expected as a result of U.S. trade policies changes, including increasing tariffs on imports, and increases in the costs of electronic components used in our products (including memory components) our gross profit/gross margin may be adversely impacted.

Operating Expenses

Selling and Marketing

Selling and marketing expenses include costs directly attributable to actively marketing our products and services using both direct employees and outside contractors or vendors. These costs include salaries, bonuses, benefits, and stock-based compensation, sales commissions, travel costs and expense reimbursements, and the costs to increase market awareness of our technology and our product advantages, including expenses related to sponsoring programs, events, conferences and consulting services.

We expect our selling and marketing expenses to increase in the foreseeable future as we continue to increase the size of our in-house sales organization and market penetration in the U.S. and internationally, and expand indications. However, we expect selling and marketing expenses to decrease as a percentage of revenue primarily as our revenue grows.

Research and Development

Research and development costs are expensed as incurred in accordance with ASC 730. See Note 3 to our financial statements included elsewhere in this Quarterly Report on Form 10-Q for further details. Our research and development team includes hardware and software engineers with deep expertise in medical technology, optics, data science, AI, and cloud-based data and security architecture and individuals with extensive clinical development expertise.

Our GI-tract capsule endoscopy solution research and development activities include both (i) activities focused on increasing the value of our solution (such as developing new capsule products, including the associated software component, and new enhancements and features) and (ii) related clinical trial development efforts. Related research and development expenses include salaries, bonuses, benefits, and stock-based compensation for our employees focused on research and development, including engineering for our AI technology and hardware development, clinical trials, or regulatory clearance, costs of independent contractors and outside vendors, costs of supplies consumed in or product inventory utilized in clinical trials, and the costs of the clinical trials themselves as charged within the negotiated budgets by trial sites or vendors responsible for multiple trial sites.

In the near term, we expect our clinical development expenses to decline as a percent of revenue as, among others, we (i) completed the enrollment of the second arm of our CapsoCam Colon pivotal study involving the second generation of that capsule (incorporating further advanced features designed to improve the accuracy of CapsoCam Colon) with the second arm involving 801 patients enrolled, and (ii) conduct additional research and studies to collect data for the development of CapsoCam UGI, which is a less expensive project.

In addition to clinical trials costs, our research and development costs also include engineering for our AI technology, hardware development, and regulatory personnel.

General and Administrative

General and administrative expenses consist primarily of personnel expenses, including salaries, bonuses, benefits, and stock-based compensation expense for personnel in executive, administrative, finance, human resources, and other supporting functions. General and administrative expenses also include professional fees for legal services, consulting services, tax matters and audits, as well as information technology expenses, office expenses, rent, insurance, and foreign exchange gains (losses).

We expect that our general and administrative expenses will increase in the foreseeable future as we increase our headcount to support the continued growth of our business. We also anticipate incurring additional expenses associated with operating as a public company, including increased expenses related to audit, legal, regulatory, compliance, director and officer insurance, investor and public relations, and tax-related services associated with maintaining compliance with the rules and regulations of the SEC and standards applicable to companies listed on a national securities exchange. However, we expect general and administrative expenses to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

Results of Operations for the Three and Nine Months Ended September 30, 2026 and 2025

The following tables set forth our results of operations for the periods presented. The period-to-period comparison of financial results is not necessarily indicative of financial results to be achieved in future periods.

	Three Months Ended September 30,			
	2026	2025	$ Change	% Change
	(in thousands, except for percentages and per share amount)			
Revenue	**$ 3,568**	**$ 3,538**	**$ 30**	**1 %**
Costs of revenue	**1,804**	**1,624**	**180**	**11 %**
Gross profit	**1,764**	**1,914**	**(150)**	**(8)%**
Gross Margin	**49 %**	**54 %**		**(5)%**
OPERATING EXPENSES				
Selling and marketing	2,060	1,773	287	16 %
Research and development	4,803	6,090	(1,287)	(21)%
General and administrative	2,285	2,070	216	10 %
Total operating expenses	**9,148**	**9,933**	**(785)**	**(8)%**
Operating loss	**(7,384)**	**(8,019)**	**635**	**(8)%**
Total non-operating income, net	**45**	**98**	**(53)**	**(54)%**
Loss before income taxes	**(7,339)**	**(7,921)**	**582**	**(7)%**
Provision for income taxes	—	—	—	— %
Net loss and comprehensive loss	**$ (7,339)**	**$ (7,921)**	**$ 582**	**(7)%**
Net loss per share – basic and diluted	**$ (0.15)**	**$ (0.17)**	**$ 0.02**	**(12)%**

	Nine Months Ended September 30,			
	2026	2025	$ Change	% Change
	(in thousands, except for percentages and per share amount)			
Revenue	**$ 10,003**	**$ 9,636**	**$ 367**	**4 %**
Costs of revenue	**5,039**	**4,417**	**622**	**14 %**
Gross profit	**4,964**	**5,219**	**(255)**	**(5)%**
Gross Margin	**50 %**	**54 %**		**(4)%**

OPERATING EXPENSES				
Selling and marketing	6,087	5,581	506	9 %
Research and development	14,547	12,589	1,958	16 %
General and administrative	6,387	5,101	1,285	25 %
Total operating expenses	**27,021**	**23,271**	**3,750**	**16 %**
Operating loss	**(22,057)**	**(18,052)**	**(4,005)**	**22 %**
Total non-operating income, net	**204**	**131**	**73**	**56 %**
Loss before income taxes	**(21,853)**	**(17,921)**	**(3,932)**	**22 %**
Provision for income taxes	—	—	—	— %
Net loss and comprehensive loss	**$ (21,853)**	**$ (17,921)**	**$ (3,932)**	**22 %**
Net loss per share – basic and diluted	**$ (0.44)**	**$ (1.05)**	**$ 0.61**	**(58)%**

Revenue

Our revenue for the three months ended September 30, 2026 and 2025 was $3.6 million and $3.5 million, respectively, representing a period-over-period growth of $0.1 million or approximately 1% (1% decrease in the U.S. and 8% increase internationally). The primary driver for the revenue growth was an increase in the number of CapsoCam Plus capsules sold internationally, offset by decrease in the number of CapsoCam Plus capsules sold in the U.S. Our revenue for the nine months ended September 30, 2026 and 2025 was $10.0 million and $9.6 million, respectively, representing a period-over-period growth of $0.4 million or approximately 4% (0% in the U.S. and 17% internationally). The primary driver for the revenue growth was a 13% increase in the number of CapsoCam Plus capsules sold internationally supported by 3% increase in average selling prices for international customers.

For the three months ended September 30, 2026 and 2025, international sales accounted for 24% and 22% of total revenue. For the nine months ended September 30, 2026 and 2025, international sales accounted for 25% and 22% of total revenue.

Costs of Revenue

As we continued to scale our business, costs of revenue increased $0.2 million, or 11%, for the three months ended September 30, 2026, compared to the three months ended September 30, 2025 from $1.6 million to $1.8 million. The increased costs of revenue was primarily attributable to higher unit material costs, a write-off of obsolete inventory and an increase in stock-based compensation expenses due to new stock-option grants. For the nine months ended September 30, 2026, compared to the nine months ended September 30, 2025 the cost of revenue was $5.0 million and $4.4 million, respectively, which represented an increase of $0.6 million, or 14% period-over-period. The increased costs of revenue was primarily attributable to $0.1 million increase of compensation expenses for production employees, $0.1 million increase in stock-based compensation expenses due to new stock-option grants, $0.1 million increase of cost for CapsoCloud and $0.2 million due to increased customs and tariffs due to the change in U.S. customs policy.

Gross Profit and Gross Margin

Gross profit decreased $0.2 million, or 8%, for the three months ended September 30, 2026, compared to the three months ended September 30, 2025, from $1.9 million to $1.8 million. For the three months ended September 30, 2026 and 2025, the gross margin was 49% and 54%, respectively. Gross profit decreased $0.3 million, or 5%, for the nine months ended September 30, 2026, compared to the nine months ended September 30, 2025, from $5.2 million to $5.0 million. For the nine months ended September 30, 2026 and 2025, the gross margin was 50% and 54%, respectively. The decrease in gross profit and gross margin is due to higher unit

material costs, a write off of obsolete inventory, and increased stock-based compensation expense related to stock options granted in June.

Operating Expenses

The following tables provide a summary for our key operating expenses for the three and nine months ended September 30, 2026 and 2025.

	Three Months Ended September 30,			
	2026	**2025**	**$ Change**	**% Change**
	(in thousands, except percentages)			
Selling and marketing	$ 2,060	$ 1,773	$ 287	16 %
Research and development	4,803	6,090	(1,287)	(21)%
General and administrative	2,285	2,070	216	10 %
Total operating expenses	**$ 9,148**	**$ 9,933**	**$ (785)**	**(8)%**

	Nine Months Ended September 30, 2026			
	2026	**2025**	**$ Change**	**% Change**
	(in thousands, except percentages)			
Selling and marketing	$ 6,087	$ 5,581	$ 506	9 %
Research and development	14,547	12,589	1,958	16 %
General and administrative	6,387	5,101	1,285	25 %
Total operating expenses	**$ 27,021**	**$ 23,271**	**$ 3,750**	**16 %**

Selling and Marketing Expenses

Selling and marketing expenses increased $0.3 million, or 16%, for the three months ended September 30, 2026, compared to the three months ended September 30, 2025, from $1.77 million to $2.1 million. The increase was primarily due to a $0.1 million increase in stock-based compensation expenses due to new stock-option grants, and a $0.1 million increase in expenses for participation in sales conferences.

Selling and marketing expenses increased $0.5 million, or 9%, for the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025, from $5.6 million to $6.1 million. The increase was primarily due to a $0.2 million increase in compensation and related benefits expenses for the sales force as a result of annual merit increases, a $0.1 million increase in stock-based compensation expenses due to new stock-option grants, and a $0.1 million increase in expenses for participation in sales conferences.

Research and Development Expenses

Research and development expenses decreased $1.3 million, or 21%, for the three months ended September 30, 2026, compared to the three months ended September 30, 2025, from $6.1 million to $4.8 million. The decrease was primarily due to a $1.3 million decrease in expenses for the development of the new CMOS image sensor under the development agreement with Canon Inc. The decrease is due to the recognition of $1.0 million non-cancellable fee in expenses in the third quarter of 2025 when the agreement was initially executed and a $0.3 million decrease of expenses due to lower progress of development in the third quarter of 2026 compared to the third quarter of 2025.

Research and development expenses increased $2.0 million, or 16%, for the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025, from $12.6 million to $14.5 million. The increase was primarily due to a $1.6 million increase attributable to expenses associated with ongoing clinical trials, and an increase in stock-based compensation expenses of $0.4 million due to new stock-option grants.

General and Administrative Expenses

General and administrative expenses increased $0.2 million, or 10%, for the three months ended September 30, 2026 compared to the three months ended September 30, 2025, from $2.1 million to $2.3 million. The increase was due to an increase in stock-based compensation expenses of $0.2 million, primarily due to new stock-option grants.

General and administrative expenses increased $1.3 million, or 25%, for the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025, from $5.1 million to $6.4 million. The increase was due to expenses operating as a public company of $0.3 million (insurance expenses increased $0.2 million, Board of Directors cash compensation expense increased $0.1 million), an increase in stock-based compensation expenses of $0.6 million, primarily due to new stock-option grants, and software expenses of $0.2 million (expenses for a new ERP implementation and software necessary for operating as a public company). This increase was partially offset by a decrease in expenses for audit and consulting ($0.3 million) that were higher in the first half of 2025 due to the preparation of the Company's financial statements in connection with the IPO. Additionally, expenses in the second quarter of 2025 were offset by $0.2 million received from the U.S. federal government as part of a COVID-19 relief program. Another $0.3 million increase of expenses period-over-period is a result of foreign currency gains in the first half of 2025 compared to immaterial loss in the comparable period of 2026.

Net Loss

Our reported net loss attributable to CapsoVision common stockholders for the three months ended September 30, 2026 and 2025 totaled approximately $7.3 million and $7.9 million, respectively, representing a period-over-period decrease of $0.6 million or 7%. Our reported net loss attributable to CapsoVision common stockholders for the nine months ended September 30, 2026 and 2025 totaled approximately $21.9 million and $18 million, respectively, representing a period-over-period increase of $3.9 million or 22%.

Liquidity and Capital Resources

Overview

To date, we have financed our operations primarily through the net proceeds we have received from the sales of our convertible preferred stock, IPO, Private Placement, sale of securities in a Registered Direct Offering via Securities Purchase Agreement and 2026 ATM Program, as well as cash generated from sales of our CapsoCam Plus capsule endoscopy solution. We have generated losses from our operations as reflected in our accumulated deficit of $177.5 million as of September 30, 2026. Net cash used in operating activities was $21.5 million and $15.2 million for the nine months ended September 30, 2026 and 2025, respectively.

Our losses primarily resulted from the costs incurred in the development and sales and marketing of our products and providing general and administrative support for our operations. We expect to continue to incur losses in the foreseeable future and to expend significant amounts of cash as we continue to scale our business, invest in research and development activities, increase sales and marketing expenses to support commercial expansion, and increase general and administrative expenses to support being a publicly-traded company.

Our interim (unaudited) financial statements for the nine months ended September 30, 2026 included in this Quarterly Report on Form 10-Q note that there is substantial doubt about our ability to continue as a going concern within one year after the date of issuance of those financial statements (see Note 2. GOING CONCERN). This means that we have expressed substantial doubt about our ability to continue our operations without an

additional infusion of capital from external sources, an increase in revenues, or cost reduction. Our interim (unaudited) financial statements have been prepared on a going concern basis and do not include any adjustments to reflect the future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may be necessary should we be unable to continue as a going concern. If we are unable to finance our operations, our business would be in jeopardy and we might not be able to continue operations and might have to liquidate our assets. In that case, investors might receive less than the value at which those assets are carried on our interim (unaudited) financial statements for the nine months ended September 30, 2026, and it is likely that investors would lose all or a part of their investment. See “Risk Factors—Business and Industry Risks—Our Quarterly Report, our unaudited financial statements for the nine months ended September 30, 2026 and our audited financial statements for the year ended December 31, 2025 include a footnote raising substantial doubt about our ability to continue as a ‘going concern’ and we will likely need to raise additional financing to fund our business and revenue growth plans."

We have lease obligations and other contractual obligations and commitments as part of our ordinary course of business. See Note 7. LEASES to our financial statements included elsewhere in this Quarterly Report on Form 10-Q for information about our lease obligations. In addition, see Note 8. COMMITMENTS AND CONTINGENCIES to our financial statements included elsewhere in this Quarterly Report on Form 10-Q for information about our other commitments and contingencies.

Source of Liquidity

As of September 30, 2026, we had approximately $21.8 million in cash and cash equivalents. From our inception through September 30, 2026, we have received aggregate gross proceeds of $143.6 million from sales of our convertible preferred stock, which were automatically converted into shares of our common stock in connection with the completion of our IPO. To provide for additional liquidity prior to the completion of our IPO, on May 28, 2025 we received $1 million as a note payable from an existing investor. The note payable, together with interest thereon (at 1% per month) was repaid shortly after completion of our IPO. On July 3, 2025 we completed our IPO from which we received the net proceeds in the amount of $23.4 million. On March 16, 2026 we closed the Private Placement and received the net proceeds in the amount of $13.4 million. On September 17, 2026 we entered into a securities purchase with investors and received the net proceeds in the amount of $17.8 million. In the third quarter of 2026 we sold 276,446 shares of our common stock under the ATM Program and received the net proceeds in the amount of $1.7 million. As of September 30, 2026, shares of our common stock having an aggregate offering price of up to approximately $98.2 million remained available for sale under the ATM Program.

Funding Requirements

As of September 30, 2026, we had an accumulated deficit of $177.5 million and cash and cash equivalents of $21.8 million. On March 16, 2026, we completed the Private Placement with the net proceeds to us of approximately $13.4 million. On September 17, 2026, we entered into a securities purchase agreement with investors pursuant to which we closed the Registered Direct Offering with net proceeds to us of approximately $17.8 million. In the third quarter of 2026, we also raised approximately $1.7 million in net proceeds under the ATM Program. Based on our current operating plan, we believe that our existing cash balances will not be sufficient to fund our operations for at least the next 12 months after the date of issuance of the financial statements included in this Quarterly Report on Form 10-Q.

We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. We may experience lower than expected cash generated from operating activities or greater than expected costs of revenue or operating expenses, and may need to raise additional capital to fund operations.

Our future capital needs will depend upon our ability to execute our revenue growth plans and many factors, including:

- the cost and pace of developing new products, enhancements to existing products and our research and development activities;
- the market acceptance of our products;
- our ability to develop and commercialize our CapsoCam capsule endoscopy solution for new indications, patient populations and clinical use cases;
- our ability to successfully complete any required clinical or other studies and timely obtain and maintain any required regulatory approval or clearances;
- insurer and third-party reimbursement of the costs associated with our GI-tract capsule endoscopy solution;
- successful management of our global supply chain including our component suppliers and assembly manufacturers for our CapsoCam solution, many of which are located in Asia (particularly Taiwan and Japan) and some of which are currently single-source suppliers;
- successful growth and leveraging of our global sales team (including, where appropriate, distributors) and marketing team to sell and market our GI-tract capsule endoscopy solution;
- the costs of attaining, defending, and enforcing our intellectual property rights;
- whether we acquire third-party products or technologies;
- the amount and nature of competition from other GI-tract diagnostic products or procedures;
- our ability to raise additional funds to finance our operations; and
- the costs associated with being a public company.

If the sources of cash together with expected cash generated from operating activities are insufficient to satisfy our liquidity requirements, we may need to engage in equity or debt financings to secure additional funds. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. In addition, the undertaking of indebtedness would increase our fixed obligations and include covenants or other restrictions that could impede our ability to manage our operations. Our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the disruptions to and volatility in the credit and financial markets in the U.S. and fluctuations in interest rates, resulting from factors that include but are not limited to, inflation, the conflict between Russia and Ukraine, escalation in Iran, political tensions between China and Taiwan and other factors, diminished liquidity and credit availability, tariffs, declines in consumer confidence, declines in economic growth, increases in unemployment rates and interest rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Further, if additional financing is needed, we may not be able to obtain additional financing on terms favorable to us or at all. Our inability to obtain adequate financing or financing on terms satisfactory to us, when we require it, could significantly limit our ability to continue supporting our business growth and responding to business challenges and opportunities.

If we are unable to obtain additional funding on a timely basis, we will be required to scale back our plans and place certain activities on hold. We currently do not have any commitments to obtain additional funds. Our management continues to evaluate different strategies to obtain the required funding for future operations. These strategies may include public and private placements of equity and/or debt securities.

Cash Flows

The following table shows a summary of our cash flows for each of the periods presented:

	Nine months ended September 30,	
	2026	2025
	(in thousands)	
Net cash used in operating activities	$ (21,511)	$ (15,178)
Net cash used in investing activities	(70)	(82)
Net cash provided by financing activities	33,261	23,589
Net increase in cash and cash equivalents	**$ 11,680**	**$ 8,329**

Net Cash Used in Operating Activities

For the nine months ended September 30, 2026, net cash used in operating activities totaled $21.5 million, primarily driven by the net loss of $21.9 million for the period. Additional contributing factors included a $1.8 million increase in inventory to meet expected increased demand, a $1.7 million increase in accrued expenses and other current liabilities, mainly due to research and development expenses, a $0.4 million increase on other long-term assets due to deferring shelf registration costs, as well as $1.9 million increase in stock-based compensation expenses, primarily due to new grants.

For the nine months ended September 30, 2025, net cash used in operating activities was $15.2 million, primarily attributable to the net loss of $17.9 million. Cash outflows were further impacted by a $0.6 million increase in inventory to meet increased demand, and a $2.2 million increase in accrued expenses and other current liabilities, mainly due to research and development expenses and increased headcount related expenses.

Net Cash Used in Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2026 and 2025 was immaterial and consisted of purchases of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2026 consisted primarily of $14.0 million in gross proceeds from the Private Placement, net of issuance costs of $0.6 million, $18.0 million in gross proceeds from Securities Purchase Agreement in the Registered Direct Offering, $1.7 million in proceeds from the ATM Program net of placement fee, and $0.2 million in proceeds from the exercise of options on common stock and warrants. For the nine months ended September 30, 2025, net cash provided by financing activities consisted primarily of $23.4 million in net proceeds from the IPO and $0.2 million in proceeds from the exercise of options on common stock and warrants.

Contractual Obligations and Commitments

Our contractual obligations at September 30, 2026 include operating lease payments of $0.9 million due within 33 months, purchase commitments to raw material suppliers of $1.0 million due within 18 months and $1.5 million in outstanding purchase commitment for the development agreement with Canon Inc. due in 6 months. We expect to fund these obligations through our existing cash balances and cash flows from operations.

The Company had no off-balance-sheet arrangements that have or are reasonably likely to have a material effect on its financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. GAAP. Preparation thereof requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses, and certain items included in the footnotes to our financial statements. See Note 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES to our financial statements included elsewhere in this Quarterly Report on Form 10-Q for information about our significant accounting policies. While we believe the processes used in developing our estimates to be reasonable, actual amounts may differ from estimates. The following reflects the critical accounting estimates used in the preparation of our financial statements. The term "critical accounting estimates" refers to those estimates that involve a significant level of estimation uncertainty that have had, or are reasonably likely to have, a material impact on our financial condition or results of operations.

Research and Development Expenses (including Clinical Trial Expenses)

Research and development expenses, generally expensed as incurred, include salaries, bonuses, benefits, and stock-based compensation for employees focused on research and development or clinical trials, costs of independent contractors and outside vendors, costs of supplies consumed in or product inventory utilized in clinical trials, costs of the clinical trials themselves as charged within the negotiated budgets by trial sites or vendors responsible for multiple trial sites, and purchased or in-licensed intellectual property used in new product development where there is no alternative future use. We capitalize prepayments for goods or services, including trial device inventory or pre-paid clinical trial amounts, that will be used, consumed, or rendered for future research and development activities and recognize expense as the related goods are delivered or services are performed. We also record expenses and accruals for estimated costs of research and development activities that have not yet been billed to us, including services for clinical trials.

Research and development expenses possess significant estimation uncertainty that have been, or are reasonably likely to be, material and include costs incurred with clinical trial sites and related vendors.

Such estimation uncertainty arises because: (i) the total time periods over which costs are expected to be incurred, and attributed to, may contract or expand based upon difficult-to-predict outcomes such as better than expected progress in, or delays in, clinical trials (including due to study protocol amendments); (ii) the costs' behavior may be variable, or fixed, requiring judgments regarding proper attribution methodologies; and (iii) visibility of the precision of the exact progress of a particular study subject through the phases of the trial may be very limited, directly implicating necessary assumptions regarding informed consent, enrollment, or completion and speed of progress.

Revenue Recognition

We recognize revenue using a five-step model prescribed by U.S. GAAP resulting in revenue being recognized as performance obligations within a contract are satisfied. Judgment is required to apply the principles-based, five-step model for revenue recognition. Management is required to make certain estimates and assumptions about our contracts with our customers. To date, with limited exception for capsule video reading service revenues, all our revenue is generated from the sale of our CapsoCam Plus capsules to our customers (classified as product revenue) and the use of CapsoCloud or CapsoAccess (together with CapsoView) as the customer selected capsule video delivery option for (i) streaming the capsule videos (via CapsoCloud) for clinician review (classified as service revenue) or (ii) downloading the capsule videos (via CapsoAccess and CapsoView) for clinician review (classified as product revenue).

Those aspects of the five-step revenue recognition model prescribed by U.S. GAAP that give rise to significant levels of estimation uncertainty and have been, or are reasonably likely to be, material to our financial condition or results of operations include (i) the estimation of stand-alone selling prices for performance obligations that are not, or are rarely, sold separately or possess a wide range of observed historical selling prices and (ii) the measurement of applicable time periods to be used for recognition of revenue which is initially deferred at the time

of sale and subsequently recognized over time or at a point in time. The estimation of stand-alone selling prices, where we rely upon a cost-plus-expected margin approach, variability in our expected profit margin assumptions can, in turn, cause variation in estimated stand-alone selling prices and therefore the amounts of revenue allocated to different performance obligations.

For the estimation of applicable time periods impacting recognition of revenue deferrals, estimates are determined using historical customer behavior and deliverable timing data. Usage of historical data requires consideration of trends, patterns, and changes in the underlying data, judgments regarding sampling, and judgments as to whether historical data needs to be adjusted for future expectations. Changes in these underlying inputs have not significantly impacted service revenues or deferrals in the most recent period.

For more information, please, refer to Note 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES and Note 6. REVENUE AND DEFERRED REVENUE.

Stock-Based Compensation

We maintain equity incentive plans to provide long-term incentives for employees, consultants and members of our board of directors. These plans allow for the issuance of non-statutory and incentive stock options to employees, non-statutory stock options to consultants and restricted stock units to Non-Employee Directors. We are required to determine the fair value of equity incentive awards and recognize compensation expense for all equity incentive awards granted.

We account for stock-based compensation awards, including stock options to employees and non-employees, based on their estimated grant date fair value. We recognize the fair value of stock options, which vest based on continued service, on a straight-line basis over the requisite service period, which is generally four years. As described in detail in Note 10. STOCK-BASED COMPENSATION to our financial statements included elsewhere in this Quarterly Report on Form 10-Q, determining the fair value of stock-based compensation to be recorded typically involves the use of an option-pricing model (which, for our Company, is the Black-Scholes option-pricing model).

A significant level of estimation uncertainty arises from certain inputs to the Black-Scholes model. Those inputs include (i) the fair value of the underlying common stock and (ii) the volatility of that fair value.

Recently Issued Accounting Pronouncements

See Note 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES to our financial statements included elsewhere in this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements applicable to our financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management,

including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our principal executive officer and our principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act and the material weaknesses previously identified and further discussed below, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were not effective at the reasonable level of assurance as of September 30, 2026, the end of the period covered by this Quarterly Report on Form 10-Q. Please see below for the disclosure of the Company's material weaknesses in internal control and the remediation plan.

Material Weaknesses in Internal Control over Financial Reporting

Prior to our IPO, we were a private company with limited accounting and financial reporting personnel and other resources to address our internal controls and procedures. We identified two material weaknesses in our financial reporting process as of December 31, 2024, which have not been fully remediated as of September 30, 2026. The first material weakness relates to our failure to design or maintain sufficient controls over implementation of information technology general controls or complementary user entity controls for applications (such as our legacy enterprise resource planning system ("ERP"), payroll, and stock option management IT systems) used in the preparation of our financial statements. More specifically, we did not design or maintain sufficient controls related to user access provisioning and monitoring, change management, program development and data management. The second material weakness relates to a lack of segregation of duties in the financial reporting function due to a limited number of staff performing the financial reporting function. More specifically, there is a limited level of multiple reviews among those tasked with preparing our financial records and with respect to our legacy ERP system proper segregation of duties was not enforced (i.e., for journal entries, we did not always divide responsibilities with one person responsible for making the journal entry and a different person responsible for approving the journal entry).

Remediation Plan for the Material Weaknesses

To remediate the material weaknesses described above and prevent similar deficiencies in the future, we have devoted, and plan to continue to devote, significant effort and resources to the remediation and improvement of our internal control over financial reporting. For example, we are evaluating the current and future accounting and financial reporting personnel to ensure proper segregation of duties. In the third quarter of 2026 we replaced our legacy ERP system with a more advanced one in the third quarter of 2026, which helped address many of the internal control issues contributing to these material weaknesses, i.e. we formalized IT controls, entity level controls and business process controls, established an Internal Controls over Financial Reporting ("ICFR") program, covering planning, risk assessment, scoping and testing that we implemented during the quarter ended September 30, 2025 with regular status updates to the Audit Committee.

Although we have begun the implementation of these remediation efforts, the material weaknesses will not be considered fully remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. Any actions we have taken or may take to remediate these deficiencies are subject to continued management review supported by testing, as well as oversight by the Audit Committee of our board of directors.

We believe these measures will assist us with meeting the Sarbanes-Oxley Act compliance requirements and improving our overall internal controls. However, we cannot assure you that these measures may fully address the material weaknesses in our internal control over financial reporting or that we may conclude that they have been fully remediated.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weaknesses in a timely manner, we will be unable to conclude that

we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

Changes in Internal Control Over Financial Reporting

Except for the remediation measures in connection with the material weaknesses described above including the replacement of the legacy ERP system with a more advanced one in the third quarter of 2026, there were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act during the quarter ended September 30, 2026 covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Part II - Other Information

Item 1. Legal Proceedings

From time to time, we may be involved in various legal proceedings arising from the normal course of business activities. We are not presently a party to any litigation the outcome of which, we believe, if determined adversely to us, would individually or taken together, materially and adversely affect our business, financial condition, or results of operations. Future litigation may be necessary to defend ourselves, our partners, and our customers by determining the scope, enforceability, and validity of third-party proprietary rights, to establish our proprietary rights or for other matters. Involvement in such proceedings is costly and can impose a significant burden on management and employees. The results of any current or future litigation cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on us because of legal expenses and settlement costs, diversion of management attention, and resources and other factors.

Item 1A. Risk Factors

This Quarterly Report on Form 10-Q contains forward-looking statements based on our current expectations. Because our business is subject to many risks and our actual results may differ materially from any forward-looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our business, financial condition, results of operations, and prospects. This discussion should be read in conjunction with the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed financial statements and the related notes, and "Management's Discussion and Analysis of Financial Condition and Results of Operations". The occurrence of any of the events or developments described below could have a material adverse effect on our business, financial condition, results of operations, and prospects. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business, financial condition, results of operations and prospects.

Summary Risk Factors

Below is a summary of the principal risks and uncertainties that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks that we face, follows this summary, and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the SEC before making investment decisions regarding our securities. This summary is qualified in its entirety by that more complete discussion of such risks and uncertainties.

The following is a summary of the principal risks and uncertainties described in more detail in this Quarterly Report on Form 10-Q:

- We have a history of net losses, and we expect to incur additional losses in the foreseeable future.
- Our Quarterly Report, our unaudited financial statements for the nine months ended September 30, 2026 and our audited financial statements for the year ended December 31, 2025 include a footnote raising substantial doubt about our ability to continue as a "going concern" and we will likely need to raise additional financing to fund our business and revenue growth plans.
- All of our revenues to date have been, and in the near-term will continue to be, generated from CapsoCam Plus related sales for the small bowel; and our ability to grow our small-bowel-related revenue is subject to our ability to successfully and timely execute related elements of our revenue growth strategy.
- CapsoCam Colon is our initial strategic effort to expand revenues for our GI-tract capsule endoscopy solution beyond small-bowel-related sales; we do not currently expect to generate CapsoCam Colon-

related revenues until the second half of 2027 based on the anticipated timing of FDA clearance for the second generation of our CapsoCam Colon solution.

- Broad adoption of our CapsoCam Colon solution (once cleared) and growing related revenues depend on, among other things, expanding beyond CapsoCam Colon's initial indicated patient population, increasing the accuracy of our initial CapsoCam Colon solution, and achieving and maintaining a satisfactory successful completion rate for capsule endoscopies using our CapsoCam Colon solution; and we may fail to successfully and timely execute related elements of our CapsoCam Colon adoption and revenue growth strategy.

- Our longer term efforts to expand our GI-tract capsule endoscopy solutions beyond small bowel and colon pathologies and medical conditions may not succeed.

- Any failure or defect in our GI-tract capsule endoscopy solution could harm our reputation, expose us to liability, and reduce our sales.

- We face substantial geopolitical and trade risks (including a possible trade war and imposition of tariffs and supply chain interruptions) and natural disaster risks associated with our business operations in Asia (particularly Taiwan and Japan).

- We may face expansion risks when expanding in existing and entering into new foreign markets.

- The clinical results of our various clinical studies (including those for our CapsoCam Colon capsule) may not be released in any peer-reviewed publications.

- We may not obtain or may experience delays in obtaining 510(k) clearance for our planned second generation of our CapsoCam Colon solution (with improved optics and other components), which would adversely impact our ability to commercialize this product and generate related revenue.

- Failure to obtain or delays in obtaining 510(k) clearance for our CapsoCam Colon capsule endoscopy solution could result in additional costs or liabilities and adversely impact our reputation, ability to sell our CapsoCam Plus capsule endoscopy solution, and our ability to compete effectively in this or other markets. Any of these outcomes could have a material adverse effect on our business, financial condition, and results of operations.

- We may face regulatory challenges and delays in obtaining 510(k) clearance for marketing of those CapsoCam capsules incorporating our self-developed AI technology, including our CapsoCam Colon capsule endoscopy solution and for updates to our previously cleared AI technology.

- If Medicare and other third-party payors, including managed care organizations, do not approve reimbursement for our products at adequate reimbursement rates, we may be unable to successfully commercialize our products which would likely have a material adverse effect on our business.

- We rely on various suppliers to assist us in the assembly and manufacture of our GI-tract capsule endoscopy solution and sourcing of critical and other components and many of these suppliers are single source suppliers located in Asia (particularly Taiwan and Japan); any disruption in our supply chain could adversely affect our ability to meet the demand for our products and fulfil our orders.

Business and Industry Risk Factors

We have a history of net losses, and we expect to incur additional losses in the foreseeable future.

We have incurred net losses since inception, and we expect to incur additional losses in the foreseeable future. For the nine months ended September 30, 2026 and September 30, 2025, we incurred net losses of $21.9 million

and $17.9 million, respectively. As of September 30, 2026 we had an accumulated deficit of $177.5 million. Our accumulated deficit reflects significant front-end spending and investment related to both completed and ongoing key operational milestones, including: (i) the initial and continued development of CapsoCam Plus and CapsoCloud, our cloud-based platform; (ii) development of our next pipeline capsule endoscope, CapsoCam Colon; (iii) initial development and ongoing improvements to our AI assisted pathology detection tools and technologies; and (iv) funding of completed and ongoing related clinical and other studies. As we execute on our business strategy to grow our business and revenues (including seeking FDA 510(k) clearance for CapsoCam Colon), we will continue to incur development costs and clinical study expenses and will make additional investments. Additionally, as a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. Accordingly, we expect to continue to incur losses for at least the near-term and we may never achieve profitability or, if we do achieve profitability, sustain profitability. Our failure to achieve and sustain profitability in the future would make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations.

Our Quarterly Report, our unaudited financial statements for the* nine months ended *September 30, 2026 and our audited financial statements for the year ended December 31, 2025 include a footnote raising substantial doubt about our ability to continue as a "going concern" and we will likely need to raise additional financing to fund our business and revenue growth plans.

Our Quarterly Report, our unaudited financial statements for the nine months ended September 30, 2026 and our 2025 audited financial statements include a footnote raising substantial doubt about our ability to continue as a going concern. We have funded our historical net losses and negative cash flows through the issuance of convertible preferred stock, our IPO, the Private Placement, the Securities Purchase Agreement pursuant to the Registered Direct Offering and sales under the ATM Program. As of September 30, 2026, we had cash and cash equivalents of approximately $21.8 million.

Our ability to continue as a going concern depends on a number of factors including whether we can successfully implement our business and revenue growth plans to generate sufficient cash flow from operating activities, and our ability to raise as needed other equity financing or loan facilities. We closed the Private Placement on March 16, 2026, and raised $14.0 million in gross proceeds from certain accredited investors. In the third quarter of 2026 we raised $18.0 million in gross proceeds through the Securities Purchase Agreement in the Registered Direct Offering and approximately $1.8 million in gross proceeds under the ATM Program. We will likely need to undertake additional capital-raising activities by early 2027 to fund our operations and our ongoing and/or planned clinical studies as contemplated by our growth strategy, such as the second arm pivotal study for the second generation CapsoCam Colon capsule and the study for early pancreatic cancer detection using the CapsoCam UGI system. There is no certainty regarding the occurrence, magnitude, or timing of these capital-raising activities. If we raise additional funds through the sale of equity, convertible debt, or other equity-linked securities, our stockholders' ownership will be diluted. The inability to secure adequate financing on favorable terms, or at all, could have a material adverse effect on our financial position, results of operations, cash flows, and ability to achieve our intended business objectives. See the risk factor titled "We may require additional capital to support business growth, and this capital might not be available on terms favorable to us, or at all, and may dilute existing stockholders' ownership of our common stock" below.

Given the substantial doubt about our ability to continue as a going concern, potential investors must exercise caution when evaluating our financial condition, results of operations, and business prospects. Our inability to raise sufficient financing or meet our strategic plans could result in a material adverse effect on our financial position, results of operations, cash flows, and ability to achieve our intended business objectives.

All of our revenues to date have been, and in the near-term will continue to be, generated from CapsoCam Plus related sales for the small bowel; and our ability to grow our small-bowel-related revenue is subject to our ability to successfully and timely execute related elements of our revenue growth strategy.

Near term actions to grow our CapsoCam Plus small-bowel-related revenues include those set forth below. We may be unable to timely and effectively execute these or other activities designed to increase our small-bowel-related revenues.

- Leveraging the patient and provider benefits of CapsoCam Plus capsule endoscopy solution (which includes the associated software products, CapsoCloud and CapsoView) to effectively compete against competitors, such as (i) Medtronic, with its comparatively greater overall brand recognition, financial resources and other competitive advantages; and (ii) the U.S. subsidiary of a non-U.S. (Chinese) competitor who was the first to use AI-driven lesion detection software to support its small bowel capsule endoscopy system.

- Further penetrating the small bowel market in the U.S. and internationally, including by (i) increasing the size and effectiveness of our U.S. and international sales teams; (ii) pursuing the pediatric market (with children comprising a significant portion of the Crohn's disease patient population) following FDA clearance in December 2024 for this newly indicated patient population; (iii) introducing complementary products such as our (a) capsule delivery device with full commercialization expected in the first quarter of 2027 and (b) patency capsule (for verifying a capsule endoscope can pass through the bowel without retention prior to an exam) with FDA 510(k) application submitted in July 2026, for which we received questions from the FDA in September 2026 and expect clearance in the first quarter of 2027; and (iv) facilitating increased telemedicine adoption following FDA clearance in December 2024 of remote ingestion of our CapsoCam Plus, allowing patients to ingest our capsules in the comfort of their own homes with remote provider supervision.

- Incorporating our AI assisted pathology detection technology into our CapsoCam Plus capsule. We conducted related clinical studies to demonstrate the benefits of our AI technology as incorporated into CapsoCam Plus and submitted the related 510(k) application to the FDA in December 2025. In response to the FDA's feedback, we submitted a proposal to the FDA in April 2026. As further requested by the FDA, we conducted further demographic analysis of the study data and submitted the analysis to the FDA at the end of August 2026. AI Highlights™, our AI-assisted reading feature for the CapsoCam Plus® system, received clearance from the FDA on September 25, 2026. The commercialization began in the US on November 2, 2026. We also made the initial EU submission in January 2026 and submitted the related technical documents in July 2026. By the time of this Quarterly Report we have commercialized in EU.

Each of these activities is subject to numerous risks. For example, (i) we may be unable to compete effectively against our competitors; (ii) the introduction of our capsule delivery device and patency capsule may be delayed or these products may not be sufficiently adopted by providers and patients initially or in the longer term; and (iii) AI Highlights™, which was only recently commercialized in the U.S. and EU, may not achieve the level of market acceptance among physicians and other healthcare providers that we expect, which could adversely affect our ability to grow our small-bowel-related revenues and our business..

For additional information, see the other risks set forth under this "Risk Factors" section including "We operate in a highly competitive industry, and competitive pressures could have a material adverse effect on our business, financial condition, results of operations, and prospects," "Our longer term efforts to expand our GI-tract capsule endoscopy solutions beyond small bowel and colon pathologies and medical conditions may not succeed," and "We may face regulatory challenges and delays in obtaining 510(k) clearance for marketing of those CapsoCam capsules incorporating our self-developed AI technology, including our CapsoCam Colon capsule endoscopy solution and for updates to our previously cleared AI technology."

CapsoCam Colon is our initial strategic effort to expand revenues for our GI-tract capsule endoscopy solution beyond small-bowel-related sales; we do not currently expect to generate CapsoCam Colon-related revenues until FDA clearance for the second generation of our CapsoCam Colon solution.

Our CapsoCam Colon capsule endoscopy solution (which includes associated software products, CapsoCloud and CapsoView) is our initial strategic effort to grow our revenues beyond small-bowel-related sales. We do not expect to generate CapsoCam Colon related sales in the U.S. or internationally until after (i) obtaining initial FDA 510(k) or EU clearance, as applicable, for our second generation of our CapsoCam Colon capsule for use by the indicated patients (who are a subset of the colorectal cancer screening and surveillance population) and (ii) satisfying the related conditions for obtaining these clearances.

The second generation of our CapsoCam Colon solution incorporates our AI assisted pathology detection technology. The second-generation product will incorporate improvements—such as a new lens and illumination optics with an increased field of view and improved image quality—designed to increase the accuracy (measured in terms of polyp-detection sensitivity and specificity) and benefits of using our CapsoCam Colon solution to visualize the colon and detect and measure polyps. We plan to focus our regulatory efforts on first obtaining U.S. FDA clearance followed by obtaining EU clearance. We plan to use the clinical results of the second arm of our pivotal study to support submission to the FDA of a 510(k) application in the fourth quarter of 2026. FDA review of our 510(k) submissions may be delayed and we may not receive 510(k) clearances from the FDA on a timely basis or at all. Staff reductions in the FDA office charged with regulating devices may cause delay. Related risks with respect to, among other things, receiving requisite regulatory clearances and the timing thereof and commercializing our CapsoCam Colon capsule endoscopy solution are described further below under this "Risk Factors" section including "Our longer term efforts to expand our GI-tract capsule endoscopy solutions beyond small bowel and colon pathologies and medical conditions may not succeed," and "We may not obtain or may experience delays in obtaining 510(k) clearance for our planned second generation of our CapsoCam Colon solution (with improved optics and other components), which would adversely impact our ability to commercialize this product and generate related revenue."

Broad adoption of our CapsoCam Colon solution (once cleared) and growing related revenues depend on, among other things, expanding beyond CapsoCam Colon's initial indicated patient population, increasing the accuracy of our initial CapsoCam Colon solution, and achieving and maintaining a satisfactory successful completion rate for capsule endoscopies using our CapsoCam Colon solution; and we may fail to successfully and timely execute related elements of our CapsoCam Colon adoption and revenue growth strategy.

Broader adoption of our CapsoCam Colon capsule endoscopy solution by providers and patients (once cleared) and growing related revenues would involve, among other things:

- increasing the indicated patient population for our CapsoCam Colon solution. The initial indicated patient population is a subset of the colorectal cancer screening and surveillance populations, more specifically, GI patients with (i) major risks for colonoscopy or moderate sedation coupled with evidence of GI bleeding of lower GI origin and (ii) an incomplete colonoscopy with adequate bowel preparation. As part of seeking FDA clearance for the planned second generation of our CapsoCam Colon solution, we plan to seek FDA clearance to remove the GI bleeding requirement. Successful removal of the GI bleeding requirement would significantly increase CapsoCam Colon's addressable market. There is no assurance that the FDA will permit this request or any future request to expand the indicated patient population for our CapsoCam Colon solution on a timely basis or at all. Any such request would involve significant effort and require, among other things, related regulatory submissions and our conducting non-clinical and clinical studies to generate data and evidence to support the request;

- continued enhancements and improvements to our CapsoCam Colon solution to increase its accuracy (measured in terms of polyp-detection sensitivity and specificity) and benefits of using CapsoCam Colon to visualize the colon and detect and measure polyps. Our success in implementing these enhancements and improvements (including obtaining related FDA 510(k) and EU clearances) is critical to (i) our initial and ongoing commercialization efforts (including efforts to increase provider and patient acceptance of our solution); (ii) our ability to increase CapsoCam Colon's indicated patient populations; and (iii) consequently, increasing that portion of the colorectal cancer screening, surveillance, and diagnostic patient populations for which our CapsoCam Colon may be used. We may be unable to successfully

make continued enhancements and improvements to sufficiently increase the accuracy and benefits of using our CapsoCam Colon system on a timely basis or at all; and

- achieving and maintaining a satisfactory and successful examination completion rate for capsule endoscopy using CapsoCam Colon. A successful completion rate for CapsoCam Colon endoscopies much lower than that for traditional colonoscopies may (i) limit the patient population for whom CapsoCam Colon is deemed appropriate; (ii) limit its acceptance by providers and patients; and (iii) result in an unacceptable number of patients requiring a follow-on colonoscopy or other diagnostic test to confirm that they lack significant colon polyps or do not have cancer. A successful colon capsule endoscopy involves successful imaging of either (i) a patient's entire colon without detecting significant polyps or (ii) a sufficient portion of the patient's colon to identify the presence of one or more significant polyps (i.e., indicating preventative or treatment driven colonoscopy is recommended). Capsule colonoscopy procedures are unsuccessful most often due to inadequate bowel preparation and/or slow capsule transit through the colon. CapsoCam Colon's successful completion rate (as demonstrated in our pivotal study) is supported by a physical design that encourages timely transit the GI-tract and a battery lifetime that is currently twice the competition's. However, the bowel preparation, which is similar to that used for colonoscopy, produces a level of cleansing that is patient specific, and capsule endoscopy does not afford an opportunity, as colonoscopy does, for targeted additional cleansing by the physician during the exam. Although we are positioned to benefit from improvements in bowel preparation medications on the market, these developments are outside our business and difficult to predict.

We may be unable to timely and effectively drive broad provider and patient adoption of our CapsoCam Colon solution (once cleared) and grow related revenue. Each of the above activities is subject to numerous risks described above or elsewhere in this "Risk Factors" section.

Our longer term efforts to expand our GI-tract capsule endoscopy solutions beyond small bowel and colon pathologies and medical conditions may not succeed.

We believe our CapsoCam Plus (small bowel) and CapsoCam Colon solutions, incorporating our panoramic imaging solution, can be adapted to address new GI medical indications. In connection with our efforts to address pancreatic cancer, we submitted an FDA "Breakthrough Device Designation" for our capsule endoscopy solution on November 6, 2025. A response from FDA in January 2026 determined that the CapsoCam UGI does allow for visualization of the papilla and its abnormalities, for both pre-cancerous and cancerous lesions. Due to the fact that the device does not specifically define diagnostic criteria, the application was not approved. Following the FDA's response, we initiated a study for early pancreatic cancer detection using the CapsoCam UGI system in May 2026. This study will build on established scientific literature and engage leading opinion leaders, including leadership of leading societies in the pancreatobiliary field, to define malignancy diagnosis criteria with the device. This study is expected to enroll up to 140 patients using the CapsoCam UGI system. As of the date of this Quarterly Report, three patients have been enrolled in this study The study continues and we are working on the expansion of a number of clinical sites participating in the study. We expect to resubmit the Breakthrough Device Designation application following the study, when additional data is available. The breakthrough designation is a part of the on-going project, potentially supplementing the regulatory pathway and approval for early pancreas cancer detection. However, additional research and studies to collect data may delay our anticipated timeline for obtaining the regulatory clearance (including obtaining the Breakthrough Device Designation) and may result in an increase in our research and development expenditures that exceed our current expectations and there can be no assurance that our reshaped strategy will be successful. A Breakthrough Device Designation prioritizes a device in the FDA's review queue for all future regulatory submissions and accelerates communications (i.e., negotiations and feedback) with the FDA, thereby expediting the marketing application process. However, our proposed capsule endoscopy solution may not meet the eligibility requirements for this 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.

We face significant competition in the capsule endoscopy market for our current and planned medical conditions. Our success in expanding our capsule endoscopy solution is contingent upon our ability to execute on our related

strategies, differentiate our technology with initial or improved product accuracy (such as sensitivity and specificity) and features, and secure acceptance in the GI medical community. Any failure in these areas could significantly impede our growth prospects and adversely affect our financial performance. There is no assurance that our efforts will yield successful outcomes in addressing pancreatic cancer, esophageal medical conditions or other targeted medical conditions.

Any failure or defect in our GI-tract capsule endoscopy solution could harm our reputation, expose us to liability, and reduce our sales.

Our GI-tract capsule endoscopy solution comprises our CapsoCam capsules and the associated software (CapsoCloud and CapsoView), including their related components. We may encounter technical, operational, or regulatory challenges or limitations in developing, testing, validating, or implementing improvements to our GI-tract capsule endoscopy solution, which could delay or prevent us from achieving our desired outcomes. Moreover, related components (including the lens module, image sensor, processor and storage module) and incorporated AI technology may fail or malfunction due to defects, errors, bugs, viruses, cyberattacks, or other causes, which could compromise the quality, accuracy, or reliability of our products and the images and analyses they produce. Any failure or defect in our GI-tract capsule endoscopy solution (including capsule components and the associated software, CapsoCloud and CapsoView) could harm our reputation, expose us to liability, and reduce our sales. Any of these outcomes could have a material adverse effect on our business, financial condition, and results of operations.

We face substantial geopolitical and trade risks (including a possible trade war and imposition of tariffs and supply chain interruptions) and natural disaster risks associated with our business operations in Asia (particularly Taiwan and Japan).

We face substantial geopolitical risks due to our business operations in Asia (particularly Taiwan and Japan). Our major assembly manufacturers are located in Taiwan. Most of our single-source suppliers of critical components of our products are located primarily in Taiwan and Japan. Political events, trade and other international disputes, geopolitical tensions, conflict, terrorism, public health issues, industrial accidents and other business interruptions in these areas can have a material adverse effect on our business operations. Restrictions on international trade, such as tariffs and other controls on imports or exports of goods, technology or data, can materially adversely affect our business and supply chain. Restrictive measures can increase the cost of our products, and can require us to take various actions, including changing suppliers and restructuring our supply chain, business relationships and operations. Changing our business and supply chain in accordance with new or changed restrictions on international trade can be expensive, time-consuming and disruptive to our operations. Such restrictions can be announced with little or no advance notice, which can create uncertainty, and we may not be able to effectively mitigate all adverse impacts from such measures. For example, an increase in the recent tensions between mainland China and Taiwan and the possibility of instability and uncertainty caused by prolonged or regular military drills in the Taiwan Strait may result in disruptions in the overall trading environment, and in turn result in higher transportation cost and interruption in delivery of our products or its critical components from our single-source suppliers in Taiwan, adversely affecting our business and financial condition. For additional information on other geopolitical and trade risks, see the risk factor titled “Changes to U.S. tariff measures and other political changes in international trade relations implemented by the U.S. could have a material adverse effect on our business, financial condition, cash flows and results of operations” below.

In addition to political risks, Taiwan and Japan are susceptible to natural disasters, such as earthquakes and typhoons, that could disrupt the normal operations of our business and adversely affect earnings. There can be no assurance that future natural disasters will not occur and result in major damages to our component suppliers and assembly manufacturers (many of whom are single-source and located in Taiwan and Japan), which could have a material adverse effect on our business, financial condition and results of operations.

We may face expansion risks when expanding in existing and entering into new foreign markets.

Our growth strategy includes increasing our international revenues and potential entry into new international markets (including through qualified exclusive distributors in targeted regions). In the nine months ended September 30, 2026 and 2025, international sales accounted for approximately 25% and 23% of our revenue, respectively. Our largest international shipping destinations in the nine months ended September 30, 2026 include France, Germany and Colombia. Some of our existing and new international markets may be highly regulated and competitive. However, we may face significant challenges and risks in expanding in existing and entering into new international markets (including risks related to expanding our market share and customer base), such as the following:

- The need to grow our sales and marketing team (including potentially through qualified distributors) in these markets.
- The need to comply with complex and evolving regulatory requirements, quality standards, and post-market surveillance obligations, which may entail significant time, cost, and resources, and may subject us to regulatory actions, penalties, or product recalls if we fail to meet them.
- The need to compete with established and emerging players in the capsule endoscopy market, which may have greater financial capabilities, brand recognition, market access, distribution networks, or technological capabilities, and which may offer lower prices, superior features, or better customer service.
- The need to secure adequate reimbursement and coverage policies from public and private payers, which may affect the affordability, accessibility, and adoption of our CapsoCam capsule endoscopy solution, and which may be subject to changes, limitations, or uncertainties due to budget constraints, policy reforms, or competitive pressures.

We may fail to successfully execute on our growth strategy, overcome these challenges and risks, or achieve our expected returns on our investments in these foreign markets. In addition, we may encounter unforeseen difficulties or liabilities related to our operations, supply chain, intellectual property, or litigation in these foreign markets. Any of these factors could negatively impact our sales, margins, reputation, or market position in new foreign markets, and as a result, our business, results of operations and financial condition.

The clinical results of our various clinical studies (including those for our CapsoCam Colon capsule) may not be released in any peer-reviewed publications.

On June 10, 2025, we submitted the results of the first arm of our pivotal study for CapsoCam Colon to the FDA as part of an initial 510(k) clearance submission for our “first generation” product. We received responses from the FDA in September 2025. During our meeting with the FDA in December 2025, the FDA raised inquiries on topics including panoramic image processing methodology, and the proposed study design, sample size and primary endpoint for an extended study. Based on our communications with the FDA, we have decided not to further pursue the first generation CapsoCam Colon capsule submission and approval, and to prioritize our resources for the development of our second generation CapsoCam Colon capsule, featuring improved imaging quality and increased field of review with use of AI and better lens.

From time to time, we may publicly disclose interim, top-line or preliminary data from our pivotal studies, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the pivotal study or additional data collected at a later time. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. The data from a study may not be released in any peer-reviewed publication, either initially or in the future. As a result, the interim, top-line, or preliminary results that we report may differ from future results of the same trial, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. The FDA may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of our study (including our CapsoCam Colon pivotal study), or potential for the regulatory approval or for commercialization.

We do not plan to release the clinical results from our various clinical studies (including the second arm of our CapsoCam Colon clinical study and our CapsoCam Plus clinical study (AI)) before submitting, as applicable, the related 510(k) clearance submission to the FDA. Typically, the submission of study results for publication in a peer-reviewed journal occurs after its use for an FDA submission. The initial or future absence of peer-reviewed research could hinder the acceptance of our GI-tract capsule endoscopy solution products within the medical community, potentially affecting its credibility and market adoption.

Furthermore, the results of the utilization of our GI-tract capsule endoscopy solution (including CapsoCam Colon) may not be accepted or replicated by the scientific or medical community, or may be challenged or disputed by our competitors or other third parties. Physicians and third-party payors may be skeptical of new technologies and may require substantial evidence of clinical efficacy and cost-effectiveness before adopting new products. If the results of our research and clinical studies and our sales and marketing activities relating to communication of these results do not convince thought-leading gastroenterologists, guidelines organizations, primary care physicians, third-party payors, and patients that our GI-tract capsule endoscopy solution (including CapsoCam Colon) is reliable, effective, and superior to existing screening methods, we may not achieve the necessary market acceptance. The publication of negative or inconclusive results, or the emergence of new or conflicting data, could undermine the validity or reliability of our study and our GI-tract capsule endoscopy solution, and could reduce the demand for or acceptance of our CapsoCam capsules by physicians, patients, payors, or other stakeholders. Any of these outcomes could have a material adverse effect on our business, financial condition, and results of operations.

We operate in a highly competitive industry, and competitive pressures could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We operate in a highly competitive industry, and competitive pressures could have a material adverse effect on our business, financial condition, results of operations, and prospects. The medical device market, particularly in the area of diagnostic imaging and endoscopic procedures, is characterized by rapid technological advancements and the continuous introduction of new products.

The competition that we face for our small bowel CapsoCam Plus is primarily from traditional enteroscopy procedures performed by trained physicians in hospital or clinical settings and other capsule-based imaging solutions manufactured by companies such as Medtronic, IntroMedic, JinShan and Ankon. Those competitors include well-established companies with significant resources and brand recognition such as Medtronic, that are constantly developing and marketing innovative products that may offer superior features or lower costs. With respect to Medtronic, it also enjoys other competitive advantages including (i) a “first mover advantage” as the first manufacturer of a small bowel capsule endoscopy and a colon capsule endoscopy (as described below); (ii) exclusive supply arrangements (sometimes up to three years) with some of the larger GI practices and hospitals (particularly in the Northeast region of the U.S.) which our sales team also targets; and (iii) greater brand recognition and financial resources.

Notably, one competitor, Ankon (through its affiliate AnX Robotics), has already established a market presence with their FDA-cleared AI product for the small bowel in the U.S. and various other markets outside the U.S. This puts us at a market disadvantage until we can launch our own AI product for the small bowel post the clearance from the FDA of our AI Highlights™, its AI-assisted reading feature for the CapsoCam Plus® system, obtained in September 2026. The commercialization began in the US on November 2, 2026. The delay in our product launch could result in a loss of market share and reduced revenue opportunities, as potential customers may opt for the already available and proven solutions from our competitors. Additionally, the competitive landscape is further impacted by the pricing strategies of Asia-based capsule endoscopy companies, such as Ankon (China), Jinshan (China) and IntroMedic (South Korea), who are offering their products at lower than average prices. This aggressive pricing approach could pressure us to lower our prices to remain competitive, potentially impacting our profit margins.

The competition that we face for CapsoCam Colon is primarily from (i) procedure-based detection technologies such as optical colonoscopy, flexible sigmoidoscopy and CTC (or “virtual” colonoscopy); (ii) stool- based DNA

tests such as Cologuard (initial FDA clearance in 2014); and (iii) other capsule-based imaging solutions like PillCam COLON 2 (initial FDA clearance in 2014). Other sources of competition include (a) common CRC screening tests, such as the fecal occult blood test ("FOBT") and the fecal immunochemical test ("FIT"), and (b) screening technologies including liquid biopsy tests, such as Epi proColon (FDA approval in 2016) and C-Scan (CE Mark obtained in 2019). Those competitors include well-established companies with significant resources and brand recognition such as Medtronic, that are constantly developing and marketing innovative products that may offer superior features or lower costs. For instance, the Medtronic PillCam COLON 2 is the only U.S. FDA approved colon capsule endoscopy and is prominent in the market outside the U.S.

The combination of these factors could significantly affect our ability to attract and retain customers, thereby adversely impacting our overall business performance and future growth prospects.

Cost-containment efforts of our customers and purchasing groups could have a material adverse effect on our sales and results of operations. Consolidation in the healthcare industry or group purchasing organizations could lead to demands for price concessions, which may affect our ability to sell our products at prices necessary to support our current business strategies.

The cost-containment efforts of our customers and integrated group purchasing organizations ("GPOs") have a material adverse effect on our sales and results of operations. In the United States, many clinics and hospitals, including some of our customers, are members of the GPOs, which are organizations that leverage the collective purchasing power of their members, such as hospitals, clinics, and other healthcare providers, to negotiate favorable pricing and terms for medical products and services. These entities negotiate pricing arrangements with medical device companies and distributors, offering these negotiated prices to affiliated hospitals and other members. GPOs typically award contracts on a category-by-category basis through a competitive bidding process, soliciting bids from multiple providers to drive down pricing or reduce the number of vendors. Due to the highly competitive nature of these contracting processes, we may face challenges in obtaining new or maintaining existing contract positions with major GPOs. The increasing leverage of the GPOs may reduce market prices for our products, thereby impacting our revenue and margins.

While securing a contract with a GPO can facilitate sales to their members and enhance our ability to meet the stringent requirements set by their members, it does not guarantee any level of sales, as purchases are typically made through individual purchase orders. Even as a sole contracted supplier for a certain product category, members of the GPO are generally free to purchase from other suppliers. Consequently, members of the GPOs may opt for alternative products based on price or quality offered by other companies, potentially leading to a decline in our sales volumes and revenue.

The rising healthcare costs over the past decade have led to numerous cost reform initiatives by legislators, regulators, and third-party payors, triggering a consolidation trend in the healthcare industry to aggregate purchasing power. This trend may result in more requests for pricing concessions in the future. We anticipate that market demand, government regulation, third-party coverage and reimbursement policies, and societal pressures will continue to evolve the healthcare industry, leading to further business consolidations and alliances among our customers. These changes may exert additional downward pressure on the prices of our products, affecting our results of operations and our ability to support our current business strategies.

The effectiveness of our CapsoCam capsules heavily relies on patients adhering to our use protocols. Other companies or institutions may develop and market novel or improved methods that may make our technologies less competitive or obsolete.

The effectiveness of our CapsoCam capsule endoscopy relies on patients adhering to proper dietary restriction and bowel cleansing protocols prior to the screening procedure. Inadequate preparation can result in suboptimal imaging, which may lead to missed screenings and diagnoses or the need for repeat procedures or alternative procedure such as colonoscopy. This dependence on patient compliance introduces a variable that is beyond our direct control, potentially impacting the reliability and accuracy of our diagnostic results. If patients do not follow

the prescribed fasting and cleansing regimen, the performance of our CapsoCam capsules may be compromised, leading to decreased diagnostic accuracy and patient dissatisfaction.

The use of our CapsoCam capsule also requires manual retrieval of the capsule by the patient, who must send it back to our download center for data collection and analysis. This manual retrieval process, while designed to be as convenient as possible, may not meet the expectations of all patients and could lead to potential errors as patients are required to diligently monitor their bowel movements to ensure the capsule is retrieved, which may be inconvenient and burdensome for them. The capsules are transported by shipping companies. There have been instances where the shipping company has either lost or damaged the capsules, leading to the loss of critical patient data. This compromises the integrity of the patient data and disrupts the entire procedure.

If other companies or institutions develop or market methods that do not require fasting or bowel cleansing or require less stringent preparation, our products may become less attractive to patients. For example, non-invasive stool-based DNA tests generally require no specific dietary restrictions or bowel preparation and enable patients to collect a stool sample at home using the provided kit and send it to the lab for analysis. Such test may be more attractive to low-risk or average-risk patients who require more convenient options for GI-tract screening. Also, recent advancements in medical research have opened up new possibilities for early detection and screening of colorectal cancer by leveraging key metabolites and early diagnostic biomarkers. Advances in technology or alternative screening methods that eliminate or reduce the need for fasting or bowel cleansing could provide a more convenient and patient-friendly option, potentially making our CapsoCam capsules less competitive. Should such alternatives gain acceptance in the market, we may experience a decline in demand for our products, which could materially and adversely affect our business, financial condition, and results of operations. Additionally, our ability to compete effectively may be further challenged if these new methods are protected by patents or other intellectual property rights that we cannot circumvent.

There are risks associated with use of our CapsoCam capsules, including capsule retention, component failures and aspiration.

Our CapsoCam capsule endoscopy is generally a safe procedure providing non-invasive visualization of the entire small bowel and colon (once cleared). However, there are risks associated with this procedure, including capsule retention, component failures and, in rare cases, aspiration.

For the three months ended September 30, 2026, we recorded a provider complaint rate of approximately 2.5% (based on number of capsules sold in such period). For 2025, we recorded a provider complaint rate of approximately 2.5% (based on number of capsules sold in 2025). The bulk of recorded complaints related to patient failure to (i) timely retrieve the capsule following completion of the procedure and (ii) enter the correct serial number or use the correct shipping label when returning the capsule for download. Although small, these failures indicate potential issues with the usability or clarity of instructions provided to patients by providers or us and shipment and inventory management issues. These issues, in turn, can significantly impact customer and patient satisfaction and our reputation and potential sales.

Capsule retention by a patient refers to the capsule getting stuck in the GI tract, which can occur due to various reasons such as strictures, tumors, or inflammatory bowel diseases. We believe the industry retention rate may be as high as 2%. Based on (i) incidences reported to us for all CapsoCam capsule patients in the three months ended September 30, 2026, and (ii) total CapsoCam capsules sold by us in the same period, retention rate was less than 1/10 of 1%. However, we believe our retention rate is understated due to (i) underreporting by providers and patients and, relatedly, (ii) the fact that most retained capsules are eventually excreted without the need for invasive intervention and medication may be used to encourage this process. In some instances, endoscopic retrieval or surgical intervention may be necessary to remove the retained capsule. Aspiration is rare but potentially fatal where the capsule is accidentally inhaled into the respiratory tract instead of being swallowed into the esophagus. For the three months ended September 30, 2026, there was no complaint regarding an aspiration incident involving a CapsoCam capsule.

While we strive to ensure the highest safety standards and patient experience for our CapsoCam capsule, we cannot guarantee that it is entirely free of safety issues, component failures or errors. Despite rigorous testing and quality control measures, unforeseen complications may arise during the use of our GI-tract capsule endoscopy solution. These could include, but are not limited to, adverse reactions, product malfunction, or unforeseen interactions with the patient's medical condition.

We may need additional capital to execute our business plan, and we may be unable to raise additional capital on acceptable terms.

Executing our business plan will require additional capital. We may need to raise funds to support research and development, and expand our sales and marketing efforts, including to advance clinical studies and pursue regulatory clearances for new or next-generation product pipeline. The scope, cost, timeline of these clinical development efforts are inherently uncertain, there can be no assurance that such efforts will yield successful outcomes or that the capital resources required to fund them will not exceed our current expectations. If we are unable to raise additional capital on acceptable terms, we may not be able to implement our business plan effectively, which could adversely affect our growth prospects and financial condition, including advancing our new-generation product pipeline. Furthermore, market conditions and other factors outside our control could make it difficult to raise capital when needed. If we are unable to secure additional financing, we may have to delay, reduce, or eliminate certain aspects of our business plan, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our existing sales and marketing team may face challenges in selling additional products and features added to our GI-tract capsule endoscopy solution.

We may face unique challenges in leveraging our existing sales channels to sell and market product and service additions to our GI-tract capsule endoscopy solution (including CapsoCam Colon once cleared). For example, the primary difference between small-bowel and colon diagnostic visualization lies in their distinct medical purposes, preparation requirements, and market dynamics. A small bowel capsule endoscopy is typically conducted to diagnose conditions such as OGIB, Crohn's disease, or small bowel tumors and a different cleansing preparation compared to a colon capsule endoscopy which requires more rigorous bowel preparation. Additionally, the market for colorectal cancer screening is highly competitive, with established products such as traditional colonoscopies, other imaging technologies (mainly CT colonography and to a decreasing extent sigmoidoscopy) and stool-based screening products already in widespread use. These and other procedure and market differences and dynamics will require additional sales force training and may necessitate tailored marketing strategies and sales approaches, which could complicate our efforts to utilize our current sales teams for products beyond small bowel.

The success of our business is substantially dependent upon the efforts of our senior management team and certain other key personnel and our ability to retain these individuals and to attract additional key personnel.

Our success depends in large part on our ability to attract and retain managerial and key personnel, including our senior executive officers and various highly skilled employees. If we were to lose any of our senior management team or these key personnel, we may experience difficulties in competing effectively, developing our technologies, and implementing our business strategies. Competition for desirable personnel is intense, and there can be no assurance that we will be able to attract and retain the necessary staff. The failure to maintain management or to attract sales and key personnel as we move towards the commercialization of our CapsoCam capsules could materially adversely affect our business, financial condition, and results of operations.

Macroeconomic conditions could materially adversely affect our business, financial condition, results of operations, and prospects.

Macroeconomic conditions, such as high inflationary pressure, potential military conflicts, possible trade wars, introduction of or changes in tariffs or trade barriers, changes to monetary policy, high interest rates, volatile currency exchange rates, credit and debt concerns, decreasing consumer confidence and spending, including

capital spending, concerns about the stability and liquidity of certain financial institutions, and global recessions can adversely impact demand for our products, which could negatively impact our business, financial condition, results of operations, and prospects. Recent macroeconomic conditions have been adversely impacted by geopolitical instability and military hostilities in multiple geographies and monetary and financial uncertainties.

The impacts of these macroeconomic conditions, and the actions taken by governments, central banks, companies, and consumers in response, have resulted in, and may continue to result in, higher inflation in the United States and globally, which is likely, in turn, to lead to an increase in costs and may cause changes in fiscal and monetary policy, including additional increases in interest rates. Other adverse impacts of recent macroeconomic conditions have been, and may continue to be, supply chain constraints, logistics challenges, liquidity concerns in the broader financial services industry, and fluctuations in labor availability. In a higher inflationary environment, we may be unable to raise the prices of our products sufficiently to keep up with the rate of inflation.

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations, financial condition and results of operations.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market-wide liquidity problems. We are exposed to concentrations of credit risk through our financial instruments, which primarily include demand deposits held at reputable financial institutions and accounts receivable. These financial instruments are subject to potential credit risk, as we rely on the financial stability and creditworthiness of these institutions and its customers. While we take measures to mitigate these risks, such as conducting thorough credit evaluations and maintaining relationships with well-established financial institutions, there remains an inherent risk of financial loss if these counterparties fail to meet their obligations.

Additionally, our cash deposits may occasionally exceed the limits insured by the U.S. Federal Deposit Insurance Corporation. This situation can arise during periods of high cash flow or when large payments are received. When cash deposits exceed FDIC insurance limits, we are exposed to the risk of loss in the event of a bank failure. Although we strive to manage this risk by spreading out our cash deposits in accounts with multiple reputable and financially stable banks, the potential for uninsured losses remains a significant risk factor that could adversely impact our financial position and operational stability.

Shutdowns of the U.S. federal government could materially adversely affect our business, financial condition, results of operations, and prospects.

The U.S. federal government has shut down multiple times in the past, and certain regulatory agencies, including the FDA, the CMS, the U.S. International Trade Commission, the U.S. Patent and Trademark Office (“USPTO”), the U.S. Department of Defense, and the U.S. Department of Veterans Affairs, have had to furlough employees and suspend some of their activities. A prolonged shutdown could delay regulatory reviews and approvals, litigation proceedings, or government program implementations and could ultimately disrupt or delay our research and development, manufacturing, commercialization, or intellectual property enforcement activities. Any such delays or disruptions could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risk Related to Regulatory Matters

We may not obtain or may experience delays in obtaining 510(k) clearance for our planned second generation of our CapsoCam Colon solution (with improved optics and other components), which would adversely impact our ability to commercialize this product and generate related revenue.

The 510(k) application process can be lengthy. There is no guarantee that the FDA will grant 510(k) clearance for our planned second generation CapsoCam Colon capsule endoscopy solution, and their timeline for doing so may not align with our planned commercialization schedule. Staff reductions in the FDA office charged with regulating

devices may also cause delay. Similar consequences may result in the case of events which affect FDA operations, such as a federal government shutdown.

Although our CapsoCam Plus solution, which visualizes the small bowel, has been cleared by the FDA, the CapsoCam Colon capsule endoscopy solution will require a distinct, unrelated regulatory submission, as it is subject to different statutory requirements. This is due to its use in the colon (part of the lower GI-tract) and incorporation of new capabilities (including AI assisted pathology detection technology) to facilitate visualization of the colon and to identify and measure polyps, each of which introduces different safety and effectiveness considerations. As a part of the marketing submission review, the FDA may require additional analysis, data, studies, or modifications to our products or labeling, which could increase our costs, delay our launch, or limit our market opportunity. The FDA may also require other conditions on our products to achieve initial clearance, such as additional studies or clinical trials, labeling restrictions, or post-market surveillance commitments, which could increase our regulatory burden and liability. Risks related to the separate FDA clearance of the AI assisted pathology detection technology incorporated in our CapsoCam Colon capsule endoscopy solution and of updates to our previously cleared AI technology are discussed in the risk factor titled “We may face regulatory challenges and delays in obtaining 510(k) clearance for marketing of those CapsoCam capsules incorporating our self-developed AI technology, including our CapsoCam Colon capsule endoscopy solution and for updates to our previously cleared AI technology below.

The FDA is required by statute to review 510(k) applications within defined timelines. For most 510(k) submissions, a 90-day maximum review period is mandated. While this requirement provides predictability for the review process, it also places constraints on available opportunities to address any questions posed by FDA. Factors critical to a timely review and clearance of our 510(k) applications include (i) the quality of our regulatory submission (including both in terms of clarity in presentation and the supportiveness of data) and (ii) the availability of qualified FDA review resources (i.e., individuals possessing relevant technical understanding and requiring a minimal “learning curve”). Although we have (x) engaged with the FDA in early communications (including several pre-submission meetings) regarding our CapsoCam Colon solution and (y) considered FDA feedback during product development, there is no guarantee that the FDA staff members involved in those discussions and/or who are familiar with the CapsoCam technology will be available to participate in the post-submission review of our 510(k) application. The involvement of less experienced FDA staff members may result in a “learning curve” potentially reducing the effective time available to the FDA to critically review our submissions. Likewise, changes in review staff levels or workload—possibly due to changes in FDA funding or operations, including as a result of a government shutdown, or the emergence of competing public health priorities (e.g., addressing a device shortage) may lead to review delay and an inability to complete the FDA review process within the statutorily mandated period, potentially leading to a longer review process for our applications.

Failure to obtain or delays in obtaining 510(k) clearance for our CapsoCam Colon capsule endoscopy solution could result in additional costs or liabilities and adversely impact our reputation, ability to sell our CapsoCam Plus capsule endoscopy solution, and our ability to compete effectively in this or other markets. Any of these outcomes could have a material adverse effect on our business, financial condition, and results of operations.

Our ability to capture the market opportunity for our GI-tract capsule endoscopy solution depends on several factors, including the following:

- acceptance in the GI medical community;
- the number of patients screened or tested for specific pathology or medical indication and the number of patients who use our CapsoCam capsules for that purpose;
- our ability to introduce enhancements and improvements aimed at increasing the value provided by our GI-tract capsule endoscopy solution;

- our ability to develop and commercialize our CapsoCam capsule endoscopy solution for new indications, patient populations and clinical use cases;

- our ability to successfully complete any required clinical or other studies and obtain and maintain any required regulatory approval or clearances;

- insurer and third-party reimbursement of the costs associated with our GI-tract capsule endoscopy solution (which may be adversely impacted by U.S. governmental budgetary and cost-cutting activity);

- successful management of our global supply chain including our component suppliers and assembly manufacturers for our CapsoCam solution, many of which are located in Asia (particularly Taiwan and Japan) and some of which are currently single-source suppliers;

- successful growth and leveraging of our global sales team (including, where appropriate, distributors) and marketing team to sell and market our GI-tract capsule endoscopy solution; and

- the amount and nature of competition from other GI-tract diagnostic products or procedures.

Our failure to effectively manage our business through the various challenges we face, may result in an inability to execute on our business plan and revenue growth strategies, respond to competitive pressures, take advantage of market opportunities, satisfy customer requirements, or maintain high-quality products, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may face regulatory challenges and delays in obtaining 510(k) clearance for marketing of those CapsoCam capsules incorporating our self-developed AI technology, including our CapsoCam Colon capsule endoscopy solution and for updates to our previously cleared AI technology.

On June 10, 2025, we submitted to the FDA the clinical results of the first arm of our CapsoCam Colon pivotal study in a related 510(k) submission and it has been accepted for review. This submission seeks FDA clearance of our initial CapsoCam Colon capsule endoscopy solution which incorporates our self-developed AI technology. Following our decision not to further pursue the first generation CapsoCam Colon capsule submission and approval, and to prioritize our resources for the development of our second generation CapsoCam Colon capsule, the second generation also features improved imaging quality and increased field of review with use of AI and better lens. Our 510(k) submissions and FDA review thereof may be delayed and we may not receive 510(k) clearances from the FDA on a timely basis or at all.

The incorporation of AI technology into our GI-tract capsule endoscopy solution (including the associated software products, CapsoCloud and CapsoView) requires appropriate FDA regulatory authorization, supported by requisite clinical and other studies, prior to its commercialization in the U.S. Under the FDA's current regulatory framework, our capsule endoscopy solution and the AI technology are assessed separately, with each component falling under a different regulatory classification and subject to distinct regulatory requirements. This bifurcated approach, set by precedent, ensures that each component meets the necessary safety, effectiveness, and performance expectations.

In the case of CapsoCam Colon, as of the date of this Quarterly Report on Form 10-Q, the FDA has only authorized one colon capsule imaging system, the Medtronic PillCam COLON 2, introduced in 2014, which does not include any AI-driven analytics; and one AI-driven capsule endoscopy analysis software, the AnX Robotics NaviCam ProScan, introduced in 2023, which exclusively supports AnX Robotics' small bowel capsule system. These devices respectively serve as predicate devices for our planned second generation CapsoCam Colon 510(k) submission. In particular, to receive FDA clearance for our second generation CapsoCam Colon, the clinical results must demonstrate that:

- CapsoCam Colon, considered without the integration of AI, demonstrates a polyp-detection accuracy that is, at a minimum, comparable to the performance of the predicate device (i.e., Medtronic PillCam COLON 2); and

- our AI technology can (i) reliably and accurately identify and analyze images and video of the colon to detect abnormalities as quantified by diagnostic accuracy measures such as sensitivity and specificity, and, in doing so, (ii) aid qualified physicians in achieving improved diagnostic performance relative to not using AI.

Clearance of the incorporated AI technology is unlikely to occur if the CapsoCam Colon solution, absent AI, fails to meet the applicable regulatory requirements. In connection with FDA clearance of our planned second generation of CapsoCam Colon, which will incorporate various hardware and image processing improvements, we will need to demonstrate that the incorporated AI technology is not compromised by these modifications.

The FDA may not agree that our AI technology meets these evidentiary requirements, or it may require us to submit additional data or information over the course of regulatory review to support the safety and effectiveness of CapsoCam Colon (including the incorporated AI technology). Also, the FDA may determine that CapsoCam Colon (including the incorporated AI technology) is not eligible for the 510(k) pathway and that we must utilize a different, more rigorous and costly regulatory pathway, such as a PMA or a De Novo request, which could significantly delay our ability to market CapsoCam Colon (including the incorporated AI technology), increase our development costs and reduce our competitive advantage. The FDA recognizes that there are challenges within the current regulatory framework for medical devices incorporating artificial intelligence and is actively pursuing regulatory reforms to better foster innovation while maintaining patient safety. We proactively monitor new FDA policies and programs and will update our regulatory strategy to reduce regulatory uncertainty and burden where applicable.

In seeking 510(k) clearance for AI Highlights™, our AI-assisted reading feature for the CapsoCam Plus® system, we (i) utilized the NaviCam ProScan as the predicate device (confirmed with the FDA) and (ii) conducted a retrospective clinical study of the CapsoCam Plus solution with the AI technology incorporated to analyze in vivo videos from completed, real-world clinical cases, to assess the performance of the AI technology for small bowel. AI Highlights™ received FDA clearance on September 25, 2026. Its commercialization began in the US on November 2, 2026.

These regulatory considerations may apply to updates or improvements to previously cleared AI technology, such as major changes in algorithm design, significant changes in clinical performance, or the addition of new functions (e.g., detection of new types of abnormalities). In these scenarios, we will be expected to demonstrate the safety and performance of the updated technology through the appropriate studies and pursue regulatory clearance through additional FDA filings prior to commercial distribution. Also, changes to the device hardware or imaging processing methods contained in CapsoCam capsules incorporating our AI technology may affect the performance of the incorporated AI technology, even if the related algorithm is not directly changed. As a result, we may be required to demonstrate that performance of the incorporated AI technology is not degraded by those critical capsule component changes and obtain regulatory clearance prior to distribution.

If Medicare and other third-party payors, including managed care organizations, do not approve reimbursement for our products at adequate reimbursement rates, we may be unable to successfully commercialize our products which would likely have a material adverse effect on our business.

Our ability to increase sales of our products depends, in significant part, on the availability of adequate coverage and reimbursement from third-party payers, including governmental payers, managed care organizations, and private health insurers. If Medicare and other third-party payors do not approve reimbursement for our CapsoCam capsules at adequate reimbursement rates, we may be unable to successfully commercialize our products which would have a material adverse effect on our business.

In particular, we believe that obtaining a positive national coverage decision and favorable reimbursement rate from the Centers for Medicare and Medicaid Services ("CMS") for our CapsoCam capsules will be a necessary element in achieving material commercial success. These third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new healthcare products approved for marketing by the FDA. As a result, there is significant uncertainty surrounding whether the use of capsules will be eligible for coverage by third-party payors or, if eligible for coverage, what the reimbursement rates will be for those products.

CMS currently reimburses properly submitted reimbursement claims for most capsule endoscopies utilizing our small bowel CapsoCam Plus capsule. For CapsoCam Colon, we expect to qualify for CMS reimbursement for our initial indicated patient population. CMS currently provides reimbursement for capsule endoscopy procedures for patients with major risks for colonoscopy or moderate sedation with evidence of GI bleeding of lower GI origin and patients who have had an incomplete colonoscopy with adequate preparation. As a part of our 510(k) FDA application for our second generation CapsoCam Colon capsule and to increase the population of indicated patients, we intend to seek FDA clearance of expanded indications that remove the requirement for evidence of GI bleeding of lower GI origin for patients with major risks for colonoscopy or moderate sedation. Successfully growing our CapsoCam Colon revenues will depend on our success in timely securing CMS reimbursement for this and any newly indicated patient population.

Reimbursement of capsule endoscopy by a third-party payor may depend on a number of factors, including a payor's determination that products using our technologies are: effective for detecting or diagnosing gastrointestinal disorders; not experimental or investigational; approved by the major guidelines organizations; reliable, safe and minimally invasive; medically necessary; appropriate for the specific patient; and cost-effective.

If we are unable to obtain positive policy decisions from third-party payors, including Medicare and managed care organizations, approving reimbursement for our CapsoCam capsules, including our CapsoCam Colon, at adequate levels, the commercial success of these products would be compromised and our revenues would be significantly limited. Moreover, coverage policies and reimbursement rates are subject to change and we cannot guarantee that even if we initially achieve adequate coverage and reimbursement rates that they will be applicable to our products in the future. Any failure to obtain or maintain favorable reimbursement could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we or our distributors fail to comply with regulatory requirements, we may be subject to stringent penalties and our business may be materially adversely affected.

The marketing and sale of our CapsoCam capsules are subject to various state, federal, and foreign regulations. Compliance with these regulatory requirements is essential to avoid significant penalties and ensure the continued commercialization of our products. However, the regulatory landscape is complex and constantly evolving, making it challenging to stay compliant. Any failure by us or our distributors to adhere to applicable regulations could result in substantial fines, sanctions, or other enforcement actions and damage to our reputation.

Healthcare policy changes and increased scrutiny of marketing practices in the medical device industry add another layer of risk. New regulations or changes to existing laws could impose additional burdens on our business, affecting our ability to operate effectively. Ensuring ongoing compliance with regulatory requirements is critical to maintaining our market position and avoiding adverse impacts on our business.

Healthcare policy and funding/budgetary changes could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In recent years, the healthcare industry in the United States has experienced significant legislative and regulatory changes aimed at reducing costs, increasing access to health insurance, and improving the overall efficiency of healthcare delivery. The Affordable Care Act (the "ACA") has been a cornerstone of these efforts, expanding health insurance coverage through public program expansion and private sector reforms. Additionally, the

American Rescue Plan Act and the Inflation Reduction Act have introduced enhanced subsidies to make health insurance more affordable. More recently, the One Big Beautiful Bill Act (the "OBBBA") was signed into law, which included significant reforms to Medicaid, including an estimated $1 trillion in reduced federal Medicaid spending from 2025 through 2034, the imposition of work requirements for certain adult enrollees, more frequent eligibility redeterminations and increased cost-sharing for beneficiaries. However, these changes bring uncertainty regarding the number of individuals who will obtain public or private health insurance and the scope of such coverage. This uncertainty can impact our business by potentially reducing the number of insured individuals or altering the scope of insurance coverage, which may affect our revenue streams and financial stability.

The ACA has been subject to continuous legislative, regulatory, and judicial challenges, creating an unpredictable environment for healthcare providers. Changes in the interpretation or implementation of the ACA could eliminate or modify provisions that are beneficial to our business while maintaining or introducing provisions that reduce our reimbursement rates or otherwise negatively impact our operations. For instance, if certain beneficial provisions are repealed or altered, we may face increased financial pressure due to reduced reimbursement rates or additional regulatory compliance costs. This uncertainty makes it challenging to plan for the future and could lead to financial instability if adverse changes are implemented.

Moreover, other health reform initiatives at both federal and state levels add another layer of complexity. These initiatives could result in funding and coverage reductions or decreased enrollment in Medicaid, further impacting our revenue. Additionally, recent reforms focused on price transparency and out-of-network charges, such as the No Surprises Act, may limit our ability to set and negotiate prices, affecting our relationships with insurers and patients. Further, the Trump administration has enacted several executive actions and the U.S. Congress is considering budget cuts that would adversely impact the U.S. federal government's budget and potential changes in budgetary priorities and spending levels (including those related to Medicare and Medicaid). Such pressures and uncertainty could (i) result in a reduction in the market opportunity and demand for our current or future pipeline products and (ii) adversely affect staffing levels and the funding for the FDA and as a result, prevent or delay marketing approval of our current or future pipeline products, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval, each of which may negatively impact our business. These factors collectively create a challenging environment that could adversely affect our financial condition, results of operations, and cash flows.

Changes to U.S. tariff measures and other potential changes in international trade relations implemented by the U.S. could have a material adverse effect on our business, financial condition, cash flows and results of operations.

Our supply chain is heavily reliant on products and components manufactured and assembled in various Asian countries (particularly Taiwan and Japan). These import operations are subject to tariff and other international trade regulations. When imported into the U.S., such products and components are subject to applicable rates of duty. The U.S. government has recently made statements and taken certain actions that have created significant uncertainty about the future relationship between the U.S. and various other countries, including Taiwan and Japan, with respect to trade policies, treaties, government regulations and tariffs, including implementing tariffs on certain countries and implementing and subsequently pausing such implementation of tariffs on certain other countries. As a result of these statements and actions, we are exposed to the risk of product supply disruption and increased costs and expenses. There continues to exist significant uncertainty about the future relationship between the U.S. and other countries with respect to such trade policies, treaties and tariffs. We cannot predict with certainty the future trade policy of the U.S. or other countries. We experienced an increase in customs and tariffs expenses as a result of the imposition of tariffs and keep evaluating measures that we might implement to address or mitigate the impact on our business. We cannot predict the likelihood, nature or extent of the potential impact or our ability to avoid the related adverse effects. Relevant factors include whether any additional tariffs are ultimately implemented, the timing and duration of implementation and the amount, scope and nature of such tariffs and potential exclusions from the application of those tariffs. These tariffs and other unfavorable government policies on international trade (such as export controls) may further increase the cost of manufacturing our commercialized products or developing our pipeline products, affect the demand for our products (if and once approved), or restrict our access to raw materials and components used in the manufacture

of our current products and the development of our future products, each of which could negatively impact our financial condition and results of operations. Further, such developments, or the perception that any such developments could occur, may have a material adverse effect on global economic conditions and the stability of global financial markets, and may have and could continue to significantly reduce global trade and, in particular, trade between the impacted nations and the U.S. Any of these factors could depress economic activity and adversely impact the price and demand for our products, increase our costs, and affect our customers and suppliers and have a material adverse effect on our business, financial condition and results of operations.

Changes in tax laws or tax rulings could adversely affect our effective tax rates, results of operations and financial condition.

The tax regimes we are subject to or operate under are unsettled and may be subject to significant change. This challenge will continue to increase as we expand our operations globally. Changes in tax laws, issuance of new tax rulings or changes in interpretations of existing laws could cause us to be subject to additional income-based taxes and non-income-based taxes, including payroll, sales, use, value-added, digital, net worth, property and goods and services taxes, which in turn could adversely affect our results of operations and financial condition. In particular, the U.S. government may enact significant changes to the taxation of business entities including, among others, an increase in the corporate income tax rate, the imposition of minimum taxes or surtaxes on certain types of income, significant changes to the taxation of income derived from international operations, and it may enact further limitations on the deductibility of business interest. For example, on August 16, 2022, the Inflation Reduction Act (the “IRA”) was signed into law in the U.S. Among other changes, the IRA, along with subsequent regulations, imposes a minimum tax on certain corporations with book income of at least $1 billion, subject to certain adjustments, and a 1% excise tax on certain stock buybacks and similar corporate actions. Furthermore, on July 4, 2025, the OBBB Act was enacted, introducing amendments to U.S. tax laws with various effective dates from 2025 to 2027, including changes to the treatment of research and development expenses under Section 174 of the Internal Revenue Code of 1986, as amended, modifications to the global intangible low-taxed income regime, new minimum or book-based taxes, and limitations on interest deductibility.

In addition, many countries in the European Union, as well as a number of other countries and organizations, have recently proposed or recommended changes to existing tax laws or have enacted new laws that could impact our tax obligations in the future. We are unable to predict what changes to the tax laws of the U.S. and other jurisdictions may be proposed or enacted in the future or what effect such changes would have on our business. Any of these or similar developments or changes to tax laws or rulings (which changes may have retroactive application) could adversely affect our effective tax rate and our results of operations and financial condition.

Our relationships with board-certified physicians are subject to various state laws and there is no assurance that our current practices will remain compliant.

We provide remote capsule endoscopy reading services through board-certified physicians to our customers with $230 and $211 thousand in revenue for the nine months ended September 30, 2026 and 2025, respectively. Our relationships with board-certified physicians are subject to various state laws including those with respect to physician licensing requirements. The interpretation and enforcement of these laws vary significantly across states, and there is no assurance that our current practices will remain compliant. If regulatory authorities determine that our arrangements with physicians violate these laws, we may be forced to restructure or terminate these relationships, leading to potential disciplinary actions, penalties, and a loss of revenue.

Our products must be manufactured in accordance with applicable laws and regulations, and we could be forced to recall our products or terminate production if we fail to comply with these regulations.

Our CapsoCam capsules are regulated as medical devices in the United States and must be manufactured in compliance with the FDA’s current good manufacturing practices (cGMPs) for medical devices, known as the QMSR. The FDA enforces the QMSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Failure to comply with applicable FDA

requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things, warning letters, fines, injunctions, civil penalties, suspension or withdrawal of marketing authorizations, product recalls, and total or partial suspension of production or distribution.

In addition, our products are subject to similar state regulations governing manufacturing. Our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our medical devices. If we or our third-party manufacturers fail to comply with applicable laws and regulations, we could be forced to recall our products or terminate production, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Some of our activities may subject us to risks under federal and state laws prohibiting "kickbacks" and false or fraudulent claims.

Our business practices and relationships with healthcare providers are subject to scrutiny under various federal and state laws designed to prevent fraud and abuse, including the federal Physician Payments Sunshine Act, Anti-Kickback Statute and the False Claims Act. The Physician Payments Sunshine Act increases the transparency of financial relationships between medical device manufacturers and healthcare providers in order to uncover potential conflicts of interest that could compromise treatment decisions and medical research, or that could increase the cost of healthcare services billed to federal health programs. The Anti-Kickback Statute prohibits the exchange of remuneration to induce or reward the referral of business reimbursable under federal healthcare programs. The False Claims Act imposes liability on individuals and companies who submit false claims under federal health care programs. Violations of these laws can result in severe penalties, including criminal and civil fines, exclusion from participation in federal healthcare programs, and significant reputational harm.

Additionally, state laws often mirror or expand upon federal prohibitions, applying to all payers, not just federal programs. Compliance with these laws requires substantial resources and ongoing monitoring of our business practices. Any failure to comply with these laws, whether intentional or inadvertent, could lead to investigations, legal actions, and significant financial penalties, which could materially and adversely affect our business, financial condition, results of operations, and prospects.

Our independent sales representatives earn commissions for capsule sales in their territories, with potential additional commissions for reorders from new accounts and quarterly bonuses. Despite our efforts to provide compliance training and integrate some of them into our direct sales team to improve regulatory oversight, there remains a risk that they might inadvertently breach laws or ethical guidelines in their pursuit of higher earnings, which is not entirely within our control. Independent sales representatives, motivated by commissions and bonuses, might engage in practices that could be construed as kickbacks. If our independent sales representatives engage in unethical or illegal practices to boost sales, it could lead to the submission of false or fraudulent claims for payment submitted to the government. Their malfeasance may expose us to legal and financial liabilities under the federal and state laws.

Failure to comply with the Foreign Corrupt Practices Act (the "FCPA"), economic and trade sanctions regulations, and similar laws could subject us to penalties and other adverse consequences.

We are subject to the FCPA and other laws that prohibit improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Our operations in countries with a high risk of corruption expose us to the risk that our employees, contractors, or agents may engage in activities that violate the FCPA or similar laws, despite our policies and procedures designed to prevent such conduct. Violations of these laws can result in severe penalties, including substantial fines, criminal sanctions, and reputational damage.

Additionally, we are subject to economic and trade sanctions regulations administered by the U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC), which restrict our ability to engage in transactions with certain countries, entities, and individuals. Non-compliance with these regulations can lead to significant financial

penalties, restrictions on our business operations, and adverse effects on our reputation. Ensuring compliance with these complex and evolving regulations requires significant resources and ongoing vigilance.

We sell our GI-tract capsule endoscopy products in the international market through a combination of our direct sales team and third-party distributors. Additionally, the bulk of our component suppliers and assembly manufacturers are currently located outside the U.S., and we anticipate increasing our international activities in the future. Despite our implementation of policies, internal controls, and other measures designed to ensure compliance with applicable anti-corruption and anti-bribery laws and regulations, as well as U.S. trade sanctions laws, there remains a risk that our employees or agents may engage in improper conduct for which we could be held accountable. Any violations, or even allegations of violations, of these laws can result in investigations and enforcement actions that may disrupt our operations, divert significant management attention, and incur substantial costs and expenses, including legal fees. If we, our sales representatives or distributors are found to have violated these laws, we could face severe penalties, including fines, profit disgorgement, injunctions, securities litigation, bans on government business transactions, delisting from securities exchanges, and other consequences that could materially and adversely affect our business, financial condition, and results of operations. Furthermore, our reputation, net sales, or stock price could suffer if we become the subject of negative publicity related to actual or potential violations of anti-corruption, anti-bribery, or trade sanctions laws and regulations.

Risks Related to Our Reliance on Third Parties

We rely on various suppliers to assist us in the assembly and manufacture of our GI-tract capsule endoscopy solution and sourcing of critical and other components and many of these suppliers are single source suppliers located in Asia (particularly Taiwan and Japan); any disruption in our supply chain could adversely affect our ability to meet the demand for our products and fulfil our orders.

To assist us in manufacturing our GI-tract capsule endoscopy products we rely on component suppliers and assembly manufacturers based in Asia (particularly Taiwan and Japan). Critical components found in our CapsoCam capsules include lens modules from Largan, complementary metal oxide semiconductor (“CMOS”) image sensors from Toshiba Corporation (“Toshiba”), and application-specific integrated circuits (“ASICs”) from Moai Electronics Corporation (“Moai”) / Speedbridge Technology Co. (“Speedbridge”). Many of our suppliers/manufacturers are single source and located in Asia. For example, the single source suppliers of our lens modules and ASICs are located in Taiwan and the single source supplier of our CMOS image sensors is located in Japan. Currently, assembled CapsoCam capsules are shipped by Largan from Taiwan to our U.S. facility where we complete the manufacturing process before distributing the capsules to our distribution network. Any disruption to our supply chain could significantly harm our ability to effectively manufacture and deliver our CapsoCam capsules and, in turn materially harm, our financial results.

The numerous supply chain related risks we face that could adversely impact our ability to manufacture and sell our CapsoCam capsules include:

- our supplier may be unable to meet our demand requirements, including demands for desired improvements or upgrades, or may prioritize the orders of its other customers;
- our supplier may be unable to meet our quality standards, specifications, or requirements for critical components, or may experience defects, errors, or failures in these components, which could compromise the quality, performance, or safety of our CapsoCam capsules and the images and analyses they produce;
- our supplier may increase or seek to increase prices, or impose unfavorable purchase terms or conditions, which could increase our costs and reduce our margins;
- our supplier may discontinue the production of critical components, or cease to do business with us, for any reason;

- it may be difficult for us to find an alternative or second supply source, which may not be available, affordable, or compatible with our CapsoCam capsules and, for commercial reasons, we may prefer or be required to work on an exclusive basis with our supplier; and

- supplier concentration in Asia (particularly Taiwan and Japan) subjects us to heightened risks related to geopolitical tensions (particularly between China and Taiwan), potential trade disputes, the imposition of new or increased tariffs or threats of tariffs, transportation interruptions, natural disasters, and manufacturing constraints, any of which can affect the manufacture and delivery of our CapsoCam capsules and lead to delays, increased costs, and potential shortages of our CapsoCam capsules and critical components. For additional information, see the risk factor titled "We face substantial geopolitical and trade risks (including a possible trade war and imposition of tariffs and supply chain interruptions) and natural disaster risks associated with our business operations in Asia (particularly Taiwan and Japan)" and "Changes to U.S. tariff measures and other potential changes in international trade relations implemented by the U.S. could have a material adverse effect on our business, financial condition, cash flows and results of operations" below.

Although we are in the process of planning or implementing various mitigation measures to address supply chain risks (including qualifying a backup supplier for certain critical components and looking to build reserve supplies of capsules and critical components to address unanticipated delays), these efforts may not be successful. For example, implementation of mitigation measures to address the supply chain disruption of CMOS image sensors would be complicated, and resolving an industry-wide issue relating to CMOS image sensors would require a significant amount of time and coordinated efforts across multiple industry participants.

In addition, our operations depend heavily on expedited and reliable shipping services to ensure the secure and timely delivery of our products to customers. Any delivery performance issues, such as loss, damage, or destruction of our CapsoCam capsules or the components thereof, would incur substantial costs for timely replacement and could tarnish our reputation, leading to decreased demand for our products and increased operational expenses. Additionally, significant increases in shipping rates could negatively affect our operating margins and overall financial performance. Service interruptions caused by strikes, severe weather, natural disasters, or other disruptions could further impede our ability to process orders promptly. These factors collectively pose a risk to our business, financial condition, and operational results, and can potentially damage our reputation.

We depend on our authorized agent and importer for a significant portion of our revenue.

We depend on Aureliance, our authorized agent and importer in the EU and EEA for a significant portion of our revenue. It has historically contributed a significant percentage of our revenue generated from EU countries, such that if it were to materially reduce or terminate its business with us, our revenue generated from such countries would suffer. For the nine months ended September 30, 2026 and September 30, 2025, Aureliance represented approximately 11% and 10% of our revenue, respectively. As of September 30, 2026 and December 31, 2025, Aureliance represented approximately 23% and 22% of our accounts receivable balance, respectively. The loss of it or a significant reduction in its business with us could have a material adverse effect on our financial condition and results of operations.

We rely on third parties to conduct and support our clinical trials. These third parties may not properly and successfully carry out their contractual duties or meet expected deadlines, which could harm our ability to obtain marketing authorization of or commercialize future products we develop.

We utilize and depend upon independent investigators and collaborators, such as third-party clinical institutions and hospitals to conduct and support portions of our clinical trials under agreements with us, and may in the future rely on CROs.

We have relied on these third parties for our clinical trials and expect to continue to do so, and we control only certain aspects of their activities. As a result, we have less direct control over the conduct, timing, and completion

of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for medical devices in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites.

If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or other bodies may require us to perform additional clinical trials. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our investigational devices must be produced in accordance with cGMP requirements known as the QMSR. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the marketing authorization process. Moreover, our business may be implicated if any of these third parties violates federal, state or foreign fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Third parties conducting or supporting portions of our clinical trials are not our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our investigational products. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other product development activities, which could affect their performance on our behalf. These third parties may not successfully carry out their contractual duties or obligations or meet expected deadlines. They may need to be replaced or the quality or accuracy of the clinical data they obtain may be compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons. Accordingly, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain marketing authorizations for or successfully commercialize our future devices.

Switching or adding third parties to conduct or support portions of our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays may occur, which could have an adverse impact on our product development, results of operations, and prospects.

We rely on relationships with contracted physicians to provide reading services to certain customers.

We contract directly or indirectly with physicians to provide remote reading services to certain customers. If these physicians terminate their contracts, we or our partners may not be able to contract with alternative physicians to provide such services in a timely manner, or at all, which would impact our ability to provide services to certain customers and could adversely affect our business, financial condition, results of operations, and prospects.

Data Privacy Risk Factors

We may face risks associated with our use and development of artificial intelligence, including our AI technology.

Clinicians are subject to fatigue and distraction and have varying degrees of expertise in identifying GI-tract abnormalities. Our AI assisted pathology detection tool is designed to (i) reduce viewing times for clinicians by highlighting the areas of interest (via a bonding box placed around suspected abnormalities) and (ii) improve diagnostic yield and provide more consistent accuracy by providing suggestions or recommendations. However, risks related to the use of our AI technology include:

- our AI assisted pathology detection technology may fail to accurately identify all or a sufficient portion of the patient's GI-tract abnormalities (measured in terms of sensitivity and specificity);

- a clinician may (i) place undue reliance on our AI assisted pathology detection technology to identify GI-tract abnormalities (e.g., polyps in colon) or (ii) fail to fully utilize product features designed to supplement a clinician's review (such as the ability to review frames adjacent to an AI bonded frame identifying a suspected GI-tract abnormality or view the video in non-AI mode);

- our AI technology may not prevent or reduce the occurrence or impact of clinician alertness fatigue; and

- product enhancements and improvements (including improvements to our AI algorithms) may fail to deliver improved viewing, accuracy improvements (including as measured in terms of sensitivity and specificity) and other expected benefits.

We plan to further invest in AI to improve our products. However, we may not achieve the expected benefits from our AI investments, or we may face technical, regulatory, ethical or legal challenges that could limit or delay the development, deployment or adoption of our AI technology. For example, AI Highlights, our AI-assisted reading feature for the CapsoCam Plus system, may not achieve the market acceptance we expect if physicians and other healthcare providers are not persuaded of its clinical utility, efficiency benefits or reliability, which could adversely affect our business. Additionally, we may encounter difficulties in integrating our AI technology with our existing or future products, software or platforms, or in ensuring the compatibility, interoperability or reliability of our AI technology.

Our AI technology may introduce errors or biases that could compromise the quality or validity of the clinician's viewing. In particular, for data collected by CapsoCloud to serve as the clinically derived reference standard ("ground truth") for enhancing AI capabilities, it is imperative that the collected data be meticulously labeled. This labeling process is resource-intensive and necessitates the involvement of qualified gastroenterologists who meticulously review and annotate the images. The accuracy of these labels is crucial, as it directly impacts the AI's ability to make precise and reliable predictions based on the data. If the models underlying our AI technologies are incorrectly designed or implemented; trained or reliant on incomplete, inadequate, inaccurate, biased, or otherwise poor quality data (including as a result of the labeling process described above), or on data to which we do not have sufficient rights or in relation to which we and/or the providers of such data have not implemented sufficient legal compliance measures; used without sufficient oversight and governance to ensure their responsible use; misused or used outside of scope of applicable regulatory authorizations; and/or adversely impacted by unforeseen defects, technical challenges, cybersecurity threats, or material performance issues, the performance of our products, as well as our reputation, could suffer or we could incur liability resulting from the violation of laws or contracts to which we are a party, regulatory enforcement actions, or civil claims.

The performance of any algorithm incorporated in our AI technology will generally be assessed by comparing the output of the algorithm against a ground truth for a specified dataset. This applies to internal evaluation of an algorithm's performance, supporting external presentations and publications, and testing to support regulatory submissions. Our algorithm output will not always agree with the opinion of a qualified gastroenterologist, and in some cases multiple qualified gastroenterologists may not agree with each other. While we constantly work to improve our GI-tract capsule endoscopy solution, our AI technology is novel and complex, and our AI technology may not perform as intended under all circumstances.

CapsoCloud is designed to automatically accumulate patient data critical to develop and train AI-based GI-tract abnormality detection and classification capabilities. If we are unable to obtain sufficient rights to use such data under applicable regulatory frameworks or our patients were to withdraw or withhold their consent, our ability to continue to develop new or improved CapsoCam capsule endoscopy products, and our revenue prospects, could be materially adversely impacted.

The regulatory landscape for AI technologies is rapidly changing as various federal, state, and international government bodies introduce or consider new laws and regulations. The FDA has issued guidance on

incorporating AI into medical devices, and existing laws may be interpreted in ways that impact AI operations or could be rescinded or amended as new administrations take differing approaches to evolving AI technologies. This creates uncertainty around implementation standards and enforcement practices, making it difficult to predict the future impact on businesses. In the U.S., the Trump administration rescinded an executive order relating to AI technologies that was previously implemented by the Biden administration. The Trump administration may continue to rescind other existing federal orders and/or administrative policies relating to AI technologies, or may implement new executive orders and/or other rule-making relating to AI technologies in the future. Any such changes at the federal level could require us to expend significant resources to modify our products, services, or operations to ensure compliance or remain competitive. U.S. legislation related to AI technologies has also been introduced at the federal level and is advancing at the state level. Such additional regulations may impact our ability to develop, use, and commercialize AI technologies in the future.

It is possible that further new laws and regulations will be adopted in the U.S. and other jurisdictions, potentially limiting the use of AI technologies or requiring changes that could negatively affect business performance. Compliance with these laws may necessitate significant resource expenditure, especially if regulations vary across jurisdictions. The cost of compliance could increase operating expenses due to additional reporting obligations. Any failure, actual or perceived, to comply with these laws and regulations could materially and adversely impact our business operations, financial condition, and future prospects.

Actual or perceived failures to comply with applicable data privacy and security laws, regulations, standards and other requirements could adversely affect our business, financial condition, results of operations, and prospects.

We collect, store, process and analyze large amounts of data for GI tract from our products, customers, patients, hospitals and other sources, to support our AI technology. With CapsoCloud, we have access to a rich and growing source of clinical data from patients, which enables us to develop ever-improving automated detection and classification of GI-tract abnormalities. However, the collection and use of such data involves significant risks and challenges, such as data breaches, cyberattacks, unauthorized access, theft, loss, corruption, misuse, manipulation, infringement, disclosure or destruction. Any of these events could compromise the security, privacy, integrity, availability or accuracy of our data, and expose us to legal, regulatory, reputational or financial liabilities, as well as potential claims, fines, penalties, sanctions, litigation or investigations.

We must comply with various U.S. laws and regulations that protect personal information, especially health-related information, such as the Health Insurance Portability and Accountability Act (HIPAA), which imposes privacy, security, and breach notification obligations and penalties on entities that handle such information. Some states, such as California, have also enacted their own privacy and security laws, which may differ from or conflict with federal laws and require additional disclosures, responses, and contracts. These laws and regulations are subject to interpretation and change, and may increase our compliance costs and risks.

We may also face data protection laws and regulations in foreign jurisdictions, such as the General Data Protection Regulation, which applies to personal data of individuals in the European Economic Area and imposes stringent requirements and fines on data processors and controllers, including for transfers of such data to third countries like the U.S. These laws and regulations may affect how we conduct business, transfer data, and provide services, and may expose us to additional costs, complaints, investigations, or fines. The Federal Trade Commission may also take action against us for misleading, deceptive, or unfair practices related to privacy and data security.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations, research protocols, and other obligations, any actual or perceived failure by us or our employees, representatives, contractors, consultants, or other third parties to comply with such requirements or adequately address data privacy and security concerns, even if unfounded, could result in, among other adverse impacts, damage to our reputation, loss of customer confidence in our security measures, withdrawal or withholding of customer consent for using patient data, government investigations, and enforcement actions and litigation and claims by third

parties, any of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We leverage cloud-based CapsoCloud for easy access to patients' in vivo videos, however use of CapsoCloud faces complicated compliance requirements.

Utilizing our cloud-based platform, CapsoCloud, physicians can remotely access and analyze their patients' in vivo videos and other exam data. However, the regulatory environment for cloud-based platforms is complex and varies across different jurisdictions, and as described below, some states or countries may impose restrictions or prohibitions on the use of cloud-based platforms or the transmission of patient data across borders. Initially, following the commercial launch of our CapsoCam Colon solution, providers will utilize CapsoCloud to download in vivo videos for remote review. Within one year of commercial launch, we plan to introduce user-friendly streaming functions to facilitate via CapsoCloud remote in vivo video review, procedure report generation and image annotation.

Outside the U.S., CapsoCloud also faces significant operational and compliance issues due to stringent data privacy and security regulations in various countries. This necessitates the development of country-specific cloud infrastructures for CapsoCloud, which can lead to increased costs, complexity, and potential delays in service delivery. Additionally, for certain U.S. government-related customers, such as the U.S. Department of Defense and Veterans Administration associated hospitals, CapsoCloud must implement additional layers of IT security to meet their stringent security requirements before these customers can utilize CapsoCloud. This could further complicate our cloud infrastructure, increase the risk of security breaches if not properly managed, and require substantial investment in specialized security measures and compliance protocols.

If we are unable to comply with these regulations or obtain the necessary approvals or licenses, we may face legal actions, fines, penalties, or loss of business, which could adversely affect our reputation, operations, and financial results. Additionally, we may incur significant costs and resources to adapt CapsoCloud to meet the changing regulatory requirements or customer preferences in different markets and countries.

Our business and operations may suffer in the event of information technology system failures, cyberattacks, or deficiencies in our cybersecurity.

We rely heavily on information technology systems and infrastructure to operate our business, including the collection, storage, and transmission of sensitive patient exam data. Our systems, including CapsoCloud, and those of our third-party service providers, are vulnerable to cyberattacks, data breaches, and other security incidents that could compromise the confidentiality, integrity, and availability of our data. Such incidents could result in significant disruptions to our operations, financial losses, and damage to our reputation.

We seek to protect against cybersecurity threats. Among other measures, our CapsoCloud systems are HIPAA-compliant and operate in an ISO 27001 certified cloud-computing environment, we have adopted various cybersecurity controls and procedures and we conduct cybersecurity related trainings. However, there is no guarantee that our systems will be immune to cyber threats. For example, in October 2019, we observed and investigated a cyberattack that breached our Amazon Web Services (AWS) account hosting the CapsoCloud service. In connection with this investigation, we determined no data was compromised during this incident and, in addition to related employee trainings, we adopted additional procedures and controls designed to protect against these types of incidents. Any failure to adequately protect our IT systems and sensitive patient exam data collected, stored and transmitted on or through our systems could lead to regulatory investigations, legal actions, and substantial costs associated with remediation and notification efforts, which could materially and adversely affect our business, financial condition, results of operations, and prospects.

Risks Relating to Our Intellectual Property

Our success will depend on our ability to obtain, maintain, enforce, and protect our intellectual property rights.

Our success and ability to compete depends in part on our ability to obtain, maintain, enforce, and protect issued patents, trademarks, trade secret, and other intellectual property rights and proprietary technology in the U.S. and elsewhere. If we cannot adequately obtain, maintain, and enforce our intellectual property rights and proprietary technology, competitors may be able to use our technologies or the goodwill we have acquired in the marketplace and erode or negate any competitive advantage we may have and our ability to compete, which could harm our business and ability to achieve profitability and/or cause us to incur significant expenses. We generally seek to protect our proprietary position by filing patent applications that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending patent applications or other intellectual property or proprietary rights from third parties. If we are unable to obtain or maintain patent protection with respect to any proprietary technology, our business, financial condition, results of operations, and prospects could be materially harmed.

We rely on a combination of contractual provisions, confidentiality procedures, and patent, trademark, copyright, trade secret and other intellectual property laws to protect the proprietary aspects of our brands, technologies, trade secrets, know-how, and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property rights and proprietary information. In addition, patents have a limited lifespan. In the U.S., for example, the natural expiration of a utility patent is generally 20 years from the earliest effective non-provisional filing date. Our success will depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how, and obtaining, maintaining, and enforcing other intellectual property rights. We may not be able to obtain, maintain, and/or enforce our intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage.

The patent prosecution process and enforcement of any resulting patents are expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, defend, or license all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner, or in all jurisdictions. Moreover, pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover relevant product, service, or the technology. There can be no assurance that our current or future patent applications will result in patents being issued or that our issued patents will afford sufficient protection against competitors or other third parties with similar products, services or technologies competitive with ours, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties.

Even our issued patents may later be found invalid or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. In addition, our issued patents may later be found to be unenforceable for a number of possible reasons, such as for a failure to properly identify material prior art or other references to the U.S. Patent and Trademark Office (the “USPTO”). The degree of future protection for our intellectual property or other proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect or be able to enforce the intellectual property or other proprietary rights relating to our products, services and technologies could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We cannot be certain that the claims in our U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign territories will be considered patentable by the USPTO, courts in the U.S., or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our future issued patents will not be found invalid or unenforceable if challenged. Our ability to obtain and maintain valid and enforceable patents depends in part on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Additionally, regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our products, services, technologies, or activities. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Failure to obtain, maintain, and/or enforce intellectual property rights necessary to our business and failure to protect, monitor and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the U.S. and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation or misappropriation of our patents, trademarks, data, technology, and other intellectual property rights by others, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated, or otherwise violated by others.

The degree of future protection for our intellectual property rights is uncertain. Therefore, we cannot ensure that others will not develop, manufacture and/or commercialize similar or alternative products, services, or technologies that do not infringe, misappropriate, or violate any patents or other intellectual property rights that we own or have rights to. We cannot ensure that any patents issued to us will provide a basis for an exclusive market for our products, services, or technologies, will provide us with any competitive advantages or will not be challenged, invalidated, modified, revoked, or circumvented by third parties. We cannot ensure that any of our challenged patents will be found to ultimately be valid and enforceable. We cannot ensure that any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products, services, or technologies. We cannot ensure that any of our pending patent applications will issue as patents, or even if issued, will include claims with a scope sufficient to protect our products, services, or technologies. We cannot ensure that we will be able to successfully develop, manufacture, and commercialize our products, services, or technologies on a substantial scale before relevant patents we may have expire. We cannot ensure that we were the first to make the inventions covered by each of our patents and pending patent applications or we were the first to file patent applications for such inventions. We cannot ensure that we will develop additional proprietary inventions, products, services, or technologies that are separately patentable. In addition, we cannot ensure that our commercial activities, products, services, or technologies will not infringe upon the patents of others. Defending against any such infringement claims is also expensive, time-consuming, complex, and can distract us from pursuing commercial activities.

If we fail to identify our patentable inventions or adequately protect our patent rights, the commercial value of our products, services or technologies may be adversely affected and our competitive position may be harmed.

We rely in part on our portfolio of issued patents and pending patent applications in the U.S. and other countries to protect our intellectual property and competitive position. However, it is also possible that we may fail to identify patentable aspects of inventions made in the course of the development, manufacture, and commercial activities conducted by or on behalf of us before it is too late to obtain patent protection on such inventions. If we fail to timely file for patent protection in any jurisdiction, we may be precluded from doing so at a later date. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, suppliers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection, and any of these parties may decide to independently file for intellectual property without naming us as owners, inventors, or co-owners for the intellectual property. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, should we become a licensee or co-owner of a third party's patents or patent applications, depending on the terms of any future in-licenses or co-ownership agreement to which we may become a party, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain or enforce the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted, maintained, and/or enforced in a manner consistent with the best interests of our business. While we may apply for patents in some countries outside of the U.S., we may not accurately predict all of the countries where patent protection will ultimately be desirable. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from importing, using, manufacturing,

and/or commercializing our own products or services, or otherwise practicing our own technology. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent positions of companies, including our patent position, may involve complex legal and factual questions that have been the subject of much litigation in recent years, and, therefore, the scope of any patent claims that we have or may obtain cannot be predicted with certainty. Accordingly, we cannot provide any assurances about which of our patent applications will issue, the breadth of any resulting patent, whether any of the issued patents will be found to be infringed, invalid, or unenforceable or will be threatened or challenged by third parties, that any of our issued patents have, or that any of our currently pending or future patent applications that mature into issued patents will include claims with a scope sufficient to protect our products, services, or technology. Our pending and future patent applications may not result in the issuance of patents or, if issued, may not issue in a form that will be advantageous to us.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. We cannot offer any assurances that the breadth of our issued patents will be sufficient to stop a competitor from developing, manufacturing, and commercializing one or more products, services, or technologies in a non-infringing manner that would be competitive with one or more of our products, services, or technologies, or otherwise provide us with any competitive advantage. Furthermore, any successful challenge to these patents or any other patents owned by us after patent issuance could deprive us of rights necessary for our commercial success. Further, there can be no assurance that we will have adequate resources to enforce our patents.

Though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products or services. Patents, if issued, may be challenged, deemed unenforceable, invalidated, narrowed, or circumvented. Proceedings challenging our patents or patent applications could result in either loss of the patent, or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Any successful challenge to our patents and patent applications could deprive us of exclusive rights necessary for our commercial success. In addition, defending such challenges in such proceedings may be costly. Thus, any patents that we own may not provide the anticipated level of, or any, protection against competitors. Furthermore, an adverse decision may result in a third party receiving a patent right sought by us, which in turn could affect our ability to develop, manufacture, commercialize, import, or otherwise use our products, services, or technologies.

Some of our patents and patent applications are or may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third- party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products, services, or technologies. In addition, we may need the cooperation of any such co-owners of our patents to enforce such patents against third parties, and such cooperation may not be provided to us.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees, and various other government fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent and/or applications and any patent rights we may obtain in the future. While an unintentional lapse of a patent or patent application can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could

result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. If we fail to maintain our patents and patent applications, we may not be able to stop a competitor from marketing products, services, or technologies that are the same as or similar to our products, services, or technologies, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our patents will eventually expire, and our patent protection will be reduced or eliminated by expiration of patents in our patent portfolio.

We have prosecuted and obtained a variety of patents to protect the intellectual property rights to our products and services. These patents protect our inventions relating to camera, image sensor, display and imaging system, capsule detection, power source control, and other key and ancillary components of our products. We rely on these patents to prevent others from using, developing, manufacturing and selling competing products or solutions or infringing on our proprietary rights.

However, patents have a limited lifespan, with the term of individual patents depends upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in jurisdictions in which they are obtained. In most countries, including the U.S., issued patents are granted a term of 20 years from the earliest effective non-provisional filing date. We have patents that are anticipated to expire. After patents in our portfolio begin to expire, we cannot guarantee that our remaining patents will be sufficient to maintain our competitive advantage or prevent competitors from developing similar or superior products. Once our patents expire, we may lose the exclusive right to prevent others from using, developing, manufacturing or selling products that incorporate our patented technology that are claimed in the expired patents. If third parties use our technology within the scope of such expired patents, we may not be able to sue them for infringement or recover any damages. This could result in increased competition, reduced market share, lower revenues and margins, and harm to our reputation and brand.

In certain instances, a patent term of a U.S. patent may be adjusted to recapture a portion of delay by the USPTO in examining the patent application or extended to account for term effectively lost as a result of the FDA regulatory review period, or both. While the adjustment of the patent term based upon delay by the USPTO is automatically calculated by the USPTO, it is possible that this patent term adjustment is improperly calculated by the USPTO and thus does not accurately reflect the true amount of adjustment that is entitled to a patent holder. Indeed, the USPTO has publicly acknowledged in 2024 that numerous errors have possibly occurred for patent term adjustments that have been calculated by the USPTO for previously issued patents. Moreover, it is possible that actions we have taken to prosecute a patent application will be considered applicant delay and will reduce the amount of patent term adjustment that is granted to a patent. For a patent term extension based upon the FDA regulatory review period, the period of extension may be up to five years, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of approval. Only one patent among those eligible for an extension may be extended. However, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions may be less than the maximum extension available. In addition, this type of patent term extension will only be granted if requested within a designated timeframe after FDA approval. If the applicable authorities do not approve the extension or if we do not make a timely application for extension, then it is possible that a term extension will not be granted for a given patent in our patent portfolio, thereby reducing the amount of enforceable term for the patent.

Changes in U.S. or foreign patent laws or their interpretations could diminish the value of our patents in general, thereby impairing our ability to protect our current and future products, services, or technologies, and could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our current or future patents.

Our ability to obtain patents and the breadth of any patents obtained is uncertain in part because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or

interpretation of claims allowed in patents in the U.S. and other countries. Changes in either patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property rights or narrow the scope of our patent protection, which in turn could diminish the commercial value of our products, services, and technologies.

Patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement, and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the U.S. are interpreted. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations.

In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we own or that we might obtain or license in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business, financial condition, results of operations, and prospects.

Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. Changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them, or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. In addition, any protection afforded by foreign patents may be more limited than that provided under U.S. patent and intellectual property laws. We may encounter significant problems in enforcing and defending our intellectual property both in the U.S. and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in other countries, our ability to protect our intellectual property rights in those countries may be limited. We cannot predict future changes in the interpretation of patent laws in the U.S. and other countries or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

In June 2023, the European Unitary Patent system and the European Unified Patent Court (“UPC”) were launched. European patent applications now have the option, upon grant of a patent, of becoming a Unitary Patent which is subject to the jurisdiction of the UPC. In addition, conventional European patents, both already granted at the time the new system began and granted thereafter, are subject to the jurisdiction of the UPC, unless actively opted out. This was a significant change in European patent practice, and deciding whether to opt-in or opt-out of Unitary Patent practice entail strategic and cost considerations. The UPC provides third parties with a new forum to centrally revoke our European patents and makes it possible for a third party to obtain pan-European injunctions against us. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. While we have the right to opt our patents out of the UPC over the first seven years of the court’s existence, doing so may preclude us from realizing the benefits of the UPC. Moreover, the decision whether to opt-in or opt-out of Unitary Patent status will require coordinating with co-applicants, if any, adding complexity to any such decision.

The legal systems in certain countries may also favor state-sponsored or companies headquartered in particular jurisdictions over our first-in-time patents and other intellectual property protection. We are aware of incidents where such entities have stolen the intellectual property of other companies in order to create competing

products. For example, through its “Annual Special 301 Report on Intellectual Property,” the Office of the United States Trade Representative has been reporting on the adequacy and effectiveness of intellectual property protection in a number of foreign countries that are U.S. trading partners and their protection and enforcement of intellectual property rights. Placement of a country on the Priority Watch List indicates that particular problems exist in that country with respect to intellectual property protection, enforcement, or market access for persons relying on intellectual property rights. Countries placed on the Priority Watch List are the focus of increased bilateral attention concerning the specific problem areas. It is possible that we will not be able to enforce our intellectual property rights against third parties that misappropriate our proprietary technology in those countries.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on our products, services, and technologies in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. The requirements for patentability may differ in certain countries, particularly in developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third-parties from practicing our inventions in all countries outside the U.S. or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, services, or technologies and, further, may export otherwise infringing products, services, or technologies to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products, services, or technologies may compete with our products, services, or technologies, and our patents or other intellectual property rights may not be effective or sufficient to prevent such competition.

Various companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries may not favor the enforcement of patents and other intellectual property protection, particularly those relating to medical devices and related services and technologies, which could make it difficult for us to stop the infringement of our patents or marketing of competing products, services, and technologies in violation of our intellectual property and proprietary rights. In addition, some jurisdictions, such as Europe, Japan, and China, may have a higher standard for patentability than in the U.S., including, for example, imposing a high standard for making claim amendments and for the submission of supplemental experimental data during patent examination. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the U.S. and other jurisdictions.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patent rights at risk of being invalidated or interpreted narrowly, could put our owned patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop, own or license. Various countries outside the U.S., including certain countries in Europe, India, and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner in such countries may have limited remedies in certain circumstances, which could materially diminish the value of such patent. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied predictably. As such, we do not know the degree of world-wide uniform protection that we will have on our technologies and products in the future.

If we cannot successfully enforce our intellectual property rights, the commercial value of our products, services, or technologies may be adversely affected and our competitive position may be harmed.

Third parties, including our competitors, may currently, or in the future, infringe, misappropriate, or otherwise violate our issued patents or other intellectual property rights, and we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time-consuming, and unsuccessful. We regularly monitor for unauthorized use of our intellectual property rights and, from time to time, analyze whether to seek to enforce our rights against potential infringement, misappropriation, or violation of our intellectual property rights. However, the steps we have taken, and are taking, to protect our proprietary rights may not be adequate to enforce our rights as against such infringement, misappropriation, or violation of our intellectual property rights. In certain circumstances it may not be practicable or cost-effective for us to enforce our intellectual property rights fully, particularly in certain developing countries or where the initiation of a claim might harm our business relationships. We may also be hindered or prevented from enforcing our rights with respect to a government entity or instrumentality because of the doctrine of sovereign immunity. Our ability to enforce our patent or other intellectual property rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products, services, or technologies. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product, services, or technologies. Thus, we may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Any inability to meaningfully enforce our intellectual property rights could harm our ability to compete and reduce demand for our products, services, and technologies. We may in the future become involved in lawsuits to protect or enforce our intellectual property rights. An adverse result in any litigation proceeding could harm our business. In any lawsuit we bring to enforce our intellectual property rights, a court may refuse to stop the other party from manufacturing, commercializing, using or importing the product, service, offering or technology at issue on grounds that our intellectual property rights do not cover, and the other party is not infringing, violating or otherwise misappropriating our intellectual property, through the manufacture, commercialization, use or importation of the product, service, offering or technology in question. Any claims we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate, or otherwise violate their intellectual property rights. If we initiate legal proceedings against a third party to enforce a patent covering a product, service, offering or technology, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of patentable subject matter, novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from USPTO, or made a misleading statement, during prosecution. Mechanisms for such challenges include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). In a patent or other intellectual property proceeding, a court may decide that a patent or other intellectual property right of ours is invalid or unenforceable, in whole or in part, construe the patent's claims or other intellectual property narrowly or refuse to stop the other party from manufacturing, commercializing, using or importing the product, service, offering, or technology at issue on the grounds that our patents or other intellectual property do not cover the manufacture, commercialization, use, or importation of the product, service, offering, or technology in question. Furthermore, even if our patents or other intellectual property rights are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation or administrative proceeding could put one or more of our patents or other intellectual property rights at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business, financial condition, results of operations and prospects. Moreover, even if we are successful in any litigation, we may incur significant expense in connection

with such proceedings, and the amount of any monetary damages may be inadequate to compensate us for damage as a result of the infringement and the proceedings.

We may become a party to intellectual property litigation or administrative proceedings that could be expensive, time-consuming, and unsuccessful, and could interfere with our ability to develop, manufacture, commercialize, import, or otherwise use our products, services, or technologies.

Our commercial success depends, in part, on our ability to develop, manufacture, commercialize, import, or use our products, services, and technologies without infringing, misappropriating, or otherwise violating the intellectual property rights of third parties. Our industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. While we do not intend to infringe upon, misappropriate, or otherwise violate the intellectual property rights of others, there may be pertinent rights of which we are presently unaware.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights. The outcomes of such proceedings are uncertain and could have a negative impact on the success of our business. It is possible that U.S. and foreign patents and pending patent applications controlled by third parties may be alleged to cover our products, services, and technologies, or that we may be accused of misappropriating third parties' trade secrets or infringing third parties' trademarks. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our products, services, or technologies, including interference proceedings, post grant review, and inter partes review before the USPTO or equivalent foreign regulatory authority. Furthermore, we may also become involved in other proceedings, such as reexamination, derivation, or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents, which our current or future products, services, or technologies infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid and enforceable, and infringed by the use of our products, services, or technologies, which could have a negative impact on the commercial success of our current and any future products, services, or technologies. If we were to challenge the validity of any such third-party U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. We will have similar burdens to overcome in foreign courts in order to successfully challenge a third-party claim of patent infringement.

Our defense of any litigation or interference proceedings may fail and, even if successful, defending such claims brought against us would cause us to incur substantial expenses and distract our management and other employees. If such claims are successfully asserted against us, we could be forced to pay substantial damages. Further, if a patent infringement or other intellectual property rights-related lawsuit were brought against us, we could be forced, including by court order, to cease developing, manufacturing, commercializing, importing, or using the infringing product, service, or technology. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Although patent, trademark, trade secret, and other intellectual property disputes have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may not be able to obtain licenses on commercially reasonable terms or at all, in which event our business would be materially and adversely affected. Even if we were able to obtain a license, the rights may be non-exclusive, which could result in our competitors and other

third parties gaining access to the same intellectual property. Ultimately, if we are unable to obtain such licenses or make any necessary changes to our products, services, or technologies, we could be forced to cease some aspect of our business operations, which could harm our business significantly.

A finding of infringement or an unfavorable interference or derivation proceedings outcome could prevent us from developing, manufacturing, commercializing, importing, or using our products, services, or technologies, or force us to cease some or all of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations, and prospects. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources and more mature and developed intellectual property portfolios. We could encounter delays in product introductions while we attempt to develop alternative products or technologies.

If third parties assert infringement, misappropriation, or other claims against our customers, these claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products, services, or technologies they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products, services, or technologies.

Our competitors may have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, and may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit, or otherwise interfere with our ability to make, use, sell, import, and/or export our products, services, or technologies. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us may increase. Moreover, individuals and groups that are non-practicing entities, commonly referred to as “patent trolls,” purchase patents, and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or “invitations to license,” or may be the subject of claims that our products, services, or technologies and business operations infringe, misappropriate, or otherwise violate the intellectual property rights of others. These matters can be time-consuming, costly to defend in litigation, divert management’s attention and resources, damage our reputation and brand, and cause us to incur significant expenses or make substantial payments. In addition, we purchase product components, including hardware and software, from suppliers, and the design of these components may be outside of our direct control. These suppliers may not indemnify us in the event that a third party alleges the use of such components infringes its intellectual property rights.

Any lawsuits relating to intellectual property rights could subject us to significant liability for damages and invalidate our intellectual property. Any potential intellectual property litigation also could force us to do one or more of the following: (a) stop developing, making, selling, importing, or using products, services, or technologies that allegedly infringe, misappropriate, or otherwise violate the asserted intellectual property right; (b) pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, misappropriating, or otherwise violating; (c) redesign those products, services, or technologies that contain the allegedly infringing intellectual property, which could be costly, disruptive, and infeasible; and attempt to obtain a license to the relevant intellectual property rights from third parties, which may not be available on commercially reasonable terms or at all, or from third parties who may attempt to license rights that they do not have; (d) lose the opportunity to license our intellectual property rights to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; (e) incur significant legal expenses; or (f) pay the attorney’s fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing, misappropriating, or otherwise violating.

Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, inter partes review, and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings). Such proceedings could

result in revocation of or amendment to our patents in such a way that they no longer cover our products, services, or technologies. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on our products, services, or technologies. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

Because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearing, motions, or other interim developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Even if we ultimately prevail, a court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. Furthermore, even if resolved in our favor, the monetary cost of such litigation and the diversion of the attention of our management could outweigh any benefit we receive as a result of the proceedings. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business. Any of the foregoing may cause us to incur substantial costs and could place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property rights.

We may also be subject to claims that our current or former employees, contractors, partners, vendors or other third parties have an ownership interest in our current or future patents, patent applications, or other intellectual property rights, including as an inventor, co-inventor, or co-owner. We may be subject to ownership or inventorship disputes in the future arising, for example, from conflicting obligations of employees, consultants, partners, vendors, or others who were or are involved in developing our products, services, or technologies. Although it is our policy to require those who may be involved in the conception or development of inventions to execute agreements assigning such inventions and intellectual property rights therein to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops inventions that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of inventions may not be self-executing, or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership of inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or the right to use, valuable intellectual property rights, and other owners may be able to license their interest in such intellectual property rights to other third parties, including our competitors. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

In addition, we may be subject to claims from third parties challenging inventorship or ownership of intellectual property rights we regard as our own, based on claims that our agreements with employees, consultants, partners, vendors, or others who were or are involved in developing our products, services, or technologies obligating them to assign their inventions and intellectual property rights therein to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions and intellectual property rights therein to another employer, to a former employer, or to another person or entity. Many of our current and former employees and consultants were previously employed at or engaged by other medical device companies, including our competitors or potential competitors. Some of these employees and consultants have executed with such previous employment or engagements confidential information non-disclosure and non-use agreements and inventions assignment agreements, which may have included non-competition provisions. Although we try to ensure that such employees and consultants do not use or otherwise disclose confidential information or intellectual property rights of others in their work for us without such other person’s consent, we may be subject to

claims that we or our current or former employees or consultants have, inadvertently or otherwise, infringed, violated, or otherwise misappropriated the confidential information or the intellectual property rights of these former employers, clients, or other third parties. To the extent that our current or former employees or consultants disclose or use confidential information or intellectual property rights owned by others in their work for us, disputes may arise as to the rights in any related or resulting inventions and litigation may be necessary to defend against these claims. It may also be necessary or we may desire to obtain a license to such third party's intellectual property rights to settle any such claim; however, there can be no assurance that we would be able to obtain such license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages or a settlement payment, a court could prohibit us from manufacturing, commercializing, using or importing the product, service, or technology features or practicing other intellectual property rights that are essential to our business, which could have a material adverse effect on our competitive position as well as our business, financial condition, results of operations, and prospects. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management and our employees. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with collaborators, partners, services provides, or contractors. A loss of key personnel or their work product could hamper or prevent our ability to develop, manufacture, commercialize, import, or use our products, services, or technologies, which could materially and adversely affect our business, financial condition, results of operations, and prospects.

If we are unable to protect the disclosure and use of our confidential information and trade secrets, the value of our products, services, and technologies and our business and competitive position could be harmed.

In addition to patent protection, we also rely on other intellectual property rights, including trade secrets, know-how, and/or other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect, and some courts are less willing or unwilling to protect trade secrets. To protect and maintain the confidentiality of our trade secrets and other proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators, and other third parties. We generally enter into confidentiality and inventions assignment agreements with our employees, consultants, and applicable third parties upon their commencement of a relationship with us. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes, and we may not enter into such agreements with all employees, consultants, and third parties who have been involved in the development of our inventions. Although we generally require all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets.

In addition, despite the protections we place on our intellectual property and our other proprietary rights, monitoring unauthorized use and disclosure by employees, consultants, and other third parties who have access to such intellectual property or other proprietary rights is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. Therefore, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such employees, consultants, advisors, or third parties, despite the existence of our protections, including non-disclosure and use restrictions. These agreements may not provide meaningful protection against the unauthorized disclosure or use or of our trade secrets, know-how, or other proprietary information in the event the unwanted use is outside the scope of the provisions of the contracts or in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how or other proprietary information that we fail to detect. There can be no assurances that such employees, consultants, advisors, or third parties will not intentionally or unintentionally breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by third parties, including our competitors. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that information to compete with us. In addition to contractual measures, we try to protect the confidential nature of our

proprietary information by maintaining physical security of our premises and electronic security of our information technology systems. Such security measures may not, for example, in the case of misappropriation of a trade secret by an employee, consultant or other third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee, consultant, or other third party from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully.

If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. The exposure of our trade secrets and other proprietary information would impair our competitive advantages and could have a material adverse effect on our business, financial condition, results of operations, and prospects. In particular, a failure to protect our proprietary rights may allow competitors to copy our products, services, or technologies, which could adversely affect our pricing and market share. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products, services, or technologies that we consider proprietary. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality, non-disclosure, and non-use provisions, and outcomes of such litigation are unpredictable. Enforcing a claim that a party illegally disclosed, used or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. While we use commonly accepted security measures, trade secret violations are often a combination of federal and state law in the U.S., and the criteria for protection of trade secrets can vary among different jurisdictions. If the steps we have taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, some courts are less willing or unwilling to protect trade secrets and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases. Finally, even if we were to be successful on the enforcement of our claims, we may not be able to obtain adequate remedies.

It is also possible that others may independently develop information or technologies that are the same as or similar to our trade secrets or other proprietary technologies and develop products, services, or technologies without obtaining access to our trade secrets or other proprietary information in which case we could not assert any intellectual property rights, including trade secret rights, against such parties in a manner that could prevent legal recourse by us. If we fail to obtain or maintain trade secret protection, or if any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or used by others without our consent or otherwise misappropriated, or if any such information was independently developed by a competitor, or if our competitors obtain our trade secrets or independently develop products, services, or technologies that are the same as or similar to ours, our competitive market position could be materially and adversely harmed.

If our trademarks and trade names are not adequately protected, we may not be able to build brand name recognition in our markets of interest and our competitive position may be harmed.

Our trademarks could be challenged, opposed, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, declared generic or descriptive, or found to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our Company, products, services, or technologies, resulting in loss of brand recognition and requiring us to devote resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion. Further, there can be no assurance that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Certain of our current or future trademarks may become so well known by the public that their use becomes generic and they lose trademark protection. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

We rely on our trademarks, trade names, and brand names to distinguish our products, services, and technologies from the products, services, and technologies of our competitors, and have registered or applied to

register many of these trademarks in the U.S. and certain countries outside the U.S.; however, we have not yet registered all of our trademarks in all of our current and potential markets. There can be no assurance that all of our trademark applications will be approved for registration. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties have opposed and may oppose in the future further our trademark applications and may seek to cancel trademark registrations or otherwise challenge our use of the trademarks. Opposition or cancellation proceedings may be filed against our trademark filings in these agencies, and such filings may not survive such proceedings. While we may be able to continue the use of our trademarks in the event registration is not available, particularly in the U.S., where trademark rights are acquired based on use and not registration, third parties may be able to enjoin the continued use of our trademarks if such parties are able to successfully claim infringement in court. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. Our trademarks or trade names may be infringed, circumvented, declared generic, or determined to be violating or infringing on other marks.

Our products contain third-party open source software components and failure to comply with the terms of the underlying open source software licenses could restrict our ability to sell our products, affect our ability to protect our proprietary information, and subject us to possible litigation.

Our products contain software tools licensed by third parties under open source software licenses. Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source software licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the code. Some open source software licenses contain requirements that the licensee make its source code publicly available if the licensee creates modifications or derivative works using such open source software, depending on the type of open source software the licensee uses and how the licensee uses it. If we combine our proprietary software with open source software in a certain manner, we could, under certain open source software licenses, be required to make available the source code of certain of our proprietary software to the public for free. This could allow our competitors to create similar products with less development effort and time and ultimately could result in a loss of product sales and revenue. In addition, some companies that use third-party open source software have faced claims challenging their use of such open source software and their compliance with the terms of the applicable open source license. We may be subject to suits by third parties claiming ownership of what we believe to be open source software or claiming non-compliance with the applicable open source licensing terms. Use of open source software may also present additional security risks because the public availability of such software may make it easier for hackers and other third parties to compromise or attempt to compromise our technology platform and systems.

Although we typically review our use of open source software to avoid subjecting our products, services or technology to conditions we do not intend, the terms of many open source software licenses have not been interpreted by U.S. courts, and there is a risk that these licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to commercialize our products, services or technology. Moreover, our processes for monitoring and controlling our use of open source software in our products, services or technology may not be effective. If we are held to have breached the terms of an open source software license, we could be required to seek licenses from third parties to continue offering our solutions on terms that are not economically feasible, to re-engineer our products, services, or technology, to discontinue the sale of our products, services, or technology if re-engineering could not be accomplished on a timely basis, to pay statutory or other damages to the license holder, or to make generally available, in source code form, our proprietary code, any of which could materially adversely affect our business, financial condition, results of operations, and prospects.

Risks Relating to Financial and Accounting Matters

Our ability to utilize our net operating loss carryforwards and research and development tax credits may be limited.

We have experienced net operating losses ("NOLs") for tax purposes since our inception. Under the Federal Tax Cuts and Jobs Act of 2017, NOLs incurred in tax years beginning on or after January 1, 2018, are carried forward indefinitely and are subject to a usage limitation of 80% of taxable income. NOLs incurred in tax years prior to January 1, 2018, are subject to a twenty-year carryforward period before expiring but are not subject to a usage limitation based on taxable income.

Utilization of NOL carryforwards and research and development tax credit carryforwards may be subject to substantial annual limitations under Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"), or, for states, under state laws, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. We have not conducted a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since inception. If we have experienced an ownership change, as defined by Section 382, at any time since inception, utilization of the NOL carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in the expiration of a portion of the NOL carryforwards or research and development tax credit carryforwards before utilization.

The inability to fully utilize the NOL carryforwards and research and development tax credits could adversely affect our financial position and results of operations. If we are unable to generate sufficient taxable income in future periods to utilize the NOL carryforwards and research and development tax credit carryforwards before they expire, we may incur higher tax liabilities, which could have a material adverse effect on our business, financial condition, and results of operations.

We have identified two material weaknesses in our internal control over financial reporting. These material weaknesses could adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our management is likewise required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses identified through such evaluation in those internal controls. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

We identified two material weaknesses in our internal control over financial reporting.

The first material weakness relates to our failure to design or maintain sufficient controls over implementation of information technology general controls or complementary user entity controls for applications (such as our legacy enterprise resource planning ("ERP"), payroll and stock option management IT systems) used in the preparation of our financial statements. More specifically, we did not design or maintain sufficient controls related to user access provisioning and monitoring, change management, program development and data management.

The second material weakness relates to a lack of segregation of duties in the financial reporting function due to a limited number of staff performing the financial reporting function. More specifically, there is a limited level of multiple reviews among those tasked with preparing our financial records and with respect to our legacy ERP

system proper segregation of duties was not enforced (i.e., for journal entries, we did not always delegate different individuals for the entry process and for approving the journal entry).

Any failure to remediate these material weaknesses could adversely impact our ability to report our financial position and results from operations on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations. Likewise, if our financial statements are not filed on a timely basis, we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities. Either of the foregoing could have a material adverse effect on our business. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our securities.

We can give no assurance that the measures we have taken and plan to take in the future will remediate the material weaknesses identified or that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our financial statements.

We may face litigation and other risks as a result of the material weaknesses in our internal control over financial reporting.

As a result of such material weaknesses and other matters raised or that may in the future be raised by the SEC, we face potential for litigation or other disputes which may include, among others, claims invoking the federal and state securities laws, contractual claims or other claims arising from the restatement and material weaknesses in our internal control over financial reporting and the preparation of our financial statements. Any such litigation or dispute, whether successful or not, could have a material adverse effect on our business, results of operations and financial condition.

Risks Relating to Our Common Stock

We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act. We will remain an “emerging growth company” until the earliest to occur of:

- the last day of the fiscal year during which our total annual revenue equals or exceeds $1.235 billion (subject to adjustment for inflation);
- the last day of the fiscal year following the fifth anniversary of our IPO;
- the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt; or
- the date on which we are deemed to be a “large accelerated filer” under the Exchange Act.

As a result of our “emerging growth company” status, we may take advantage of exemptions from various reporting requirements that would otherwise be applicable to public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates plus the aggregate amount of gross proceeds to us as a result our IPO is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million.

If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our annual report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. Investors may find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the market price of our common stock may be adversely affected and more volatile.

We will incur increased costs and are subject to additional regulations and requirements as a result of operating as a public company, which could lower our profits or make it more difficult to run our business.

As a public company, we will incur significant legal, accounting, and other expenses that we have not incurred as a private company, including costs associated with public company reporting requirements. We will also incur costs associated with the Sarbanes-Oxley Act and related rules implemented by the SEC and The Nasdaq Stock Market, LLC. The expenses generally incurred by public companies for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations also could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage.

These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions, other regulatory action, and potentially civil litigation.

If we are unable to design, implement, and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may decline.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. In addition, beginning with our second annual report on Form 10-K, we will be required to furnish a report by management on the effectiveness of our internal control over financial reporting, pursuant to the rules and regulations of the SEC regarding compliance with Section 404 of the Sarbanes-Oxley Act. The process of designing, implementing and testing the internal control over financial reporting required to comply with this obligation is time consuming, costly and complicated. See the risk factor titled “We have identified two material weaknesses in our internal control over financial reporting. These material weaknesses could adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.” Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows.

Further, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we or, if required, our auditors, are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market

price of our common stock could decline, and we could also become subject to investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities, which could require additional financial and management resources. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

In addition, as we continue to scale and improve our operations, including our internal systems and processes, we are currently evaluating the implementation of a variety of critical systems, such as supply chain management, customer relationship management, billing and human resource information systems. We cannot assure you that new systems, including any increases in scale or related improvements, will be successfully implemented or that appropriate personnel will be available to facilitate and manage these processes. Failure to implement necessary systems and procedures, transition to new systems and processes or hire the necessary personnel could result in higher costs, compromised internal reporting and processes and system errors or failures. For example, in the third quarter of 2026, we replaced our legacy ERP system, which facilitates orderly maintenance of books and records with a new ERP system. ERP system implementations are complex projects that require significant investment of capital and human resources, the reengineering of many business processes and the attention of many employees who would otherwise be focused on other aspects of our business. If the new ERP system or any other new critical system does not work as planned, or if we experience issues related to the transition, including data migration errors or difficulties in maintaining effective internal controls during and after the transition, our business and our ability to timely and accurately report our financial results could be adversely affected, which could have a material adverse effect on our operations.

We do not intend to pay dividends in the foreseeable future. As a result, your ability to achieve a return on your investment will depend on appreciation in the market price of our common stock.

We have never declared or paid cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination related to dividend policy will be made at the discretion of our board of directors, subject to applicable laws, and will depend upon, among other factors, our results of operations, prospects, financial condition, contractual restrictions and capital requirements. In addition, our ability to pay cash dividends on our capital stock may be limited by the terms of any future debt or preferred securities we issue or any future credit facilities we enter into.

Accordingly, investors must for the foreseeable future rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

We may require additional capital to support business growth, and this capital might not be available on terms favorable to us, or at all, and may dilute existing stockholders' ownership of our common stock.

We intend to continue to make investments to support our business growth and may require additional funds to respond to business challenges and opportunities, including the need to advance clinical studies and pursue regulatory clearances for new or next-generation product pipeline. The scope, cost, timeline of these clinical development efforts are inherently uncertain, there can be no assurance that such efforts will yield successful outcomes or that the capital resources required to fund them will not exceed our current expectations. Accordingly, we may need to engage in equity or debt financings to secure additional funds. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Sales of our common stock under the ATM Program, which may be made from time to time at prevailing market prices, will also dilute our existing stockholders. In addition, the incurrence of indebtedness would increase our fixed obligations and include covenants or other restrictions that would impede our ability to manage our operations. Further, if additional financing is needed, we may not be able to obtain additional financing on terms favorable to us or at all. Our inability to obtain adequate financing or financing on terms satisfactory to us, when we require it, could significantly limit our ability to continue supporting our business growth and advancing our new or next-generation product pipeline.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. Lock-up agreements covering approximately 41.1 million pre-IPO shares of our outstanding common stock entered into in connection with our initial public offering expired in early January 2026 and these shares may now be sold, subject to any applicable volume limitations under federal securities laws, at any time. In addition, the shares issued in the Private Placement have been registered for resale, the shares issued in the Registered Direct Offering were issued under a shelf registration statement, and additional shares may be sold by us under the ATM Program from time to time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly and impair our ability to raise adequate capital through the sale of additional equity or equity-linked securities at a time and price that we deem appropriate. If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market , the trading price of our common stock could decline.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions include the following:

- A classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- No cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- The exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death, or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- The ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- The ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- The required approval of at least 66⅔% of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or to repeal certain provisions of our amended and restated certificate of incorporation;
- A prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- The requirement that a special meeting of stockholders may be called only by our board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- Advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may

discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the General Corporation Law of the State of Delaware (the "Delaware General Corporation Law"). Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Claims for indemnification by our directors, officers, and other employees or agents may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors, officers and certain other employees provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.

- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.

The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees, and agents and to obtain insurance to indemnify such persons.

- We may not retroactively amend our amended and restated bylaws provisions to reduce our indemnification obligations to directors, officers, employees, and agents.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, or stockholders to us or to our stockholders, any action asserting a claim against us arising pursuant to the Delaware General Corporation

Law, our amended and restated certificate of incorporation, or our amended and restated bylaws (as either may be amended from time to time), or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation also provides that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees, or agents and arising under the Securities Act. Nothing in our amended and restated certificate of incorporation or amended and restated bylaws precludes stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

If any action the subject matter of which is within the scope described above is filed in a court other than a court located within the State of Delaware (a "Foreign Action"), in the name of any stockholder, such stockholder shall be deemed to have consented to the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce the applicable provisions of our amended and restated certificate of incorporation and having service of process made upon such stockholder in any such action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder. Although our amended and restated certificate of incorporation contains the choice of forum provision described above, it is possible that a court could find that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums, and protection against the burdens of multi-forum litigation. However, this choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees, or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. In addition, this choice of forum provision may result in increased costs for stockholders to bring a claim. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable.

The market price of our common stock may be volatile, which could cause the value of your investment to decline.

The market price of our common stock may be highly volatile and could be subject to wide fluctuations. Securities markets worldwide experience significant price and volume fluctuations. This market volatility, as well as general economic, market, or political conditions, could reduce the market price of our common stock regardless of our operating performance. In addition, our results of operations could be below the expectations of public market analysts and investors due to a number of potential factors, including variations in our quarterly results of operations, additions or departures of key management personnel, failure to meet analysts' earnings estimates, publication of research reports about our industry, litigation and government investigations, data privacy and security-related events, changes or proposed changes in laws or regulations or differing interpretations or enforcement thereof affecting our business, adverse market reaction to any indebtedness we may incur or securities we may issue in the future, changes in market valuations of similar companies or speculation in the press or investment community, announcements by our competitors, adverse publicity about the medical device industry, or individual scandals, and, in response, the market price of our common stock could decrease significantly.

Stock markets experience extreme price and volume fluctuations. In the past, following periods of volatility in the overall market and the market price of a company's securities, securities class action litigation has often been

instituted against these companies. Such litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the market price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our results of operations fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

General Risk Factors

Product and professional liability suits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates.

Our CapsoCam capsules are cleared or authorized by the FDA for specific intended uses. However, if physicians elect to use our products in manners outside of these intended uses, such use may result in adverse outcomes and may pose significant risks, especially for individuals with known or suspected gastrointestinal obstructions, strictures, or fistulas, as the capsule may become lodged, potentially leading to an obstruction that requires urgent medical or surgical intervention. We cannot prevent physicians from using our products off-label or from using non-our products in conjunction with our products. The risk of injury to patients may increase if physicians attempt off-label use. Additionally, we cannot guarantee that physicians are adequately trained by us or their peers before using our products. Complications from off-label use or use by untrained physicians may not effectively treat conditions and may expose us to product liability claims or litigation, harming our reputation.

The sale and use of our CapsoCam capsules could lead to product or professional liability claims based on allegations that one of our CapsoCam capsules contained a design or manufacturing defect, which resulted in the failure to detect the disease for which it was designed. A product or professional liability claim could result in substantial damages and be costly and time-consuming to defend, either of which could materially harm our business or financial condition. We cannot assure you that our liability insurance would protect our assets from the financial impact of defending a liability claim.

Any claim brought against us, with or without merit, could increase our liability insurance rates or prevent us from securing insurance coverage in the future. Furthermore, product liability claims could result in negative publicity, injury to our reputation, and loss of revenue. Even successful defense would require significant financial and management resources, which could adversely affect our business, financial condition, results of operations, and prospects.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders and reduce our financial resources.

In the future, we may enter into transactions to acquire other businesses, products, or technologies. Because we have not made any acquisitions to date, our ability to do so successfully is unproven. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors.

We may decide to incur debt in connection with an acquisition or issue our common stock or other securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies, and operations into our existing business in an effective, timely, and non-disruptive manner.

We or the third parties we depend on may be adversely affected by natural disasters and other catastrophic events, and our business continuity and disaster recovery plans may not adequately protect us from a serious natural disaster or other catastrophic event. Any interruption in our operations or the operations of third parties who supply components or other materials for our products may have a material adverse effect on our business, financial condition, results of operations, and prospects.

Severe weather, natural disasters and other catastrophic events, including pandemics or other public health crises (such as the COVID-19 pandemic), earthquakes, tsunamis, hurricanes, floods, fires, explosions, accidents, power outages, cyber attacks, telecommunications failures, mechanical failures, unscheduled downtimes, civil unrest, strikes, transportation interruptions, unpermitted discharges or releases of toxic or hazardous substances, other environmental risks, wars or other conflicts (including wars in Ukraine and the Middle East), sabotage, terrorist attacks, or other intentional acts of vandalism or misconduct could severely disrupt our operations, or the operations of third parties who manufacture or supply components or other materials for our products, and have a material adverse effect on our business, financial condition, results of operations, and prospects.

If a natural disaster or other catastrophic event occurs that prevents us or third-party suppliers or manufacturers from using all or a significant portion of our or their headquarters or other facilities, that damages critical infrastructure or that otherwise disrupts operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar catastrophic event. The potential impact of any disruption would depend on the nature and extent of the damage caused by a disaster. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, our corporate headquarters and manufacturing facilities are located in Saratoga, California, near major earthquake faults and fire zones. We do not carry earthquake insurance. Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen, and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sale of Equity Securities

None.

Use of Proceeds from Initial Public Offering

Not Applicable.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other *Information*

Rule 10b5-1 Trading Plans

During the quarter ended September 30, 2026, none of our directors or officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended) adopted, modified or terminated a “Rule 10b5-1 (c) trading arrangement” or a “non-Rule 10b5-1 trading arrangement”, as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on July 3, 2025 (File No. 001-42705)).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on July 3, 2025 (File No. 001-42705)).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 2 to the Registrant's Registration Statement (File No. 333-287148), filed on June 13, 2025).
4.2	Amended and Restated Investors' Rights Agreement, dated November 21, 2019 (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on the Registrant's Registration Statement (File No. 333-287148), filed on May 9, 2025).
4.3	Form of Representative's Warrant (incorporated by reference to Exhibit 4.3 to Amendment No. 3 to the Registrant's Registration Statement (File No. 333-287148), filed on June 27, 2025).
10.1*	Controlled Equity OfferingSM Sales Agreement, dated August 13, 2026, by and between CapsoVision, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-42705) filed on August 13, 2026).
10.2*	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-42705) filed on September 18, 2026).
10.3#	Amended and Restated Consulting Agreement with Joanne C. Imperial MD, dated as of July 2, 2026 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-42705) filed on July 2, 2026).
10.4#	Consulting Agreement with David S. Shields MD, dated as of July 2, 2026 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-42705) filed on July 2, 2026).
31.1†	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2†	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1††	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2††	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Cover Page Interactive Data File (embedded within the Inline XBRL document).
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

† Filed herewith

†† Furnished herewith

* Certain personally identifiable information of this exhibit has been omitted pursuant to Item 601(a)(6) of Regulation S-K.

# Indicates management contract or compensatory plan.

SIGNATURES

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

CAPSOVISION, INC.

Date: November 12, 2026

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

Kang-Huai (Johnny) Wang
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2026

By: /s/ David Garcia

David Garcia
Senior VP of Finance
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kang-Huai (Johnny) Wang, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CapsoVision, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2026

/s/ Kang-Huai (Johnny) Wang

Kang-Huai (Johnny) Wang

Director, President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David Garcia, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CapsoVision, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2026

/s/ David Garcia

David Garcia

Senior VP of Finance
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of CapsoVision, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Periodic Report"), I certify pursuant to 18 U.S.C. §1350, as adopted by pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Periodic Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2026

/s/ Kang-Huai (Johnny) Wang

Kang-Huai (Johnny) Wang

Director, President and Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of CapsoVision, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Periodic Report"), I certify pursuant to 18 U.S.C. §1350, as adopted by pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Periodic Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2026

/s/ David Garcia

David Garcia

Senior VP of Finance
(Principal Financial Officer and Principal Accounting Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.