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

DIVISION OF
CORPORATION FINANCE

March 7, 2025

Kang-Huai Wang
Chief Executive Officer
CapsoVision, Inc.
18805 Cox Avenue, Suite 250
Saratoga, CA 95070

Re: CapsoVision, Inc.
Draft Registration Statement on Form S-1
Submitted February 7, 2025
CIK No. 0001378325

Dear Kang-Huai Wang:

We have reviewed your draft registration statement and have the following comments.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe a comment applies to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to this letter and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1 submitted February 7, 2025

Prospectus Summary, page 1

1. Please balance your disclosure in the Prospectus Summary with equally prominent disclosure of the limitations you face in implementing your business strategy and gaining market acceptance, including, but not limited to the competition from companies in the capsule endoscopy market that are developing or have already established a market presence with FDA-cleared devices; your history of operating losses; and the going concern opinion provided by the company's auditors in relation to your audited financial statements for the year ended December 31, 2023.
2. We note your disclosure on page 113 that your CapsoCam Plus product is currently classified as a Class II device and has received FDA marketing authorization through the 510(k) clearance process. Please revise to include disclosure of the Class II

classification in the Summary as well. Please also disclose the FDA classification for your CapsoCam Colon product.

Market Overview
Overview and Challenges of Detecting Colon Polyps, page 2

3. Here, and throughout your filing, including your description of business and the market in which you intend to operate, when referring to a statistic that is not common knowledge, a research article, or clinical trial, please cite the source and, at first instance, provide a summary of the material findings. For example only, you disclose that "[e]ach year in the U.S., there are approximately 153,000 new cases of CRC and approximately 53,000 deaths." Please provide appropriate sources for these and other, relevant statements throughout the filing, or characterize the same as management's opinions or beliefs, where appropriate.

Our Growth Strategies, page 4

4. We note your disclosure that your goal is to obtain 510(k) clearance for your updated CapsoCam Plus product from the FDA in late 2025. When discussing FDA or other regulatory approvals, please revise to include a statement acknowledging that FDA or other regulatory agency, foreign or domestic, approval is not guaranteed and may take longer than planned. Further, when discussing trials, please revise to state that there is no guarantee that the trials will produce positive results or that the results will support the company's claims. Please make conforming changes throughout your filing.

Government Regulation, page 12

5. We refer to your disclosure throughout the registration statement that you began commercial sales of your small bowel CapsoCam capsule system in Europe in 2012. Please revise your disclosure in this section to discuss any regulatory requirements you may be subject to in Europe.

Our amended and restated certificate of incorporation will provide that..., page 55

6. We note your disclosure that the choice of forum provision in your amended and restated certificate of incorporation may limit a shareholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with you and may discourage such lawsuits. Please revise this risk factor and your disclosure in the Business section to disclose that there is also a risk that your choice of forum selection provision may result in increased costs for investors to bring a claim.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations, page 68

7. Where you describe two or more business reasons that contributed to a material change in a financial statement line item between periods, please quantify, where possible, the extent to which each factor contributed to the overall change in that line item, including any offsetting factors. For your discussion of revenue fluctuations, explain the context around the generic reference to "acceptance of CapsoCam Plus" and "growth in the small-bowel capsule endoscopy" and quantify the impact of domestic versus international sales fluctuations during the periods presented. In

addition, where you identify intermediate causes of changes in your operating results, also describe the reasons underlying the intermediate causes. Please ensure that you explain in sufficient detail the reasons driving the changes in your results of operations and that your overall revised disclosures assist in satisfying the requirements of Item 303(a)-(b) of Regulation S-K and the three principal objectives of MD&A:

- to provide a narrative explanation of a company's financial statements that enables investors to see the company through the eyes of management;
- to enhance the overall financial disclosure and provide the context within which financial information should be analyzed; and
- to provide information about the quality of, and potential variability of, a company's earnings and cash flow, so that investors can ascertain the likelihood that past performance is indicative of future performance.

Business, page 78

8. We refer to your disclosure on page 83 and elsewhere in the registration statement that "prior studies have demonstrated the CapsoCam's superior detection of the normal papilla relative to non-panoramic systems." Please clarify whether you have conducted a head-to-head clinical trial comparing CapsoCam with other competing endoscopy devices, and if so, please revise to include a discussion of the scope, size and design of the head-to-head study in this section. If you have not conducted a head-to-head clinical trial, please expand your disclosure of these prior studies and discuss any known differences in trial protocols, conditions and patient populations that could materially impact the comparability of the trial data presented.
9. We note your disclosure of your plans to submit to the FDA the clinical results of the first arm of our CapsoCam Colon pivotal study in a 510(k) submission and to seek FDA 510(k) clearance for the use of AI in CapsoCam Plus in the first half of 2025. You also state that you plan to commence clinical investigation of CapsoCam's accuracy in detecting abnormalities indicative of pancreatic neoplasia and screening esophageal varices in cirrhotic patients. Please revise to provide greater detail of the current status and expected timeline of your studies and clinical investigations.

Our Program, page 81

10. We note your disclosure that you have completed the feasibility and pilot studies for your CapsoCam Colon capsule endoscopy system. Please revise to specify when you completed these studies.

Pivotal Study, page 98

11. We refer to your disclosure of the pivotal study for your CapsoCam Colon that was completed in 2021. Please revise to clarify whether the pivotal study was powered for statistical significance, and if so, please expand your discussion of the statistical significance and p-values and revise your characterizations of the study to discuss the data, rather than drawing conclusions from the results.

Exclusive Distribution Agreements, page 102

12. We note your disclosure that you have had approximately 50 exclusive distributors covering multiple non-U.S. countries or regions, including Europe and Africa, and one exclusive distributor for sales of your CapsoCam capsule for the veterinary market worldwide. Please revise your disclosure to specify the jurisdictions in which these regional distributors operate and clearly state whether you have entered into any distribution agreements or other types of firm commitment arrangements with these regional distributors. If you have entered into distribution agreements, please expand your disclosure to provide a brief description of the material terms of such agreement and file the agreement as an exhibit to your registration as required by Item 601(b)(10) of Regulation S-K, or tell us why you believe you are not required to do so.

Manufacturing and Supply, page 104

13. We note your disclosure on page 104 that you have entered into a development agreement with Toshiba Corporation and a development and manufacturing agreement with Moai Electronics Corporation. Please expand your disclosure to ensure all material terms of these agreements are described, including, without limitation, any minimum purchase commitments and the termination provisions.

Intellectual Property, page 106

14. We refer to your disclosure of your patent portfolio. Please revise your disclosure to identify the type of patent protection (such as composition matter, use, or process) for each patent and pending patent application.

Facilities, page 112

15. We note your disclosure here that you lease two office facilities in Taiwan, one of which expired on February 14, 2025. Please revise to disclose whether you renewed your expired lease in Taiwan.

State Corporate Practice of Medicine and Fee-Splitting Laws, page 119

16. We note your disclosure that you have entered into arrangements with contracted telemedicine providers. Please revise to briefly describe the material terms of these agreements are described, including, without limitation, the term of the agreement and the termination provisions. Please also file the agreement as an exhibit to the registration statement or explain to us why you are not required to do so. Refer to Item 601(b)(10) of Regulation S-K.

Employment Agreements, page 128

17. We note your disclosure that "[you] have entered into offer letter with each of the NEOs..." Please revise to describe the material terms of these agreements, including but not limited to any termination provisions, and file the actual agreements rather than the form of employment agreement as exhibits to your registration statement. Refer to Item 601(b)(10) of Regulation S-K.

Transactions with VeriSilicon, page 134

18. We refer to your disclosure on page 134 that you entered into the ASIC Design, Manufacturing and Product Sales Agreement with VerSilicon, Inc. in May 2022. Please revise to briefly describe the material terms of the VerSilicon agreement and file the agreement as an exhibit to your registration statement or explain to us why you believe you are not required to do so. Refer to Item 601(b)(10) of Regulation S-K.

Financial Statements
Revenue Recognition, page F-11

19. We note that your contracts with customers contain both fixed and variable consideration. Please expand your disclosures for variable consideration to identify each type of variable consideration you estimate and to provide the disclosures required by ASC 606-10-50-1(b), 50-17 and 50-20.

20. Please describe in further detail the payment terms you offer your customers, the rights of return you offer your customers, and any warranties you offer them. Separately provide the information for group purchasing organizations if the information differs between your different categories of customers. Refer to ASC 606-10-50-12.

6. Revenue and Deferred Revenue, page F-20

21. Please separately disclose revenues attributable any individual foreign country, if material. Refer to ASC 280-10-50-41(a).

General

22. Please provide us with supplemental copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, have presented or expect to present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not you retained, or intend to retain, copies of the communications.

Please contact Kristin Lochhead at 202-551-3664 or Michael Fay at 202-551-3812 if you have questions regarding comments on the financial statements and related matters. Please contact Robert Augustin at 202-551-8483 or Jane Park at 202-551-7439 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Industrial Applications and Services

cc: Portia Ku, Esq.