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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 17, 2023

MOTUS GI HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38389**	**81-4042793**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(IRS Employer Identification No.)*

1301 East Broward Boulevard, 3rd Floor Ft. Lauderdale, FL	**33301**
(Address of principal executive offices)	*(Zip Code)*

Registrant's telephone number, including area code: **(954) 541-8000**

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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. ☒

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

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchanged on Which Registered**
Common Stock, $0.0001 par value per share	MOTS	The Nasdaq Capital Market

Item 7.01. Regulation FD.

On May 17, 2023, Motus GI Holdings, Inc. (the "Company") issued a press release announcing the initiation of a clinical evaluation of the Pure-Vu Gen 4 Gastro, which is designed for upper gastrointestinal (GI) bleeding procedures, in collaboration with the Ecuadorian Institute of Digestive Diseases (IECED). A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01 Other Events.

On May 17, 2023, the Company issued a press release announcing the initiation of a clinical evaluation of the Pure-Vu Gen 4 Gastro, which is designed for upper GI bleeding procedures, in collaboration with the IECED. The Pure-Vu Gen 4 Gastro builds off the success of the patented and proprietary pulsed vortex irrigation and smart sense suction used in the colon device, and has been enhanced to target blood and blood clots in the upper GI tract. The system has been further streamlined to allow for easy navigation through the GI tract and allows the physician to grip the endoscope directly so that there is virtually no ergonomic impact in performing a procedure.

Item 9.01. Financial Statements and Exhibits.

(d) The following exhibit is furnished with this report:

Exhibit No.	Description
99.1	Press Release issued by Motus GI Holdings, Inc., dated May 17, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

MOTUS GI HOLDINGS, INC.

Dated: May 17, 2023

By: */s/ Mark Pomeranz*
Name: Mark Pomeranz
Title: Chief Executive Officer

Exhibit 99.1

Motus GI Completes First Clinical Evaluation of New Pure-Vu® Gastro in Upper Gastrointestinal (GI) Procedures to Support FDA Submission

- *Pure-Vu Gastro achieves high usability scores in supporting upper endoscopy procedures with first time users*
- *On track to submit a 510(k) to the U.S. FDA for the Pure-Vu Gen 4 Gastro device in Q4 2023 to support the 400,000 upper GI bleeds and other procedures with impaired visualization in the U.S.*
- *Pure-Vu Gen 4 Gastro to be used during the 9th IECED Live Endoscopy Course 2023 through the Pentax Learning Center in June 2023*

FORT LAUDERDALE, FL, May 17, 2023– Motus GI Holdings, Inc., (NASDAQ: MOTS) ("Motus GI" or the "Company"), a medical technology company providing endoscopy solutions that improve clinical outcomes and enhance the cost-efficiency associated with the diagnosis and management of gastrointestinal conditions, today announced in collaboration with the Ecuadorian Institute of Digestive Diseases (IECED) initiation of a clinical evaluation of the Pure-Vu Gen 4 Gastro, which is designed for upper gastrointestinal (GI) bleeding procedures - an area of high unmet patient need.

"We are excited to initiate this important clinical evaluation of the Pure-Vu Gen 4 Gastro with Dr. Carlos Robles-Medranda and the team at IECED. The focus of these procedures was aimed at evaluating the device's ability to improve a physician's visualization while identifying and treating upper GI bleeds. Dr. Robles-Medranda has already successfully conducted his first series of procedures utilizing the Pure-Vu Gen 4 Gastro and provided positive initial feedback on the device's performance. We plan to submit a 510(k) application to the U.S. FDA for the Pure-Vu Gastro device in Q4 of this year," commented Mark Pomeranz, Chief Executive Officer. "We believe this is a significant potential new market for the Pure-Vu platform."

"We are continuously reviewing new devices and techniques that may allow us to offer more accurate diagnoses for the benefit of patients suffering upper GI bleeds. We believe the Pure-Vu Gen 4 Gastro can be a very useful tool for these difficult procedures in patients with a high rate of mortality. We are also excited about the newest generation of the Pure-Vu device for the colon, which is much lighter then prior generations and navigates the colon similar to a bare scope. We look forward to advancing this study and presenting our findings to the medical community," commented Dr. Robles-Medranda. "As part of our broader evaluation of the new generation of the Pure-Vu System, we will include it in our 9th IECED Live Endoscopy Course 2023 being conducted in June through the Pentax Training Center Ecuador."

This initial clinical evaluation provided excellent insight into the ability of the Pure-Vu Gen 4 Gastro device to navigate and evaluate the entire anatomy in the upper GI tract with usability scores in the very good to excellent range with input from multiple physcians. The procedures in the upper GI tract were efficient for these first time users with the upper procedures averaging only 11 minutes. Simarly in the colon they were able to improve the average Boston Bowel Prep Scale (BBPS) in 9 patients from 5.9 prior to the use of Pure Vu to 8.9 after the use of Pure-Vu with total procedure times averaging 24 minutes (note: the BBPS scale ranges from 0 (extremely dirty) to 9 (pristinely clean). Further evaluations of the Pure-Vu Gen 4 system will continue to evaluate its ability in critical indications like upper GI bleeding and in new therapeutic applications, such as underwater endoscopic mucosal resection.

The Pure-Vu Gen 4 Gastro builds off the success of the patented and proprietary pulsed vortex irrigation and smart sense suction used in the colon device and has been enhanced to target blood and blood clots in the upper GI tract. The system has been further streamlined to allow for easy navigation through the GI tract and allows the physician to grip the endoscope directly so that there is virtually no ergonomic impact in performing a procedure. The Company is also leveraging this Gen 4 technology to enhance the Pure-Vu device in the colon. Both the Pure-Vu Gen 4 Gastro and Colon will utilize the same workstation to create an effective platform to improve visualization in both the upper and lower GI tract to facilitate use in multiple indications.

Upper GI bleeds occurred in the U.S. at a rate of approximately 400,000 cases per year in 2019, according to iData Research Inc. The existence of blood and blood clots in these patients can impair a physician's view, making it difficult to identify the bleed source. We believe removing adherent blood clots from the field of view is a significant need in allowing a physician the ability to identify and treat the bleed source. The mortality rate of this condition can reach up to approximately 10%, as noted in Thad Wilkins, MD, et al., American Family Physician (2012).

IECED is recognized as one of the best Endoscopic Ultrasound (EUS) centers in the world based on EURO EUS 2023. Additionally known as the most advanced gastroenterological and endoscopic center in Latin America, which has state-of-the-art equipment, the only ones endorsed in Ecuador by the World Endoscopy Organization (WEO). IECED, with the objective of providing its best service, is constantly updated with the quality certification under the ISO 9001:2015 standard.

About Motus GI

Motus GI Holdings, Inc. is a medical technology company, with subsidiaries in the U.S. and Israel, providing endoscopy solutions that improve clinical outcomes and enhance the cost-efficiency associated with the diagnosis and management of gastrointestinal conditions.

For more information, visit www.motusgi.com and connect with the Company on Twitter, LinkedIn and Facebook.

Forward-Looking Statements

This press release contains certain forward-looking statements. Forward-looking statements are based on the Company's current expectations and assumptions. The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements. These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms, including without limitation, risks related to the continued impact of the COVID-19 pandemic, risks inherent in the development and commercialization of potential products, possible or assumed future results of operations, business strategies, potential grow opportunities, uncertainty in the timing and results of clinical trials or regulatory approvals, maintenance of intellectual property rights or other risks discussed in the Company's quarterly and annual reports filed with the Securities and Exchange Commission, and its other filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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