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 24, 2022

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 24, 2022, Motus GI Holdings, Inc. (the "Company") issued a press release announcing positive topline data from the European Union Feasibility Study ("EU Study") of the Pure- Vu® System in hard to prepare patients. The data were presented during Digestive Week 2022 with a poster titled "An Intracolonoscopy Bowel Cleansing System For Hard-to-Prepare Patients - a Prospective Multicenter Study (Poster #: Tu1012)." A copy of the press release which includes the poster 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 24, 2022, the Company issued a press release announcing positive topline data from the EU Study of the Pure-Vu® System in hard to prepare patients. The data were presented during Digestive Week 2022 with a poster titled "An Intracolonoscopy Bowel Cleansing System For Hard-to-Prepare Patients - a Prospective Multicenter Study (Poster #: Tu1012)". The Company reported that the Pure-Vu system was able to improve the adequate cleansing rate from 31.8% to 97.7% in patients with a history of poor bowel preparation. The EU study evaluated the safety and efficacy of the Pure-Vu Gen2 system in patients with a history of poor bowel preparation in the last two years and undergoing outpatient screening or surveillance colonoscopy. Patients were prescribed a low volume preparation consisting of 300mL (10.1 oz) split dose sodium picosulfate/magnesium citrate + 2-day low fiber diet, liquid diet upon starting bowel prep along with additional intraprocedural cleansing with the Pure-Vu System. The primary outcome for the study was the percentage of adequately prepared patients as measured by the Boston Bowel Preparation Scale (BBPS) score per segment. The secondary outcomes included cecal intubation rate (CIR), procedure times, and safety.

Results from the study show that the adequate prep rate reached 97.7% in this difficult patient population. The average procedure time was 28.1 minutes, including a mean of 6.6 minutes for cleaning. The study concluded that the Pure-Vu system provides adequate cleaning in patient with a history of poor bowel preparation. In addition, the Pure-Vu system might prevent repeat colonoscopies and clinical admissions for intensified bowel preparation.

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 24, 2022.
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 24, 2022

By: */s/ Timothy P. Moran*
Name: Timothy P. Moran
Title: Chief Executive Officer

Exhibit 99.1

Motus GI Announces Positive Topline Data From EU Study of the Pure-Vu System in Hard-to-Prepare Patients Presented at Digestive Disease Week 2022

- The Pure-Vu system improved the adequate cleansing rate more than 200% to 97.7% in patients with a history of poor bowel preparation

FORT LAUDERDALE, FL, May 24, 2022 – 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, announced today positive topline data from an investigator initiated EU study that show the Pure-Vu system provides adequate cleaning in patients with a history of poor bowel preparation. These data were presented in a poster during Digestive Disease Week 2022.

"We are pleased to report that topline data from the EU study show our Pure-Vu Gen2 system was able to improve the adequate cleansing rate from 31.8% to 97.7% in patients with a history of poor bowel preparation. By allowing physicians to achieve adequate cleaning, and therefore proper visualization in these difficult to prep patients, they can avoid cancelled or incomplete procedures that may need to be rescheduled, which places stress on the patient and the healthcare system," commented Tim Moran, Chief Executive Officer of Motus. "Based on these data, we see a path forward for physicians to adopt a broad plan when scheduling colonoscopies for hard-to-prepare patients that includes having the Pure-Vu system at-the-ready. In addition, we believe that the enhancements provided by our recently launched Pure-Vu EVS system further incentivize physicians to adopt this technology to save time and costs."

The EU study evaluated the safety and efficacy of the Pure-Vu Gen2 system in patients with a history of poor bowel preparation in the last two years and undergoing outpatient screening or surveillance colonoscopy. Patients were prescribed a low volume preparation consisting of 300mL (10.1 oz) split dose sodium picosulfate/magnesium citrate + 2-day low fiber diet, liquid diet upon starting bowel prep along with additional intraprocedural cleansing with the Pure-Vu System. The primary outcome for the study was the percentage of adequately prepared patients as measured by the Boston Bowel Preparation Scale (BBPS) score per segment. The secondary outcomes included cecal intubation rate (CIR), procedure times, and safety.

Results from the study show that the adequate prep rate reached 97.7% in this difficult patient population. The average procedure time was 28.1 minutes, including a mean of 6.6 minutes for cleaning. The study concluded that the Pure-Vu system provides adequate cleaning in patient with a history of poor bowel preparation. In addition, the Pure-Vu system might prevent repeat colonoscopies and clinical admissions for intensified bowel preparation. Since these patients often have a complicated anatomy (scarring after surgery, diverticulosis, etc.), adequate patient selection is advised to avoid incomplete procedures.

The poster titled "An Intracolonoscopy Bowel Cleansing System For Hard-to-Prepare Patients - a Prospective Multicenter Study (Poster #: Tu1012)" was presented by Milou L.M. van Riswijk, MD, PhD candidate gastroenterology and hepatology, during the Clinical Practice IV session at DDW from 12:30 PM to 1:30 PM on Tuesday, May 24, 2022. The poster is available on the publications section of the Motus GI website at (click here).

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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