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): September 8, 2021

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 September 8, 2021, Motus GI Holdings, Inc. (the "Company") issued a press release announcing enrollment of patients at a second site in the European Union (EU) study of the Pure-Vu System, which is evaluating the clinical outcomes in patients with a history of poor bowel preparation using a low volume preparation with limited diet restrictions and the Pure-Vu System. 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 September 8, 2021, the Company announced the enrollment of patients at GastroZentrum Lippe, a private endoscopy clinic in Germany, the second site for the Company's European Union (EU) study of the Pure-Vu System, which is evaluating the clinical outcomes in patients with a history of poor bowel preparation using a low volume preparation with limited diet restrictions and the Pure-Vu System.

Germany is currently the largest colonoscopy market in Europe, with approximately 1.7 million procedures expected to be performed in 2021, according to iData Research Inc.

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 September 8, 2021.
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: September 8, 2021

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

Exhibit 99.1

Motus GI Announces Enrollment of Patients at Second Site in the European Union
Outpatient Study of the Pure-Vu® System

FORT LAUDERDALE, FL, September 8, 2021 – 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 that GastroZentrum Lippe, one of the top private endoscopy clinics in Germany, has enrolled patients into the European Union (EU) outpatient study of the Pure-Vu System, which is evaluating the clinical outcomes in patients with a history of poor bowel preparation using a low volume preparation with limited diet restrictions and the Pure-Vu System. The study was initiated in mid-June 2021 with patients at the Radboud University Medical Center (Netherlands).

"We are pleased to have an opportunity to participate in this study of the Pure-Vu System at the GastroZentrum Lippe, which is one of the first independent GI focused outpatient clinics in Germany. This study offers a path to potentially identifying the Pure-Vu System as a more effective and efficient method to providing quality colonoscopies for patients that have a history of poor bowel preparation. If successful, this study could help change the management of patients who struggle to get an adequately prepped colon due to their age or medical condition," stated Professor Helmut Neumann.

"We are excited to report progress of the EU study highlighted by the enrollment of the initial patients in Germany. Currently, Germany is the largest colonoscopy market in Europe, with approximately 1.7 million procedures expected to be performed in 2021, according to iData Research Inc.," commented Tim Moran, Chief Executive Officer at Motus GI. "We believe the EU study provides increased exposure of the Pure-Vu System to the European gastroenterology community, including leading physicians and hospital administrators, as well as potential EU-based commercialization partners. As such, this is an exciting step towards establishing additional clinical data for the eventual commercial entrance of the Pure-Vu System into the large European market."

The EU study will enroll approximately 44 patients who have a history of poor bowel preparation and are scheduled for either screening, diagnostic, or surveillance colonoscopy across two sites, including the Radboud University Medical Center (Netherlands) and the University Medical Center Mainz (Germany). The patients will undergo a low volume bowel preparation, with just 2x150ml picoprep. The patients will also be allowed to eat a low fiber diet for two days prior to the colonoscopy as opposed to the typical clear liquid diet the day before a colonoscopy. The patients will then receive intra-procedural bowel cleansing with the Pure-Vu System. The primary endpoint for the study is improvement of the bowel preparation from baseline to post procedure as assessed by the Boston Bowel Preparation Scale (BBPS), which assesses the cleanliness of each of the three segments of the colon on a zero to three scale and requires a minimum score of two or better per segment to be considered adequately prepped. The study will also look at key clinical endpoints related to the quality of the examination including detection of critical pathology in the colon.

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 Company's cost reduction plan, the cost savings and the cash expenses related to the implementation of the plan, risks related to the continued impact of the COVID-19 pandemic, risks inherent in the development and commercialization of potential products, 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 Form 10-K filed on March 16, 2021, 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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