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): June 16, 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 June 16, 2021, Motus GI Holdings, Inc. (the "Company") issued a press release announcing enrollment of the first patients 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 June 16, 2021, the Company announced the enrollment of the first patients 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.

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.

The Company believes there is a large potential commercial market opportunity for the Pure-Vu System in the EU. According to iData Research Inc., there were approximately six million colonoscopies conducted in the EU during 2019, making it one of the Company's largest addressable markets.

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 June 16, 2021.

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: June 16, 2021

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

Motus GI Announces First Patients Enrolled in the European Union Feasibility Study of the Pure-Vu® System as a New Method for Bowel Cleansing in Patients With a History of Poor Bowel Preparation

FORT LAUDERDALE, FL, June 16, 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, announced today enrollment of the first patients 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.

"We are excited to initiate this study assessing the ability of the Pure-Vu System to help patients that have a history of poor preparation that has caused failed and repeated procedures. If this study is successful, we believe it could lead the way for our Pure-Vu System to change the management of patients who struggle to get an adequately prepped colon due to their age or medical need and historically have been unable to receive a proper examination. This study is the first to target this high need outpatient population, where we believe reducing the dependency on pre-procedural preparation to facilitate a quality exam is critically important," stated Tim Moran, Chief Executive Officer of Motus GI. "We believe there is a large potential commercial market opportunity for the Pure-Vu System in the EU. According to iData Research Inc., there were approximately six million colonoscopies conducted in the EU during 2019, making it one of our largest addressable markets. We continue to evaluate potential partnership agreements that could best support our success in the EU, while also complementing our commercial activities in the U.S."

"Advancing this study will allow us to further evaluate the potential for the Pure-Vu System to provide patients that struggle with bowel preparation a better solution than a cycle of repeat procedures with arduous preparation regimes to try and get a quality exam, in order to reduce the patients' risk of colorectal cancer is an important medical need. Also, I believe getting these patients on a normal schedule, would not only improve their quality of life but also reduce the burden to the healthcare system by avoiding the cycle of early repeat procedures," commented Peter D. Siersema, MD, PhD, Professor of Endoscopic Gastrointestinal Oncology at the Radboud University Medical Center, Nijmegen, The Netherlands, and Medical Advisor to Motus GI.

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 the Pure-Vu System

The Pure-Vu System integrates with standard and slim colonoscopes, as well as gastroscopes, to improve visualization during colonoscopy and upper gastrointestinal (GI) procedures while preserving established procedural workflow and techniques. Through irrigation and evacuation of debris, the Pure-Vu System is designed to provide better-quality exams. Challenges exist for inpatient colonoscopy and endoscopy, particularly for patients who are elderly, with comorbidities, or active bleeds, where the ability to visualize, diagnose and treat is often compromised due to debris, including fecal matter, blood, or blood clots. Motus GI believes this is especially true in high acuity patients, like upper GI bleeds where the existence of blood and blood clots can impair a physician's view and removing them can be critical in allowing a physician the ability to identify and treat the source of bleeding on a timely basis. Motus GI believes the Pure-Vu System may lead to positive outcomes and lower costs for hospitals by safely and quickly improving visualization of the colon and upper GI tract, enabling effective diagnosis and treatment the first time. In multiple clinical studies to date, involving the treatment of challenging inpatient and outpatient cases, the Pure-Vu System has consistently helped achieve adequate bowel cleanliness rates greater than 95% following a reduced prep regimen. The Pure-Vu System may also be useful in the future as a tool to help reduce user dependency on conventional pre-procedural bowel prep regimens. Based on Motus GI's review and analysis of 2019 market data and 2021 projections for the U.S. and Europe, as obtained from iData Research Inc., it is estimated that during 2021 approximately 1.5 million inpatient colonoscopy procedures will be performed in the U.S. and approximately 4.8 million worldwide. 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 Pure-Vu System is cleared by the U.S. Food and Drug Administration to help facilitate the cleansing of a poorly prepared gastrointestinal tract during colonoscopy and to help facilitate upper GI endoscopy procedures. The Pure-Vu system has received a CE Mark in the EU for use on colonoscopy.

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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