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 3, 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 3, 2021, Motus GI Holdings, Inc. (the "Company") issued a press release announcing the publication of data from the Company's REDUCE ("Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement") study in an article titled, "A multicenter, prospective, inpatient feasibility study to evaluate the use of an intra-colonoscopy cleansing device to optimize colon preparation in hospitalized patients: the REDUCE study" in the peer-reviewed journal BMC Gastroenterology. 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 3, 2021, the Company announced the publication of data from the Company's REDUCE ("Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement") study in an article (the "Article") titled, "A multicenter, prospective, inpatient feasibility study to evaluate the use of an intra-colonoscopy cleansing device to optimize colon preparation in hospitalized patients: the REDUCE study" in the peer-reviewed journal BMC Gastroenterology.

The Company noted evaluations of the data from its REDUCE study continue to support the Company's belief that the Pure-Vu System can improve bowel preparation quality in hospitalized subjects undergoing colonoscopy. The Company believes the Article will assist with educating the market on the potential for the Pure-Vu System to enhance patient care while also lowering costs for hospitals and payers.

The Article suggests clarity of last bowel movement may be a useful indicator in predicting poor bowel preparation. However, larger studies powered to evaluate clinical

outcomes, hospital costs, and blinded BBPS assessments are required to evaluate the significance of these findings.

The Article covers clinical data from the REDUCE study. The REDUCE study was a multi-center inpatient prospective trial designed to evaluate Pure-Vu® System's ability to consistently and reliably improve bowel preparation to facilitate a successful colonoscopy in a timely manner in patients who were indicated for a diagnostic colonoscopy. The study enrolled 95 hospitalized patients on schedule regardless of their level of pre-procedural bowel preparation. The primary endpoint for the study was improvement of 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 0 to 3 scale and requires a minimum score of 2 or better per segment to be considered adequately prepped.

Topline data from the REDUCE study evaluating the Pure-Vu® System was first announced in May 2019 at Digestive Disease Week® 2019 ("DDW").

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 3, 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 3, 2021

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

Motus GI Announces Publication of Pure-Vu® System Clinical Data in Peer-Reviewed Journal BMC Gastroenterology

FORT LAUDERDALE, FL, June 3, 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 the publication of data from the REDUCE ("Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement") study in an article titled, *"A multicenter, prospective, inpatient feasibility study to evaluate the use of an intra-colonoscopy cleansing device to optimize colon preparation in hospitalized patients: the REDUCE study"* in the peer-reviewed journal BMC Gastroenterology. Among the important findings that the Company continues to emphasize since the data from the REDUCE study were first announced is the Pure-Vu system's 97% clinical success rate. The full publication can be found at (click here).

"Evaluation of the data from our REDUCE study continues to support our belief that the Pure-Vu System can significantly improve bowel preparation quality in hospitalized subjects undergoing colonoscopy. Peer-reviewed articles such as this continue to help us educate the market on the potential for the Pure-Vu System to enhance patient care while also lowering costs for hospitals and payers," stated Tim Moran, Chief Executive Officer of Motus GI. "Additionally, an interesting observation noted in this study, subject to additional research, is the potential to use clarity of last bowel movement as a useful indicator in predicting poor bowel preparation."

"In our ongoing efforts to improve bowel preparation for our patients undergoing colonoscopy, we are pleased to see the publication of this compelling data that demonstrates that Pure-Vu can effectively cleanse the entire colon during colonoscopy and was used to achieve a successful procedure 97% of the time in the REDUCE study cases. The sub-analysis that shows a statistically significant correlation of the patient's last bowel movement to adequacy of prep can be instrumental in implementing Pure-Vu into a hospital's protocol with the goal to eliminate costly delays and delayed diagnoses for these inpatients," stated Dr. Jason Samarasena, Associate Clinical Professor of Medicine at the University of California Irvine.

The article covers clinical data from the REDUCE study. Prior to Pure-Vu, adequate cleansing (Boston Bowel Preparation Scale ("BBPS") of ≥ 2) were reported in 60%, 62%, and 47% for the left colon, transverse colon, and right colon segments, respectively. After intra-colonoscopy cleansing with the Pure-Vu System, adequate colon preparation was reported in 100%, 99%, and 97% of the left colon, transverse colon, and right colon segments, respectively.

About the REDUCE Study

The REDUCE ("Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement") study was a multi-center inpatient prospective trial designed to evaluate Pure-Vu® System's ability to consistently and reliably improve bowel preparation to facilitate a successful colonoscopy in a timely manner in patients who were indicated for a diagnostic colonoscopy. The study enrolled 95 hospitalized patients on schedule regardless of their level of pre-procedural bowel preparation. The primary endpoint for the study was improvement of bowel preparation from baseline to post procedure as assessed by the BBPS, which assesses the cleanliness of each of the three segments of the colon on a 0 to 3 scale and requires a minimum score of 2 or better per segment to be considered adequately prepped.

Topline data from the REDUCE study evaluating the Pure-Vu® System was first announced in May 2019 at Digestive Disease Week® 2019 ("DDW").

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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