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): October 26, 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 October 26, 2021, Motus GI Holdings, Inc. (the "Company") issued a press release announcing results from an independent single-center study of the Pure-Vu System as an adjunct to colon cleansing in patients with inadequate bowel preparation (IBP), which were featured in a poster presentation at the 2021 American College of Gastroenterology (ACG) Annual Scientific Meeting. 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 October 26, 2021, the Company announced the presentation of results from an independent single-center study of the Pure-Vu System as an adjunct to colon cleansing in patients with inadequate bowel preparation (IBP) in a poster presentation at the 2021 American College of Gastroenterology (ACG) Annual Scientific Meeting.

In the independent study, the Pure-Vu System was used in 40 patients (14 inpatient procedures (35%) and 26 outpatient procedures (65%)) with IBP to complete the colonoscopy. The indication for colonoscopy was either diagnostic or colorectal cancer (CRC) screening/surveillance. Pure-Vu was used as an adjunct to IBP to allow completion of procedure in 37 patients. In patients with IBP, the mean BBPS score improved from 3.1 (range: 0-6) to 8.5 (range 5-9) after intra-procedural cleansing. Three patients had active lower gastrointestinal bleeding (LGIB), and the Pure-Vu System was used without bowel preparation to promptly detect the etiology and possibly treat. When used in emergency colonoscopy without bowel preparation, procedures could be completed in all three patients detecting and treating diverticular and post-polypectomy bleeding in one patient each and diagnosing severe right sided ischemic colitis in another. The study authors concluded the utility of the Pure-Vu System without prior bowel preparation in LGIB needs further study. Use of Pure-Vu System did not interfere with the performance of endoscopic interventions including biopsy, cold/hot snare

polypectomy, or EMR. Besides minor mucosal trauma in two cases, no major complications were observed with the Pure-Vu System.

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 October 26, 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: October 26, 2021

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

Exhibit 99.1

Motus GI Announces Presentation of Results from Independent Study of Pure-Vu System in IBP Patients at the 2021 ACG Annual Scientific Meeting

FORT LAUDERDALE, FL., October 26, 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 that results from an independent single-center study of the Pure-Vu System as an adjunct to colon cleansing in patients with inadequate bowel preparation (IBP) were featured in a poster presentation at the 2021 American College of Gastroenterology (ACG) Annual Scientific Meeting.

"We are excited to see the positive results of this real-world, independent study of the Pure-Vu System supporting both inpatient and outpatient procedures for screening and emergency colonoscopies at the ACG meeting. While we have conducted extensive research of the Pure-Vu System around inpatient screening colonoscopies following bowel preparation, this evaluation of the Pure-Vu System included three patient cases where the Pure-Vu System was successfully used in emergency colonoscopy without bowel preparation. We believe there is tremendous potential for the Pure-Vu System to support colonoscopies following limited bowel preparation, which supports results from other studies," commented Tim Moran, Director and Chief Executive Officer at Motus GI. "It has been a pleasure working with the GI team at the University of Texas Medical Branch (UTMB) at Galveston as they evaluated the use of the Pure-Vu System as an adjunct to colon cleansing in patients with inadequate bowel preparation."

"We concluded in this study that this device is a very useful tool in colonoscopies with patients with IBP, especially in those with a history of incomplete procedures," stated Dr. Sreeram Parupudi, Professor in the Division of Gastroenterology and Hepatology, Department of Internal Medicine at UTMB in Galveston. "Of the 40 procedures that we completed, the Pure-Vu was used as an adjunct to IBP to allow completion of procedure in 37 patients. Additionally, we successfully completed three procedures without any bowel preparation in patients with lower GI bleeds. We believe that the utility of the Pure-Vu in these types of cases merits further study."

In the study, the Pure-Vu was used in 40 patients (14 inpatient procedures (35%) and 26 outpatient procedures (65%)) with IBP to complete the colonoscopy. The indication for colonoscopy was either diagnostic or colorectal cancer (CRC) screening/surveillance. Pure-Vu was used as an adjunct to IBP to allow completion of procedure in 37 patients. In patients with IBP, the mean BBPS score improved from 3.1 (range: 0-6) to 8.5 (range 5-9) after intra-procedural cleansing. Three patients had active lower gastrointestinal bleeding (LGIB), and Pure-Vu was used without bowel preparation to promptly detect the etiology and possibly treat. When used in emergency colonoscopy without bowel preparation, procedures could be completed in all three patients detecting and treating diverticular and post-polypectomy bleeding in one patient each and diagnosing severe right sided ischemic colitis in another. Use of Pure-Vu did not interfere with the performance of endoscopic interventions including biopsy, cold/hot snare polypectomy, or EMR. Besides minor mucosal trauma in two cases, no major complications were observed with Pure-Vu.

The ACG poster presentation can be viewed on 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 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, 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 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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