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 20, 2019

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 Disclosure.

On May 20, 2019, Motus GI Holdings, Inc. (the "Company") issued a press release announcing clinical results from all patients enrolled in the Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement Study (the "REDUCE Study") evaluating 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 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 Securities Exchange Act of 1934, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01. Other Events

On May 20, 2019, the Company announced clinical results from all patients enrolled in the Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement Study (the "REDUCE study") evaluating the Pure-Vu System.

Study Design

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. One patient was excluded due to the discovery of ulcerative colitis during procedure which was a study exclusion. Ninety-four hospitalized patients (41% females/59% males), mean age 62 years and mean BMI of 28.1 kg/m2 were included in the final analysis.

Primary Endpoint

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"), a validated assessment instrument, 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. The analysis from the REDUCE study showed statistically significant improvement in each colon segment after Pure-Vu System use. The per segment BBPS improved from an average baseline of 1.74, 1.74 and 1.5 to 2.89, 2.91 and 2.86, respectively, with a statistically significant p value of .001 for all three segments of the colon. In the patients that received Pure-Vu System, adequate bowel preparation improved from a baseline of 38% to 96% in segments evaluated.

Other Study Data

Other data collected in the study included rate of patients with successful colonoscopy for the intended indication in the first attempt and safety. The predominate indication for optical colonoscopy ("OC") in the study was GI bleeding, in 65 of the cases (68%). Other indications for OC in the study included iron deficiency anemia, suspected neoplasia/colorectal cancer, abdominal pain/diarrhea, suspected lesion in the colon, and evaluation for transplantation.

A total 84 patients (89.4%) enrolled in the trial had colonoscopies in which the Pure-Vu System was used.In 79 cases (84%), the physician was able to successfully diagnosis or rule out GI bleed in the colon per the patients' colonoscopy indication using only the Pure-Vu System. In two cases (2.1%), diagnosis could not be made due to inadequate prep. In five cases (5.3%), the physician changed from a standard scope with the Pure-Vu System loaded to a slim scope without the Pure-Vu System to help successfully complete the procedure prior to the availability of the Pure-Vu SIim Oversleeve. In four other cases (4.3%) in which a slim scope was used when Pure-Vu Slim was available, the physician chose to use a slim scope without Pure-Vu and successfully completed the procedure. In one case (1.1%) the physician switched to an Enteroscope due to the colon being to long for a standard colonoscope to reach the cecum and successfully completed the procedure. In three cases (3.2%) diagnosis was not reached due to: (a) severe diverticulosis, (b) diagnosis reached with esophagogastroduodenoscopy (EGD) procedure and (c) cecum was reached but the terminal ileum was not intubated. There was one procedure related perforation which required surgical repair, following which the patient was discharged 48 hours post operatively and fully recovered.

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 Holding, Inc. May 20, 2019

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 20, 2019

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by Motus GI Holding, Inc. May 20, 2019

Exhibit 99.1

Motus GI Presents Positive Clinical Results from REDUCE Study Evaluating Pure-Vu® System in Hospitalized Colonoscopy Patients at Digestive Disease Week® 2019

– Pure-Vu® System achieved primary endpoint demonstrating safety and effectiveness, showing statistically significant improvement in bowel cleanliness

– Adequate bowel preparation rate improved from 38% to 96% following use of Pure-Vu® System

– Commercial launch of Pure-Vu® GEN2 in the U.S. hospital market on track for 2019

FORT LAUDERDALE, FL, May 20, 2019 – Motus GI Holdings, Inc., (NASDAQ: MOTS) ("Motus GI" or the "Company"), a medical technology company dedicated to improving clinical outcomes and enhancing the cost-efficiency of colonoscopy, today announced it will present positive full clinical results from the Company's REDUCE ("Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement") study evaluating the Pure-Vu® System at Digestive Disease Week® 2019 ("DDW").

Vladimir Kushnir, M.D., Division of Gastroenterology, Washington University, St. Louis, MO, will present the REDUCE study clinical results poster titled, "*Evaluation of Bowel Cleansing Efficacy in Hospitalized Patient Population Using the Pure-Vu® System"* during the Lower GI 2 session being held today, May 20, 2019 at 12:00 p.m. PDT.

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.

The analysis from the REDUCE study showed statistically significant improvement in each colon segment after Pure-Vu® System use. The per segment BBPS improved from an average baseline of 1.74, 1.74 and 1.5 to 2.89, 2.91 and 2.86, respectively, with a statistically significant *p value* of ..001 for all three segments of the colon. Inpatients that received Pure-Vu® System, adequate bowel preparation improved from a baseline of 38% to 96% in segments evaluated.

"Inadequate bowel preparation affects the quality of a colonoscopy exam and often leads to canceled, delayed and aborted procedures, resulting in prolonged hospitalizations and increased costs. The Pure-Vu® System provides an important innovative solution to address the significant clinical challenges and inefficiencies associated with inadequate prep as witnessed with the positive REDUCE study results," commented Dr. Kushnir. "I believe the Pure-Vu ® System has the potential to improve the care for this challenging patient population."

"We are excited about the results from the REDUCE study. The data further validates that the Pure-Vu® System has the potential to provide a paradigm shifting solution for patients with insufficient bowel prep, enabling physicians and hospital administrators to improve patient care and reduce costs," commented Tim Moran, Chief Executive Officer of Motus GI. "We are on track for the commercial launch of Pure-Vu® GEN2 in 2019. We anticipate the results of the REDUCE study will be an essential part of driving early adoption in the market."

Following the presentation, the poster will be available on Motus GI's website in the Pure-Vu® Publications section. Motus GI also has a booth at DDW located in the Exhibit Hall at Booth #4315.

About Digestive Disease Week®

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place May 18-21, 2019, at the San Diego Convention Center. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

About Motus GI and the Pure-Vu® System

Motus GI Holdings, Inc. is a medical technology company, with subsidiaries in the U.S. and Israel, dedicated to improving clinical outcomes and enhancing the cost-efficiency of colonoscopy. The Company's flagship product is the Pure-Vu ® System, a U.S. FDA cleared medical device indicated to help facilitate the cleaning of a poorly prepared colon during the colonoscopy procedure. The device integrates with standard and slim colonoscopes to enable safe and rapid cleansing during the procedure while preserving established procedural workflow and techniques. The Pure-Vu® System has received CE mark approval in Europe. The Pure-Vu® System is currently being introduced on a pilot basis in the U.S. market, and the Company is planning to initiate a commercial launch focused on the U.S. hospital market in 2019. Challenges with bowel preparation for inpatient colonoscopy represent a significant area of unmet need that directly affects clinical outcomes and increases the cost of care in a market segment that comprises approximately 1.5 million annual procedures in the U.S. and approximately 4 million annual procedures worldwide. Motus GI believes the Pure-Vu ® System may improve outcomes and lower costs for hospitals by reducing the time to successful colonoscopy, minimizing delayed and incomplete procedures, and improving the quality of an exam. In clinical studies to date, the Pure-Vu ® System significantly increased the number of patients with an adequate cleansing level, according to the Boston Bowel Preparation Scale Score, a validated assessment instrument.

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 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 26, 2019, 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.

Investor Contact:
Jenene Thomas
Jenene Thomas Communications, LLC
(833) 475-8247
mots@jtcir.com

Media Contact:
Erich A. Sandoval
Lazar Partners
(917) 497-2867
esandoval@lazarpartners.com