

**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 11, 2023

MOTUS GI HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware

*(State or other jurisdiction
of incorporation)*

001-38389

*(Commission
File Number)*

81-4042793

*(IRS Employer
Identification No.)*

**1301 East Broward Boulevard, 3rd Floor
Ft. Lauderdale, FL**

(Address of principal executive offices)

33301

(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 May 11, 2023, Motus GI Holdings, Inc. (the "Company") issued a press release announcing that an abstract of new clinical data from the University of Minnesota and Minneapolis VA Medical Center (MVA) showing a hospital-wide improvement in the rate of incomplete bowel prep (IBP) for colonoscopies during a 12-month study assessing the Pure-Vu[®] EVS was selected for an oral presentation during Digestive Disease Week 2023, which was held May 6 - 9, 2023 in Chicago, IL. 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 May 11, 2023, the Company announced that an abstract of new clinical data from the MVA which showed a hospital-wide improvement in the rate of incomplete bowel prep (IBP) for colonoscopies during a 12-month study assessing the Pure-Vu[®] EVS was selected for an oral presentation during Digestive Disease Week 2023, which was held May 6 - 9, 2023 in Chicago, IL. Data from the investigator-initiated study show that, six months after the implementation of the Pure-Vu EVS, the MVA's rate of patients with IBP improved to 5.9% (69 patients out of 1,169 total) compared with 9.3% (111 patients out of 1,198 total) for the preceding six months.

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 May 11, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

2

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 11, 2023

By: /s/ Mark Pomeranz

Name: Mark Pomeranz

Title: Chief Executive Officer

3



Motus GI Announces DDW 2023 Clinical Study Presentation Showing Pure-Vu EVS Drove a 33% Hospital-Wide Improvement in Incomplete Bowel Prep Rate at Minneapolis VA Medical Center

- *Study demonstrates the real-world effects Pure-Vu EVS had at a major hospital center after implementation, showing a decrease in canceled and poor quality procedures, leading to improved resource utilization and patient experience*

FORT LAUDERDALE, FL, May 11, 2023 – 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 an abstract of new clinical data from the University of Minnesota and Minneapolis VA Medical Center (MVA) showing a hospital-wide improvement in the rate of incomplete bowel prep (IBP) for colonoscopies during a 12-month study assessing the Pure-Vu® EVS was selected for an oral presentation during Digestive Disease Week 2023, which was held May 6 - 9, 2023 in Chicago, IL.

Data from the investigator-initiated study show that, six months after the implementation of the Pure-Vu EVS, the MVA’s rate of patients with IBP improved to 5.9% (69 patients out of 1,169 total) compared with 9.3% (111 patients out of 1,198 total) for the preceding six months. The study defined IBP as a Boston Bowel Preparation Score (BBPS) of <6 (out of 9) or poor or inadequate prep using the Aronchick scale exceeding minimum standards. Pure-Vu EVS was used in 46 IBP patients during the six month Pure-Vu phase of the study. Overall procedural success was achieved in 36 of 46 cases (78.3%) that used the Pure-Vu EVS. Most unsuccessful cases (8/9) were either due to patient intolerance of sedation or anatomical reasons (tortuous colon/tight angulation) that would not allow even a standard colonoscope to pass. The cecal intubation rate was 97.3% in successful Pure-Vu EVS cases. The mean BBPS in successful cases improved from 4.8 at the beginning of the procedure to 8.7 after using the Pure-Vu EVS. The study concluded that the MVA’s rate of IBP went from being on the cusp of failing to achieve minimum standard of adequate bowel preparation rate to exceeding minimum standards after the implementation of the Pure-Vu EVS.

“The data presented at DDW this week offer an example of the real-world impact that the Pure-Vu EVS can have at a hospital almost immediately after implementation. Pure-Vu EVS successfully enabled physicians to significantly improve visualization during colonoscopy procedures in patients with IBP, significantly reducing the number of patients with IBP and enabling quality procedures in cases that would otherwise get cancelled or potentially miss critical diagnoses,” commented Mark Pomeranz, Chief Executive Officer. “We believe hospital-wide implementation of Pure-Vu EVS can have important impact in terms of a decreased suboptimal exams or canceled procedures, an improved patient experience, a longer duration of surveillance colonoscopy intervals, and better resource utilization.”

“We believe the data from MVA highlight the benefits Pure Vu can provide to the over 170 VA hospitals across the country. Looking ahead, we are currently working with VAs to be in their 2024 budgets and leveraging Motus GI’s official position as a sole source provider and small business by the VHA, which provides Motus with direct access to the Veterans Health Administration procurement arm, thereby streamlining the purchasing and contracting process with VA hospitals,” stated Mr. Pomeranz.

Tessa Herman, MD, University of Minnesota, discussed these data in an oral presentation at Digestive Disease Week 2023 which was titled, “Improved Rates of Adequate Bowel Preparation After Implementation of an Intra-procedural Cleansing System Over a 12-Month Period At A Single Center.” The slides used during the presentation will be published on the Motus GI Website: https://motusgi.com/site/assets/files/2357/hanson_ddw_2023.pdf. The MVA study is planned for continuation to assess its IBP rates over the next couple of years to control for seasonal changes in overall colonoscopy volume, as well as more experience with the Pure-Vu EVS.



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 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 quarterly and annual reports filed with the Securities and Exchange Commission, 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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