

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 25, 2021

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 25, 2021, Motus GI Holdings, Inc. (the "Company") issued a press release announcing that Sinai Hospital of Baltimore, a LifeBridge Health center, will move ahead with fully adopting 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 May 25, 2021, the Company announced that Sinai Hospital of Baltimore, a LifeBridge Health center, will move ahead with fully adopting the Pure-Vu® System with the aim of improving efficiencies and clinical outcomes of inpatient colonoscopy procedures for patients who present with inadequate bowel preparation.

Sinai Hospital of Baltimore treats many patients coming from nursing facilities with significant comorbidities, which can often make bowel preparation difficult. During the evaluation period, the Company was able to showcase the Pure-Vu System's value proposition by enabling patient cases to proceed on time, despite suboptimal prep. The Company believes engaging with Sinai Hospital of Baltimore is a key milestone for its sales program, as it will be the first hospital within the LifeBridge Health system to adopt the Pure-Vu System. As previously disclosed, the Company is expanding its commercial focus to include large regional, multi-center integrated delivery networks.

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 25, 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: May 25, 2021

By: /s/ Timothy P. Moran

Name: Timothy P. Moran

Title: Chief Executive Officer



Motus GI's Pure-Vu System® Adopted by Sinai Hospital of Baltimore

Implementation of the Pure-Vu System is designed to improve efficiencies and outcomes of GI endoscopy procedures

FORT LAUDERDALE, FL, May 25, 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 Sinai Hospital of Baltimore, a LifeBridge Health center, will move ahead with fully adopting the Pure-Vu® System with the aim of improving efficiencies and clinical outcomes of inpatient colonoscopy procedures for patients who present with inadequate bowel preparation. Sinai Hospital, a nonprofit teaching hospital with renowned Centers of Excellence, is the largest community hospital in Maryland with 483 beds.

Dr. John Rabine, Director of Gastroenterology Diagnostic Center & Chief of GI, Sinai Hospital, stated, "Insufficient bowel preparation for inpatient colonoscopies can limit our visibility and cause delays in both diagnosis and treatment. We are eager to see how this new system's irrigation capabilities improve visualization and may aid our clinicians as they evaluate GI issues, including potential GI bleeds, and save the time needed for additional bowel prep."

"Following a successful evaluation period, we are excited to partner with Dr. Rabine and the GI team at Sinai Hospital to expand the use of the Pure-Vu System for patients in need. Sinai treats many patients coming from nursing facilities that are fairly ill with significant comorbidities, which can often make bowel preparation difficult. During the evaluation period, we were able to showcase the Pure-Vu System's value proposition by enabling such patient cases to proceed on time, despite suboptimal prep," stated Tim Moran, Chief Executive Officer of Motus GI. "Bringing Sinai on board is a key milestone for our sales program, as it will be the first hospital within the LifeBridge Health system to adopt the Pure-Vu System. As we have described previously, we are now expanding our commercial focus to include large regional, multi-center integrated delivery networks."

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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