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): April 30, 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 April 30, 2021, Motus GI Holdings, Inc. (the "Company") issued a press release announcing that the Company has received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for a version of the Pure-Vu System that is compatible with gastroscopes used during upper gastrointestinal (GI) endoscopy procedures. 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 April 30, 2021, the Company announced that it has received 510(k) clearance from the FDA for a version of the Pure-Vu System that is compatible with gastroscopes used during upper gastrointestinal (GI) endoscopy procedures to remove blood, blood clots and debris in order to provide a clear field-of-view for the endoscopist. This proprietary technology is the latest innovation for the Pure-Vu System platform that is specifically designed to integrate with therapeutic gastroscopes to enable safe and rapid cleansing during the procedure, while preserving established procedural workflow and techniques.

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 existence of blood and blood clots in these patients can impair a physician's view, making it difficult to identify the bleed source. The Company believes removing adherent blood clots from the field of view is a significant need in allowing a physician the ability to identify and treat the bleed source. The mortality rate of this condition can reach up to approximately 10%, as noted in Thad Wilkins, MD, et al., American Family Physician (2012).

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 April 30, 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: April 30, 2021

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

Exhibit 99.1

Motus GI Receives FDA Clearance to Market the Pure-Vu® System for Upper GI Endoscopy

FORT LAUDERDALE, FL, April 30, 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 it has received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for a version of the Pure-Vu® System that is compatible with gastroscopes used during upper gastrointestinal (GI) endoscopy procedures to remove blood, blood clots and debris in order to provide a clear field-of-view for the endoscopist. This proprietary technology is the latest innovation for the Pure-Vu System platform that is specifically designed to integrate with therapeutic gastroscopes to enable safe and rapid cleansing during the procedure, while preserving established procedural workflow and techniques.

"We are pleased to receive FDA clearance for the Pure-Vu System now compatible with gastroscopes for the purpose of providing enhanced visibility during upper GI endoscopies. We believe this regulatory milestone broadens our ability to participate in a larger percentage of procedures performed by our key customers, providing us a natural extension of our commercial strategy. In addition, we have received consistent feedback from leading physicians indicating their view that there is a substantial unmet need in this area, particularly for Upper GI Bleed procedures," stated Tim Moran, Chief Executive Officer of Motus GI. "This FDA clearance is a testament to our innovation team's ability to deliver on customer needs in a timely manner."

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 existence of blood and blood clots in these patients can impair a physician's view, making it difficult to identify the bleed source. We believe removing adherent blood clots from the field of view is a significant need in allowing a physician the ability to identify and treat the bleed source. The mortality rate of this condition can reach up to approximately 10%, as noted in Thad Wilkins, MD, et al., American Family Physician (2012).

About the Pure-Vu System

The Pure-Vu System integrates with standard and slim colonoscopes to improve visualization during a colonoscopy while preserving established procedural workflow by irrigating the colon and evacuating debris to provide a better-quality exam. Challenges with bowel preparation for inpatient colonoscopy, particularly patients who are elderly, with comorbidities, or active bleeds, represent a significant area of unmet need that directly affects clinical outcomes and increases the cost of care. 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 for a quality exam 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. Motus GI estimates that in 2021 approximately 4.8 million inpatient colonoscopy procedures will take place worldwide.

The Pure-Vu System has received a CE Mark in the EU and is cleared by the U.S. Food and Drug Administration to help facilitate the cleaning of a poorly prepared colon during the colonoscopy procedure.

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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