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): February 14, 2022

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 February 14, 2022, Motus GI Holdings, Inc. (the "Company") issued a press release announcing that it received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for the Pure-Vu® EVS 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 February 14, 2022, the Company issued a press release announcing that it received 510(k) clearance from the FDA for the Pure-Vu® EVS System. The design of the Pure-Vu EVS System is intended to improve speed of set-up, enhance navigation capabilities in tortuous anatomy, build upon the existing cleansing capabilities of the Pure-Vu system and enable physicians to overcome the challenges of poorly prepared colons during a colonoscopy.

The new Pure-Vu EVS is designed to offer usability advancements over the currently marketed device, including enhanced physician navigation and control, on-demand bedside loading, expanded cleansing capacity, and a smaller workstation footprint. All upgrades are tied to the market development work the Company has done over the last year. The commercial launch of the Pure-Vu EVS in the first quarter of 2022 is anticipated to accelerate adoption in the U.S. and global markets over time. In addition, the

advancements made by the Pure-Vu EVS are expected to support future innovation and indication expansion of the Pure-Vu platform.

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 February 14, 2022.
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: February 14, 2022

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® EVS System

-All New Pure-Vu EVS offers rapid set-up, improved navigation and enhanced cleansing capabilities to support expanded clinical utilization

-Scientific literature shows ~51% of hospitalized inpatient colonoscopies are delayed due to insufficient bowel prep leading to unnecessary extended hospitalizations

-Pure-Vu EVS commercialization in US market expected to commence immediately

FORT LAUDERDALE, FL, February 14, 2022 – 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 it has received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for the Pure-Vu® EVS System. The new Pure-Vu EVS System is intended to improve speed of set-up, enhance navigation capabilities in tortuous anatomy, build upon the excellent cleansing capabilities of the Pure-Vu system and enable physicians to rapidly overcome the challenges of poorly prepared colons during a colonoscopy.

"My experience with the Pure-Vu Gen2 system has allowed me to treat and diagnose patients who otherwise would have been delayed. The new Pure-Vu EVS ergonomics are much better than the current version. The oversleeve and the scope feel much more integrated and it is easier to torque the scope, offering significantly improved navigation," said Scott Larson, MD, Gastroenterologist, Houston, TX.

"Pure-Vu EVS is much easier to use, and will be more physician and technician friendly. The set-up is significantly simpler, and the slimmer, more flexible design felt like I didn't have an oversleeve on my scope," commented Neha Mathur, MD, Gastroenterologist, Houston, TX.

"We believe our Pure-Vu EVS system now offers physicians the right tool to help address challenging colonoscopy procedures. The development and innovation we've implemented in Pure-Vu EVS is the result of listening to valuable feedback from leading physicians and clinical staff that have utilized our Pure-Vu platform. This FDA clearance of Pure-Vu EVS is expected to allow a greater number of physicians and hospitals to bring this important technology to their patients," commented Tim Moran, Chief Executive Officer. "We believe the Pure-Vu EVS enhances every aspect of our system from speed of set-up to procedural ease-of-use, while also offering optimized navigation, handling and cleaning capacity. Additionally, the new EVS oversleeve is able to be loaded on a 'dirty' scope in the procedure room, an important new capability that will allow broader utilization of Pure-Vu to help physicians complete difficult cases and better visualize the colon mucosa. We have also implemented an improved manufacturing cost structure that we believe better positions the Company to broaden commercial utilization, improve margins and establish distribution relationships in more cost sensitive global markets over time."

The Pure-Vu platform facilitates the cleaning of a poorly prepared colon to improve visualization during the colonoscopy procedure. The platform integrates with standard and slim colonoscopes and preserves established procedural workflow by irrigating the colon and evacuating debris to provide a better-quality exam. The new Pure-Vu EVS is designed to offer significant usability advancements over the currently marketed device, including enhanced physician navigation and control, on-demand bedside loading, expanded cleansing capacity, and a smaller workstation footprint. All upgrades are tied to the extensive market development work the Company has done over the last year. The commercial launch of the Pure-Vu EVS in the first quarter of 2022 is anticipated to accelerate speed of adoption in the U.S. and global markets over time. In addition, the advancements made by the Pure-Vu EVS are expected to support future innovation and indication expansion of the Pure-Vu platform.

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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