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): December 21, 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 December 21, 2022, Motus GI Holdings, Inc. (the "Company") issued a press release announcing successful pre-clinical testing of the Pure-Vu EVS System for use in upper gastrointestinal bleeding procedures. The results have demonstrated that the gastro version of the Pure-Vu EVS System can effectively break up and suction blood and blood clots, as well as free up a gastroscope's working channel for other therapeutic tools. 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 December 21, 2022, the Company announced that results from recent pre-clinical testing have demonstrated that the gastro version of the Pure-Vu EVS System can effectively break up and suction blood and blood clots, as well as free up a gastroscope's working channel for other therapeutic tools. Additional pre-clinical and clinical tests of the Pure-Vu EVS System are planned for the first half of 2023. The results of these tests are expected to support the Company's submission of a 510(K) application to the U.S. Food and Drug Administration (FDA) in the second half of 2023.

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 December 21, 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: December 21, 2022

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

Exhibit 99.1

Motus GI Announces Improvement of Pure-Vu® EVS System for Use in Upper Gastrointestinal (GI) Bleeding Procedures Following Successful Pre-Clinical Tests

- Pre-clinical tests show enhanced functionality of Pure-Vu EVS that can enable physicians to overcome common visualization challenges encountered during emergency upper GI bleeding procedures
- Additional pre-clinical and clinical tests of Pure-Vu EVS System are planned in 1H 2023; development program on track to submit 510(K) application to FDA in 2H 2023
- Company intends to evaluate potential strategic distribution and licensing partnerships in U.S. and abroad

FORT LAUDERDALE, FL, December 21, 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 provided an update on the development of its Pure-Vu® EVS system 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.

Recently, the Company successfully completed multiple pre-clinical tests in both porcine and cadaver models to evaluate Pure-Vu EVS platform for use in upper GI bleeding with multiple U.S. physicians. The results of these tests show that the Gastro version of Pure-Vu EVS can effectively break up and suction blood and blood clots, as well as frees up a gastroscope's working channel for other therapeutic tools. By eliminating the need to utilize existing irrigation and suction through the working channel of the gastroscope, physicians can use tools in tandem with Pure-Vu EVS. For example, the use of snares to break up large clots and then immediately suction out the smaller pieces using the large Pure-Vu EVS smart sense suction channel. In addition, during cases with significant bleeding, Pure-Vu EVS allows the physician to clean the area of interest and immediately apply therapy to achieve hemostasis, since the physician can have their therapeutic device prepositioned in the gastroscope's working channel and deliver it before the blood flow covers the area of interest after cleansing.

The Company plans on conducting additional pre-clinical and clinical tests for Pure-Vu EVS Gastro device in the first half of 2023. The results of these tests are expected to support submission of a 510(K) application to the U.S. Food and Drug Administration (FDA) in the second half of 2023.

"We are excited to announce the significant progress we've made in developing our Pure-Vu EVS Gastro for use with both diagnostic and therapeutic gastroscopes in upper GI bleeding procedures. By building off our latest generation of the Pure-Vu platform, and further optimizing it for Upper GI bleeding, the Pure-Vu EVS Gastro will offer many advantages compared to our Gen2 system, including a larger and more powerful suction channel, more efficient irrigation jets, a smaller profile distal tip that offers enhanced flexibility during insertion and even faster set-up," commented Tim Moran, Chief Executive Officer. "Based on our current clinical and regulatory strategy, we believe Pure-Vu EVS Gastro could be ready for U.S. commercial launch in late-2023. Over the coming quarters, we will evaluate enhancing the planned commercial program for Pure-Vu EVS in upper GI through potential strategic distribution and licensing partnerships. Considering the unique capabilities of this proprietary system in the upper GI bleed market, along with the general size of the GI endoscopy market, we believe there may be broad interest in our system especially once it can support procedures in both the Upper and Lower GI tract."

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. Approximately 50% of these patients have blood and blood clots that impair a physician's view during the procedure, thereby making it difficult to rapidly identify the bleeding source. Motus GI 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 13%, as noted in Thad Wilkins, MD, et al., American Family Physician (2012).

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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