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 7, 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 May 7, 2021, Motus GI Holdings, Inc. (the "Company") issued a press release announcing the Publication of a Sponsored Pure-Vu System® Cost Effectiveness Analysis in the Journal of Cost Effectiveness and Resource Allocation. 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 7, 2021, the Company announced the publication of a sponsored Pure-Vu System® Cost Effectiveness Analysis in the Journal of Cost Effectiveness and Resource Allocation, which is titled, "*Colonoscopy in poorly prepped colons. A cost effectiveness analysis comparing standard of care to a new cleansing technology.*" Sponsorship of analysis and development of the manuscript was provided by the Company.

The publication presents new data from a cost effectiveness and resource allocation analysis of the Pure-Vu System® on the outcomes of cost, quality of life, and aversion of colorectal cancers (CRC), as compared to the current standard of care (SOC) for outpatient colonoscopy. The publication suggests use of the Pure-Vu System has the potential to provide the U.S. healthcare system lifetime savings of approximately $833-$992 per patient depending on the insurer compared to the current standard of care for outpatient CRC screening and surveillance colonoscopy.

The publication estimates approximately 3.75 million patients present as inadequately prepared for colonoscopies per year, as calculated based on an estimated 15 million colonoscopies performed annually in the U.S. (according to the 2012 Survey of Endoscopic Capacity (SECAP)), and an estimated 25% of patients presenting as inadequately

prepared for colonoscopies (as reported in a poster presented at the 2011 British Society of Gastroenterology Annual General Meeting; March 14–17, 2011; Birmingham, UK).

The publication also suggests that, assuming a national average compliance rate for colonoscopy in the U.S. at 60%, as reported by the American Cancer Society in 2017, the implementation of the Pure-Vu System may generate significant savings for the U.S. healthcare system and the estimated 3.75 million inadequately prepped patients per year, while potentially reducing the incidence of colorectal cancers as a result of early detection and ensuring a similar or improved quality of life for patients.

The objective of the Markov Model lifetime cost-effectiveness analysis was to evaluate the Pure-Vu System and its ability to minimize repeat colonoscopies on the outcomes of cost, quality of life, and aversion of CRC screening. Researchers evaluated the Pure-Vu® System using TreeAge 2019 software in patients who presented with inadequate prep in outpatient settings in the U.S. Pure-Vu was compared to the SOC for outpatient colonoscopy. Peer reviewed literature was used to identify the CRC incidence of cancers based on missing polyps. Costs for procedures were derived from 2019 Medicare records and from estimated private payer reimbursements. Base case costs, sensitivity analysis and incremental cost effectiveness (ICE) were evaluated. The analysis results suggest that, assuming a national average compliance rate of 60% for colonoscopy, as reported by the American Cancer Society in 2017, the use of the Pure-Vu System has the potential to provide the healthcare system lifetime savings of approximately $833-$992 per patient depending upon the insurer when compared to SOC for outpatient colonoscopy. The analysis results also suggest that, quality of life may be improved with the Pure-Vu System mainly due to a lower incidence of CRCs due to early detection. In the sensitivity analysis, SOC becomes less expensive than Pure-Vu when compliance to screening for CRC using colonoscopy is ≤28% or the cost of Pure-Vu exceeded $1,753. In incremental cost effectiveness analysis, the Pure-Vu System improved over the SOC.

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 7, 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 7, 2021

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

Motus GI Announces Publication of a Pure-Vu System® Cost Effectiveness Analysis in the Journal of Cost Effectiveness and Resource Allocation

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- The article states Pure-Vu System is estimated to provide lifetime saving of $833- $992 per patient when compared to standard of care for outpatient colorectal cancer (CRC) screening and surveillance colonoscopy

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- The researchers indicated that approximately 25% of 15 million outpatient colonoscopies performed annually in the US, or 3.75 million are inadequately prepped

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- The article indicates that quality of life may be improved with the Pure-Vu System due primarily to a potential lower incidence of Colorectal Cancers as a result of early detection.

FORT LAUDERDALE, FL, May 7, 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, today announced the publication of new data from a cost effectiveness and resource allocation analysis of the Pure-Vu System® on the outcomes of cost, quality of life, and aversion of colorectal cancers (CRC), as compared to the current standard of care (SOC) for outpatient colonoscopy in the peer-reviewed journal *Cost Effectiveness and Resource Allocation*. Sponsorship of analysis and development of the manuscript was provided by Motus GI.

The article, which is titled, *"Colonoscopy in poorly prepped colons. A cost effectiveness analysis comparing standard of care to a new cleansing technology,"* concludes that using the Pure-Vu System to improve bowel prep could generate significant savings for the U.S. healthcare system, while potentially ensuring a similar quality of life and reducing the incidence of CRCs. The full publication can be found at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8082895.

"We are delighted that this cost effectiveness analysis of the Pure-Vu System has been accepted for publication in the respected peer-reviewed journal*Cost Effectiveness and Resource Allocation*. There are important and compelling findings outlined in this article that show the use of the Pure-Vu System has the potential to generate lifetime savings of up to $992 per patient compared to the current SOC for outpatient CRC screening and surveillance colonoscopy. Moreover, the conclusion suggests that the implementation of the Pure-Vu System may generate significant savings for the U.S. healthcare system and the more than three million inadequately prepped patients per year, while potentially reducing the incidence of colorectal cancers and ensuring a similar or improved quality of life for patients," commented Tim Moran, Chief Executive Officer, Motus GI.

The article estimates approximately 3.75 million patients present as inadequately prepared for colonoscopies per year, as calculated based on an estimated 15 million colonoscopies performed annually in the U.S. (according to the 2012 Survey of Endoscopic Capacity (SECAP)), and an estimated 25% of patients presenting as inadequately prepared for colonoscopies (as reported in a poster presented at the 2011 British Society of Gastroenterology Annual General Meeting; March 14–17, 2011; Birmingham, UK).

"We believe that the significance of the data presented in this peer-reviewed article may further support our efforts to seek reimbursement coverage from CMS and commercial payers for the Pure-Vu System in the outpatient colorectal cancer screening market," commented Mr. Moran.

The objective of this Markov Model lifetime cost-effectiveness analysis was to evaluate the Pure-Vu System and its ability to minimize repeat colonoscopies on the outcomes of cost, quality of life, and aversion of CRC screening. Researchers evaluated the Pure-Vu® System using TreeAge 2019 software in patients who presented with inadequate prep in outpatient settings in the U.S. Pure-Vu was compared to the SOC for outpatient colonoscopy. Peer reviewed literature was used to identify the CRC incidence of cancers based on missing polyps. Costs for procedures were derived from 2019 Medicare records and from estimated private payer reimbursements. Base case costs, sensitivity analysis and incremental cost effectiveness (ICE) were evaluated. The analysis results suggest that, assuming a national average compliance rate of 60% for colonoscopy, as reported by the American Cancer Society in 2017, the use of the Pure-Vu System has the potential to provide the healthcare system lifetime savings of approximately $833- $992 per patient depending upon the insurer when compared to SOC for outpatient colonoscopy. The analysis results also suggest that, quality of life may be improved with the Pure-Vu System mainly due to a lower incidence of CRCs as a result of early detection. In the sensitivity analysis, SOC becomes less expensive than Pure-Vu when compliance to screening for CRC using colonoscopy is ≤28% or the cost of Pure-Vu exceeded $1,753. In incremental cost effectiveness analysis, the Pure-Vu System improved over the SOC.

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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