

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 10, 2019

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 2.02. Results of Operations and Financial Condition.

Motus GI Holdings, Inc. (the "Company") issued a press release on May 10, 2019, disclosing financial information for its fiscal quarter ended March 31, 2019, and discussing its business outlook. A copy of the Company's press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

See "Item 2.02 Results of Operations and Financial Condition" above.

The information in this Current Report on Form 8-K under Items 2.02 and 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 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 or the Securities Exchange Act of 1934, except as shall be expressly set forth by a specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) The following exhibit is furnished with this report:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Motus GI Holding, Inc. May 10, 2019

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 10, 2019

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Motus GI Holding, Inc. May 10, 2019



Motus GI Reports First Quarter 2019 Financial Results and Provides Corporate Update

– Full clinical results of REDUCE Study to be presented at Digestive Disease Week® 2019

– Pure-Vu® System GEN2 Special 510(k) Notice to FDA Submitted

– Commercial launch of Pure-Vu® System GEN2 in the U.S. hospital market on track for 2019

FORT LAUDERDALE, FL, May 10, 2019 – Motus GI Holdings, Inc., (NASDAQ: MOTS) (“Motus GI” or the “Company”), a medical technology company dedicated to improving clinical outcomes and enhancing the cost-efficiency of colonoscopy, today reported its financial results for the quarter ended March 31, 2019 and provided a corporate update.

“We have been working diligently on key market development activities to prepare for a successful launch of the second generation of the Pure-Vu® System – Pure-Vu® GEN2 — upon approval from the FDA. We continue to build meaningful relationships with world renowned gastroenterologists who have become experts in the use of our system and whom we plan to collaborate with in developing Centers of Excellence as we deploy the Pure-Vu® System in 2019,” commented Tim Moran, Chief Executive Officer of Motus GI. “Additionally, we continue to generate compelling data validating the Pure-Vu® System’s ability to improve clinical and economic outcomes commonly associated with insufficient bowel prep for colonoscopy. We are encouraged by the statistically significant interim data from the REDUCE study conducted in real-world hospital settings and look forward to presenting the full clinical results from the study in May at the 2019 Digestive Disease Week. We are also excited about a number of additional investigator-initiated clinical studies focused on accelerating the time to a successful colonoscopy in inpatients, including our EXPEDITE study, as well as high risk outpatient populations.”

Recent Corporate Highlights

- Announced that REDUCE study per protocol planned interim analysis of the first 45 patients showed statistical significance for the primary endpoint of improvement in bowel cleanliness from baseline.
- Announced its upcoming presentation at Digestive Disease Week® 2019 (“DDW”) of clinical results from all patients enrolled in the REDUCE study evaluating the Pure-Vu® System.
- Strengthened intellectual property portfolio with issuance of additional patents related to the Pure-Vu® System to expand global patent estate to support strategic pathway for the Pure-Vu® System to become standard of care.
- Announced that its manuscript titled, “*An intra-procedural endoscopic cleansing device for achieving adequate colon preparation in poorly prepped patients*,” was published in the peer-reviewed Journal of Clinical Gastroenterology and its manuscript titled, “*A novel device for intra-colonoscopy cleansing of inadequately prepared colonoscopy patients – a feasibility study*,” was published in the peer-reviewed journal, Endoscopy.

Pure-Vu® System Update

Motus GI has submitted the Special 510(k) to the FDA for the Second-Generation Pure-Vu® System (“Pure-Vu® GEN2”). Pure-Vu® GEN2 has been designed to improve the mobility and setup logistics of the system and will retain all the same functionality as the current generation of the Pure-Vu® System in terms of colon cleansing.



The Company is currently focused on post-approval clinical trials and market development programs with leading U.S. hospitals that are utilizing the Pure-Vu[®] System on a pilot basis in preparation for commercial launch in the U.S. The initial launch will focus on the inpatient colonoscopy market where challenges with insufficient bowel prep slow diagnosis, diminish the quality of care, and add significant costs to hospital systems. Motus GI believes that the Pure-Vu[®] System may improve quality of care and potentially reduce healthcare costs by reliably and predictably moving patients through the hospital system to a successful examination.

Clinical Programs Update

Motus GI recently announced it will present clinical results from all patients in its REDUCE (Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement) study at Digestive Disease Week[®] 2019 (“DDW”) in May 2019. The REDUCE study is a multi-center inpatient prospective trial designed to evaluate the Pure-Vu[®] System’s ability to consistently and reliably cleanse the colon to facilitate a successful colonoscopy a timely manner in patients who are indicated for a diagnostic colonoscopy. The primary endpoint of the study is to determine the Pure-Vu[®] System’s rate of improved bowel cleansing level using the BBPS index for all segments examined. The data being presented is embargoed until the day of the presentation. Following the presentation, the poster will be available in the [Pure-Vu[®] Publications](#) section on Motus GI’s [website](#).

The Company previously reported that per protocol planned interim analysis of the first 45 patients showed statistical significance for the primary endpoint of improvement in the BBPS for segments of the colon that were examined. Other key data being collected in the study includes the proportion of patients who receive a successful colonoscopy for the intended indication in the first attempt, which correlates to the quality of the exam as well as hospital length of stay and costs required for the episode of care.

Over the course of 2019, Motus GI plans to sponsor as well as support additional investigator initiated clinical studies focused on accelerating the time to a successful inpatient colonoscopy as well as high risk outpatient populations. These clinical studies include EXPEDITE, which is primarily designed to assess the Pure-Vu[®] System’s ability to minimize the use of conventional bowel preparation regimens in order to further accelerate the time to a successful colonoscopy in the inpatient population. Faster diagnosis of critical emergent conditions such as GI bleeding may improve clinical outcomes and potentially reduce costs and complications.

Near-Term Milestones Expected to Drive Value

- Announce full top-line results from the REDUCE study at Digestive Disease Week[®] 2019 in May 2019;
 - Commence investigator-initiated clinical studies focused on accelerating the time to a successful colonoscopy for inpatients as well as high risk outpatient populations;
 - Secure regulatory approval and launch of Pure-Vu[®] GEN2 that offers enhanced features and superior usability ahead of full commercial launch;
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- Continue to expand field-based sales and clinical resources in key U.S. locations;
- Continue to expand market development programs to engage hospitals, physician champions and staff through pilot utilization of the Pure-Vu® System;
- Continue to grow clinical and health economic awareness through peer-reviewed publications;
- Continue to refine in-servicing and training programs in preparation for the full commercial launch;
- Commercial launch of the Pure-Vu® System in the U.S. for inpatient colonoscopy in the U.S.;
- Continue building an extensive intellectual property portfolio to provide long-term protection for multiple key aspects of the Pure-Vu® System; and
- Participate in key scientific conferences over the course of 2019.

Financial Results for the Quarter Ended March 31, 2019

For the quarter ended March 31, 2019, Motus GI reported a net loss of approximately \$6.3 million, or a net loss per diluted share of \$0.29, which included non-cash expenses of approximately \$1.0 million principally related to stock based compensation.

The Company ended the quarter with \$15.3 million in cash, cash equivalents and investments. Cash used in operations in the quarter included annual cash payments for 2018 corporate bonuses and 2019 corporate insurance policies.



Motus GI Holdings, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	March 31,	December 31,
	2019	2018
	(unaudited)	(*)
ASSETS		
Current assets		
Cash and cash equivalents	\$ 10,248	\$ 18,050
Investments	5,078	3,043
Accounts receivable	1	5
Inventory	115	23
Prepaid expenses and other current assets	1,034	930
Total current assets	16,476	22,051
Fixed assets, net	842	846
Right-of-use assets	990	—
Other non-current assets	13	57
Total assets	\$ 18,321	\$ 22,954
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 2,195	\$ 2,140
Operating lease liabilities - current	316	—
Other current liabilities	80	253
Total current liabilities	2,591	2,393
Contingent royalty obligation	1,926	1,953
Operating lease liabilities - non-current	683	—
Other non-current liabilities	38	91
Total liabilities	5,238	4,437
Shareholders' equity		
Preferred Stock \$0.0001 par value; 8,000,000 shares authorized; zero shares issued and outstanding	—	—
Preferred Series A Stock \$0.0001 par value; 2,000,000 shares authorized; zero shares issued and outstanding	—	—
Common Stock \$0.0001 par value; 50,000,000 shares authorized; 21,450,877 and 21,440,148 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	2	2
Additional paid-in capital	80,732	79,893
Accumulated deficit	(67,651)	(61,378)
Total shareholders' equity	13,083	18,517
Total liabilities and shareholders' equity	\$ 18,321	\$ 22,954

(*) Derived from audited consolidated financial statements

The accompanying notes are an integral part of these condensed consolidated financial statements.



About Motus GI and the Pure-Vu[®] System

Motus GI Holdings, Inc. is a medical technology company, with subsidiaries in the U.S. and Israel, dedicated to improving clinical outcomes and enhancing the cost-efficiency of colonoscopy. The Company's flagship product is the Pure-Vu[®] System, a U.S. FDA cleared medical device indicated to help facilitate the cleaning of a poorly prepared colon during the colonoscopy procedure. The device integrates with standard and slim colonoscopes to enable safe and rapid cleansing during the procedure while preserving established procedural workflow and techniques. The Pure-Vu[®] System has received CE mark approval in Europe. The Pure-Vu[®] System is currently being introduced on a pilot basis in the U.S. market, and the Company is planning to initiate a full commercial launch focused on the inpatient colonoscopy market in the U.S. and select international markets in 2019. Challenges with bowel preparation for inpatient colonoscopy represent a significant area of unmet need that directly affects clinical outcomes and increases the cost of care in a market segment that comprises approximately 1.5 million annual procedures in the U.S. and approximately 4 million annual procedures worldwide. Motus GI believes the Pure-Vu[®] System may improve outcomes and lower costs for hospitals by reducing the time to successful colonoscopy, minimizing delayed and incomplete procedures, and improving the quality of an exam. In clinical studies to date, the Pure-Vu[®] System significantly increased the number of patients with an adequate cleansing level, according to the Boston Bowel Preparation Scale Score, a validated assessment instrument.

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 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 26, 2019, 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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