
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): August 14, 2018

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: **786 459 1831**

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 communications 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 communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications 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.

Item 2.02. Results of Operations and Financial Condition.

Motus GI Holdings, Inc. (the “Company”) issued a press release on August 14, 2018, disclosing financial information for its fiscal quarter ended June 30, 2018, 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. August 14, 2018

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: August 14, 2018

By: /s/ Mark Pomeranz

Name: Mark Pomeranz

Title: President and Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release issued by Motus GI Holding, Inc. August 14, 2018</u>



Motus GI Reports 2018 Second Quarter Financial Results and Provides Business Update

- Building clinical and health economic evidence demonstrating potential value of the Pure-Vu[®] System in high need patient populations with focus on inpatient colonoscopy market –*
- Initiated enrollment in the REDUCE study, evaluating the ability of the Pure-Vu[®] System to facilitate successful, timely colonoscopy for emergent inpatients –*
- Advancing market development programs to build foundation for expected commercial launch of the Pure-Vu[®] System for inpatient colonoscopy in 2019 –*

FORT LAUDERDALE, FL, August 14, 2018 – 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, announced today its financial results for the quarter ended June 30, 2018 and provided a business update.

“The first half of 2018 was marked with significant progress toward our primary strategic objective of establishing the Pure-Vu[®] System as a new standard of care to streamline and facilitate inpatient colonoscopy procedures to improve clinical outcomes and significantly reduce costs for hospitals,” stated Mark Pomeranz, CEO of Motus GI. “We continue to amass a growing body of clinical and health economic data while our market development programs are enabling us to establish strong working relationships with physician champions and their staff within leading institutions who are providing vital, real-time clinical feedback which we believe will help to accelerate adoption of the Pure-Vu[®] System.”

“We are focused on the continued successful execution and completion of our clinical studies that can provide important clinical and health economic evidence of how the Pure-Vu[®] System may accelerate the time to colonoscopy, overcome the burden of insufficient bowel prep, improve diagnosis, avoid repeat preps and procedures, reduce length of stay and open up much needed hospital beds to new patients. We are excited to be working with key experts and clinical centers in the U.S. and Europe and are expanding our outreach to additional centers during this pre-launch, market development phase as we prepare for the full commercial launch of the Pure-Vu[®] System in 2019. We believe we are well positioned to achieve key catalysts for the business and create shareholder value in both the near and long-term,” concluded Mr. Pomeranz.

Recent Corporate Highlights

- Announced the appointment of Jeff Hutchison as VP of U.S. Sales and Commercial Operations who brings over 25 years of executive sales leadership and new market development experience in the medical device industry, having previously served as Area Vice President of Sales for Medtronic GI Solutions (NYSE: MDT) and Director of U.S. Sales for BÂRRX Medical. Mr. Hutchison will be responsible for building Motus GI’s U.S. sales organization and driving the Company’s pre-launch market development programs ahead of the planned launch of the Pure-Vu[®] System into the inpatient colonoscopy market in 2019.
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- Commenced patient enrollment in the REDUCE (Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement) inpatient study designed to facilitate bowel cleansing in approximately 100 hospitalized patients who are indicated for a diagnostic colonoscopy procedure. Motus GI expects to complete the study in the fourth quarter of 2018.
- Presented data from a cost-minimization analysis simulating the average lifetime costs and incidence of new colorectal cancer (CRC) comparing colonoscopy using Motus GI's Pure-Vu[®] System versus standard colonoscopy (SC) at Digestive Disease Week[®] 2018 ("DDW"). The data presented indicates that the Pure-Vu[®] System has the potential to reduce inadequate colon prep rate for colonoscopy, leading to reduced cost of repeated colonoscopy procedures due to inadequate prep by approximately 77% - 82% and lower projected incidence of CRC in average and high-risk patients.
- Strengthened Intellectual Property portfolio with issuance of additional patents related to the Pure-Vu[®] System to expand global IP portfolio to support strategic pathway for Pure-Vu[®] System to become standard of care.
- Appointed Seth A. Gross, MD, FACG, FASGE, AGAF, to its Medical Advisory Board comprised of leading experts in the gastroenterology and endoscopy field who actively work with the Company to advise, develop and execute the clinical trials and development strategy. Dr. Gross also serves as the principal investigator in the Company's REDUCE study.

Pure-Vu[®] System Update

The Pure-Vu[®] System, Motus GI's flagship, FDA-cleared medical device system, enables physicians to rapidly cleanse the colon during the colonoscopy procedure to facilitate improved visualization and enable a quality exam. The device integrates with standard colonoscopes to enable cleaning during the procedure while preserving standard procedural workflow and techniques.

The Company is currently focused on post-approval clinical trials and marked development programs with leading U.S. hospitals that are utilizing the Pure-Vu[®] System on a pilot basis in preparation for a full commercial launch in the U.S. and select international markets in 2019 focused on the inpatient colonoscopy market where challenges with insufficient bowel prep slow diagnosis, diminish the quality of care, and add significant costs to the hospitals. 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. Published studies have found that the inpatient population experiences rates of insufficiently prepped colons at the time of colonoscopy as high as 55%. This has been shown to lead directly to significantly longer hospital stays and other additional costs due to the need for repeated preps, repeated colonoscopies and additional diagnostic procedures. This is exemplified in a recently published study from Northwestern University Hospital System which showed an average hospital stay extension of two days and cost increase of as much as \$8,000 per patient as a result of challenges associated with bowel preparation. 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

Patient enrollment is underway in the REDUCE study, a multi-center prospective trial designed to evaluate the Pure-Vu[®] System's ability to consistently and reliably cleanse the colon to facilitate a successful colonoscopy in a timely manner in patients who are indicated for an inpatient diagnostic colonoscopy procedure. The primary endpoint of the study is to determine the Pure-Vu[®] System's rate of improved bowel cleansing level using the Boston Bowel Preparation Scale ("BBPS") index, a validated assessment instrument. Other key data to be collected as part of the study include the proportion of patients who receive a successful colonoscopy for the intended indication in the first attempt and the time to successful colonoscopy compared to current care algorithms, both key data in evaluating speed and quality of diagnosis as well as evaluating hospital costs and length of stay. The Company remains on track to complete the REDUCE study in the fourth quarter of this year.

Over the course of the remainder of the year, Motus GI plans to initiate additional clinical studies which will include the evaluation of inpatients with reduced preparation including lower GI bleed patients who may benefit from accelerated diagnosis. The clinical studies in the inpatient settings are designed to evaluate the Pure-Vu[®] System's ability to rapidly cleanse poorly prepped patients during colonoscopy with BBPS as the measure of cleanliness, as well as assess its ability to reduce healthcare costs by reliably and predictably moving patients through the hospital system to a successful examination.

Near-Term Milestones Expected to Drive Value in 2018 and Beyond

- Launch slim-scope compatible version of the Pure-Vu[®] System;
 - Initiate accelerated, reduced preparation inpatient study with a focus on lower GI bleeding;
 - Continue to grow clinical and health economic awareness through peer reviewed publications;
 - Complete the REDUCE inpatient study;
 - Participate in key scientific conferences in 2018 including United European Gastroenterology (UEG) Week, the American College of Gastroenterology (ACG) Annual Meeting, and the New York Society for Gastroenterology (NYSG) Annual Meeting;
 - Continue building an extensive intellectual property portfolio to provide long-term protection for multiple key aspects of the Pure-Vu[®] System;
 - Continue to expand market development programs to engage hospitals, physician champions and staff through pilot utilization of the Pure-Vu[®] System;
 - Continue to refine in-servicing and training programs in preparation for the full commercial launch;
 - Finalize development, secure regulatory approval and launch 2nd generation of the Pure-Vu[®] System that offers enhanced features and superior usability ahead of full commercial launch; and
 - Full commercial launch of the Pure-Vu[®] System in the U.S. and select international markets for inpatient colonoscopy in 2019.
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Financial Results for the Quarter Ended June 30, 2018

For the quarter ended June 30, 2018, Motus GI reported a net loss of approximately \$4.2 million, or a net loss per diluted share of \$0.27. For the six months ended June 30, 2018, Motus GI reported a net loss of approximately \$11.5 million, or a net loss per diluted share of \$0.80, which included a one-time non-cash warrant expense charge of \$3.2 million.

At June 30, 2018, the Company had cash and cash equivalents, and short-term investments of approximately \$14.9 million.

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 510(k) U.S. Food and Drug Administration cleared medical device indicated to help facilitate the cleaning of a poorly prepared colon during the colonoscopy procedure. The device integrates with standard colonoscopes to enable cleaning during the procedure while preserving standard 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 aborted 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](#), [Facebook](#) and [Google+](#).



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

	<u>June 30,</u> <u>2018</u> <u>(unaudited)</u>	<u>December 31,</u> <u>2017</u> <u>(*)</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 5,071	\$ 6,939
Short-term investments	9,874	—
Accounts receivable	31	5
Inventory	81	6
Prepaid expenses and other current assets	862	734
Deferred financing fees	—	602
Total current assets	<u>15,919</u>	<u>8,286</u>
Fixed assets, net	825	783
Other long-term assets	86	99
Total assets	<u>\$ 16,830</u>	<u>\$ 9,168</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 1,403	\$ 1,733
Other current liabilities	69	250
Total current liabilities	<u>1,472</u>	<u>1,983</u>
Contingent royalty obligation	1,821	1,662
Other long-term liabilities	66	—
Total liabilities	<u>3,359</u>	<u>3,645</u>
Shareholders' equity		
Common Stock \$0.0001 par value; 50,000,000 shares authorized; 15,645,755 and 10,493,233 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	2	1
Preferred Series A stock \$0.0001 par value; 2,000,000 shares authorized; 0 and 1,581,128 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	—	—
Preferred stock \$0.0001 par value; 8,000,000 shares authorized; zero shares issued and outstanding	—	—
Additional paid-in capital	64,110	44,643
Accumulated deficit	(50,641)	(39,121)
Total shareholders' equity	<u>13,471</u>	<u>5,523</u>
Total liabilities and shareholders' equity	<u>\$ 16,830</u>	<u>\$ 9,168</u>

(*) Derived from audited consolidated financial statements



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 28, 2018, 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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