
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): November 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 November 14, 2018, disclosing financial information for its fiscal quarter ended September 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>
<u>99.1</u>	<u>Press Release issued by Motus GI Holding, Inc. November 14, 2018</u>

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: November 14, 2018

By: /s/ Timothy P. Moran

Name: Timothy P. Moran

Title: 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. November 14, 2018</u>



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

- Third quarter featured strengthening of executive team with proven commercial leadership, building additional clinical and health economic evidence demonstrating potential value of the Pure-Vu® System, and achieving important regulatory milestones –
- Active enrollment continues in REDUCE study evaluating the ability of the Pure-Vu® System to facilitate successful, timely colonoscopy for emergent inpatients with topline data expected Q1 2019 –
- Ongoing market development programs continue to build foundation for full commercial launch of the Pure-Vu® System in 2019 –

FORT LAUDERDALE, FL, November 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 September 30, 2018 and provided a business update.

“We have made significant progress in recent months to ensure the Company is positioned for a successful commercial launch of the Pure-Vu® System in 2019. I firmly believe that a critical part of that process includes having the right team in place, not only at the executive level but across our commercial organization. We have made and are continuing to make strategic hires for key sales positions and have established goals to call on and secure new accounts,” commented Tim Moran, Chief Executive Officer of Motus GI. “We have also filled critical positions on our customer-facing clinical team who will work with existing accounts to facilitate proper training and streamline patient flow to ensure maximum account penetration. Additionally, we continue to take a methodical approach to our market development activities which are aimed at generating robust health economic data while establishing physician champions within key institutions to help accelerate the Value Analysis Committee approval and adoption of the Pure-Vu® System.”

Recent Corporate Highlights

- Presented positive clinical data from one of its U.S. prospective clinical studies at the American College of Gastroenterology (ACG) 2018 Annual Meeting demonstrating safety and effectiveness of the Pure-Vu® System in patients who had minimal preparation regimens and who were allowed to consume solid food the day before the procedure. Patients in the study had an average baseline Boston Bowel Preparation Scale (BBPS), a validated and widely used measure with a 0 to 9 point scale, of 3.67 ± 2.86 which was improved to an average of 8.91 ± 0.35 (p value < 0.0001) following use of the Pure-Vu® System. The results were statistically significant and the post-cleansing BBPS score is meaningfully higher than results generally seen with standard liquid diet plus purgative-based bowel prep regimens. Further, the use of the Pure-Vu® System enabled intraprocedural cleansing of the colon and enabled 100% successful completion of all colonoscopies performed.
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- Received special 510(k) clearance from the U.S. Food and Drug Administration (FDA) and preformed first patient use of Pure-Vu® Slim Sleeve. The Pure-Vu® Slim Sleeve enables access to the full colonoscopy market where Motus GI estimates, through consultation with colonoscopy manufacturing companies, approximately 30% of procedures are performed with a slim colonoscope. The Pure-Vu® Slim Sleeve has been designed to be compatible with smaller diameter and more flexible slim colonoscopes with additional enhancements to the Company's low friction lubricious coating technology to aid in navigation through the colon and has the same cleansing performance as the standard Pure-Vu® Sleeve and both versions work with the same Pure-Vu® workstation control system.
- Bolstered the executive leadership team with the appointment of veteran medical device commercial leader Tim Moran as Chief Executive Officer. Additionally, Mark Pomeranz continues with the organization in key role as President and Chief Operating Officer. The combination of Tim's commercial leadership expertise with Mark's operational track record are an integral piece of successfully positioning Motus GI for the Company's full commercial launch of the Pure-Vu® System in 2019. Mr. Moran joined Motus GI from ConvaTec Group Plc where he served as President of the Americas since 2015. Prior to ConvaTec, Mr. Moran spent 18 years at Covidien and Medtronic, including serving as Vice President and General Manager of the Patient Care and Safety division.
- Appointed 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 BARRX Medical. Mr. Hutchison is responsible for building Motus GI's U.S. sales organization and driving the Company's pre-launch market development programs to help ensure a successful launch.
- 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.

Pure-Vu® System Update

The Pure-Vu® System, Motus GI's flagship product is 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 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 a full commercial launch in the U.S. and select international markets in 2019.

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

Patient enrollment is actively underway for the REDUCE (Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement) 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 announce topline data from the REDUCE study in the first quarter of 2019.

Recently, the Company presented positive data from one of its U.S. prospective clinical studies at the ACG 2018 Annual Meeting demonstrating safety and effectiveness of the Pure-Vu® System in patients who had minimal preparation regimens and who were allowed to consume solid food the day before the procedure. Data from the study demonstrated that the use of the Pure-Vu® System enabled intraprocedural cleansing of the colon and enabled 100% successful completion of all colonoscopies performed. The primary endpoint of the study was evaluation of the quality of colon visualization using the BBPS. Patients in the study had an average baseline BBPS of 3.67 ± 2.86 which was improved to an average of 8.91 ± 0.35 (p value < 0.0001) following use of the Pure-Vu® System. The post-cleansing BBPS score is meaningfully higher than results generally seen with standard liquid diet plus purgative-based bowel prep regimens. The mean total procedure time for all arms was 26.61 minutes with the Mag Citrate arms trending lower at 25.03 minutes which is nearing the time of a standard colonoscopy. The presented poster is available on the Motus GI website and can be accessed by clicking [here](#).

Over the course of the remainder of the year and into early next year, Motus GI plans to initiate additional investigator initiated clinical studies, including the EXPEDITE inpatient study evaluating the Pure-Vu® System for reduced preparation (no purgative based solution required) with a focus on patients who may benefit from accelerated diagnosis, such as lower GI bleeding. The Company will also be initiating studies in outpatient populations that are at high risk for inadequate preparation to build strong evidence in this additional market opportunity. The Company's clinical trials, such as the ongoing REDUCE study and its upcoming EXPEDITE study, are designed to evaluate the Pure-Vu® System's ability to rapidly cleanse the colon intra-procedurally during emergent colonoscopies done on an inpatient basis in hospitals, and to assess the Pure-Vu® System's ability to reduce the time to successful diagnosis and eliminate delays, costs and complications associated with conventional bowel preparation requirements.

Near-Term Milestones Expected to Drive Value

- Continue to grow clinical and health economic awareness through peer reviewed publications;
 - Complete enrollment in REDUCE inpatient study and announce topline results in Q1 2019;
 - Participate in key scientific conferences for the remainder of 2018 including the New York Society for Gastroenterology (NYSG) Annual Meeting;
 - Commence investigator initiated clinical studies focused on accelerating the time to a successful inpatient colonoscopy as well as high risk outpatient populations;
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- Continue building an extensive intellectual property portfolio to provide long-term protection for multiple key aspects of the Pure-Vu® System;
- Expand field-based sales and clinical resources in key US locations;
- 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.

Financial Results for the Quarter Ended September 30, 2018

For the quarter ended September 30, 2018, Motus GI reported a net loss of approximately \$5.2 million, or a net loss per diluted share of \$0.33. For the nine months ended September 30, 2018, Motus GI reported a net loss of approximately \$16.7 million, or a net loss per diluted share of \$1.13, which included a one-time non-cash warrant expense charge of \$3.2 million.

At September 30, 2018, the Company had cash and cash equivalents, and short-term investments of approximately \$11.6 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 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](#).



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

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
	<u>(unaudited)</u>	<u>(*)</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 6,887	\$ 6,939
Short-term investments	4,744	—
Accounts receivable	23	5
Inventory	46	6
Prepaid expenses and other current assets	1,188	734
Deferred financing fees	59	602
Total current assets	<u>12,947</u>	<u>8,286</u>
Fixed assets, net	871	783
Other long-term assets	88	99
Total assets	<u>\$ 13,906</u>	<u>\$ 9,168</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 2,416	\$ 1,733
Other current liabilities	58	250
Total current liabilities	<u>2,474</u>	<u>1,983</u>
Contingent royalty obligation	1,906	1,662
Other non-current liabilities	84	—
Total liabilities	4,464	3,645
Shareholders' equity		
Common Stock \$0.0001 par value; 50,000,000 shares authorized; 15,690,151 and 10,493,233 shares issued and outstanding as of September 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 September 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	65,251	44,643
Accumulated deficit	(55,811)	(39,121)
Total shareholders' equity	<u>9,442</u>	<u>5,523</u>
Total liabilities and shareholders' equity	<u>\$ 13,906</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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