
**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): March 29, 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 March 29, 2018, disclosing financial information and operating metrics for its fiscal year ended December 31, 2017, 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	<u>Press Release issued by Motus GI Holding, Inc. March 29, 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: March 29, 2018

By: /s/ Mark Pomeranz

Name: Mark Pomeranz

Title: President and Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release issued by Motus GI Holding, Inc. March 29, 2018</u>



Motus GI Announces 2017 Financial Results and Provides Business Outlook

– Successfully completed \$17.5M IPO and listed on NASDAQ Capital Market –

– Pilot commercial launch of the Pure-Vu® System in the U.S. ongoing with full commercial launch in the U.S. and select international markets on track for 2019 –

– Growing body of clinical data expected over the course of 2018 –

– Company well positioned to establish a strong presence in the growing GI endoscopy market –

FORT LAUDERDALE, FL, March 29, 2018 – Motus GI Holdings, Inc., (NASDAQ: MOTS) (“Motus GI” or the “Company”), a medical technology company dedicated to improving endoscopy outcomes and experiences, announced today its financial results for the year ended December 31, 2017 and provided its 2018 business outlook.

“Motus GI has accomplished a number of important corporate milestones over the past year, including the completion of our initial public offering and the listing of our common stock on NASDAQ. These achievements have allowed us to establish a secure platform from which we believe we can successfully build our business for the long-term and appeal to a broad investor base to create shareholder value,” said Mark Pomeranz, CEO of Motus GI. “As we continue to execute on our deliberate commercial strategy, we plan to spend the bulk of 2018 focusing on generating important clinical and health economic data to demonstrate the Pure-Vu® System’s ability to overcome the significant clinical challenges of insufficient bowel prep for colonoscopy, enhance clinical outcomes and potentially reduce healthcare costs. We are excited to be working with some of the top institutions in the U.S. during our pilot launch in 2018.”

Recent Corporate Highlights

- Received European CE mark approval for the Pure-Vu® System, enabling future expansion opportunity into European market where 6 million colonoscopies are performed annually;
 - Expanded intellectual property portfolio with issuance of key European and U.S. patents covering the Pure-Vu® System;
 - Closed \$17.5 million initial public offering and listed common stock on the NASDAQ Capital Market;
 - Bolstered Board of Directors with the appointment of Gary J. Pruden, the previous Executive Vice President and Worldwide Chairman for the Johnson & Johnson (“J&J”) (NYSE: JNJ) Medical Devices group; and
 - Presented positive clinical data from performance study of the Pure-Vu® System at the 25th United European Gastroenterology Week.
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Pure-Vu[®] System Update

The Pure-Vu[®] System is a medical device that cleans the colon intra-procedurally to facilitate improved visualization during a colonoscopy procedure to enable a quality exam and has demonstrated effective cleaning in hundreds of procedures. The device integrates with existing colonoscopes and is activated by a convenient foot pedal to put control of cleansing the colon in the hands of the physician to gain clear visualization of the colon mucosa to facilitate a quality exam.

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 in the U.S. and select international markets in 2019. Motus GI recently received CE mark approval for the Pure-Vu[®] System in Europe and expects to continue to involve key European clinical centers along with a broad range of U.S. clinical centers in the post-approval clinical trials that it plans to conduct during the next 12 months and beyond.

Clinical Programs – Building a strong foundation of clinical and health economic data

In November 2017, Motus GI reported positive results from its most recent European clinical study evaluating the Pure-Vu[®] System's performance in cleansing poorly prepared colons at the 25th United European Gastroenterology ("UEG") Week conference. Results from the 47-patient study showed that the Pure-Vu[®] System significantly increased the number of subjects with an adequate cleansing level (Boston Bowel Prep Scale (BBPS) ≥ 2 for all 3 colon segments) from 19.1% at baseline to 100% after using the Pure-Vu[®] System. Mean per patient post-treatment BBPS score was 9 vs. 3 prior to Pure-Vu[®] System use. The BBPS ranges from 0 to 9 on a per patient basis with the higher the score the cleaner the colon.

Over the course of the next 24 months, Motus GI plans to initiate a number of clinical studies in both the in-patient and out-patient settings that will evaluate its ability to rapidly cleanse poorly prepped patients during colonoscopy with BBPS as the measure of cleanliness, as well as assess the Pure-Vu[®] System's ability to reduce healthcare costs by reliably and predictably moving patients through the system to a successful examination.

The Company is initially targeting the in-patient population segment comprised of the more than 4 million in-patient colonoscopy procedures performed annually worldwide, which represents a significant unmet need. In in-patient settings, an insufficiently prepped colon can lead to longer hospital stays, resulting in an average increase of \$8,000 per patient. Motus GI plans to initiate its REDUCE study, a multi-center in-patient prospective trial in Q2 2018. The study is expected to enroll ~100 patients with the primary endpoint of improvement of colon cleanliness (BBPS) which has been shown to directly correlate to improved outcomes. Motus GI expects to report results from the REDUCE study in the fourth quarter of this year.

Motus GI is also planning to initiate its Micro-Prep study to evaluate the Pure-Vu[®] System's effectiveness in cleansing patients who ate a low residue diet (eggs, toast, pasta, etc.) and had a low dose of an over-the-counter laxative (magnesium citrate) prior to the exam. The study results are expected in the fourth quarter of this year.

The Company expects to launch several additional prospective clinical studies in 2018 focused on important patient populations in the in-patient and out-patient setting that have known challenges with existing bowel prep regimens that can delay or prevent successful colonoscopy procedures. These include GI bleed patients that require accelerated diagnosis, spinal cord injury patients and other high-medical need patients that cannot readily tolerate conventional bowel prep regimens such as diabetic patients, obesity patients, elderly and other patients that require more frequent colonoscopy due to medical conditions such as colorectal cancer, irritable bowel syndrome, inflammatory bowel disease, and anemia.



Near-Term Milestones Expected to Drive Value

- Initiate REDUCE in-patient study in Q2 2018;
- Complete Micro-Prep I for prep optimization studies in Q2 2018;
- Initiate Micro-Prep II multi-center labeling study in Q3 2018;
- Finalize reimbursement strategy in 2H 2018;
- Initiate study in the VA for high medical need patient populations in Q3 2018;
- Complete REDUCE in-patient study in Q4 2018;
- Launch slim-scope compatible system in Q3 2018;
- Complete enrollment in Micro-Prep II labeling expansion trial by the end of 2018;
- Continue to build an extensive intellectual property portfolio to protect key aspects of the Pure-Vu® System to drive market penetration and expansion;
- Participate in key scientific conferences throughout 2018, including Digestive Disease Week (DDW), United European Gastroenterology (UEG) Week and the American College of Gastroenterology (ACG) Annual Meeting; and
- Continue to refine in-servicing and training programs in preparation of the full market launch in 2019.

“We have a clear clinical and commercial plan that we continue to implement, and we are excited about the opportunities ahead of us. Moving forward, we remain focused on developing our Pure-Vu® System, which may establish a new standard of care for addressing the extensive challenges of bowel preparation in the 30 million global annual colonoscopy market. We look forward to providing continued updates over the course of the year and executing on our strategic path forward,” concluded Mr. Pomeranz.

Financial Results for Year Ended December 31, 2017

For the year ended December 31, 2017, Motus GI reported a net loss of approximately \$13.2 million, or a net loss per diluted share of \$1.28, compared to a net loss of approximately \$8.0 million or a net loss per diluted share of \$7.00 for the year ended December 31, 2016.

The Company ended the year with \$6.9 million in cash and cash equivalents. In February 2018, the Company completed its initial public offering of its common stock at a public offering price of \$5.00 per share, resulting in gross proceeds of \$17.5 million. Based on current projections, the Company believes it has sufficient capital through the first half of 2019.



About the Pure-Vu® System

The Pure-Vu® System is 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.

About Motus GI

Motus GI Holdings, Inc. is a medical technology company, with subsidiaries in the U.S. and Israel, dedicated to improving endoscopy outcomes, lowering costs and enhancing patient experiences. The Company is focused on the development and commercialization of the Pure-Vu® System to improve the colonoscopy experience and assist in the early detection and prevention of colorectal cancer and other diseases of the rectum and colon. 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.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31,	
	2017	2016
ASSETS		
Current assets		
Cash and cash equivalents	\$ 6,939	\$ 11,644
Short-Term Deposits	76	-
Inventory	6	81
Prepaid expenses and other	663	263
Deferred financing fees	602	-
Total current assets	8,286	11,988
Fixed assets, net	783	141
Long-term deposits	99	62
Total assets	\$ 9,168	\$ 12,191
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 882	\$ 107
Other current liabilities	1,101	645
Total current liabilities	1,983	752
Contingent royalty obligation	1,662	1,410
Commitments and contingent liabilities		
Shareholders' equity		
Common Stock \$0.0001 par value; 50,000,000 authorized; 10,493,233 and 9,294,463 issued and outstanding as of December 31, 2017 and 2016, respectively	1	1
Preferred Series A stock \$0.0001 par value; 2,000,000 authorized; 1,581,128 and 1,214,845 issued and outstanding as of December 31, 2017 and 2016, respectively	-	-
Preferred stock \$0.0001 par value; 8,000,000 authorized; zero issued and outstanding as of December 31, 2017 and 2016, respectively	-	-
Additional paid-in capital	44,643	35,949
Accumulated deficit	(39,121)	(25,921)
Total shareholders' equity	5,523	10,029
Total liabilities and shareholders' equity	\$ 9,168	\$ 12,191



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. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this presentation. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in the Company's filings with the Securities and Exchange Commission.

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