
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 15, 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 May 15, 2018, disclosing financial information for its fiscal quarter ended March 31, 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. May 15, 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: May 15, 2018

By: /s/ Mark Pomeranz

Name: Mark Pomeranz

Title: President and Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
<u>99.1</u>	<u>Press Release issued by Motus GI Holding, Inc. May 15, 2018</u>



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

– Q1 2018 marked by significant corporate and clinical advancements, including successfully completing \$17.5M IPO and listing on NASDAQ Capital Market –

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

FORT LAUDERDALE, FL, May 15, 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 quarter ended March 31, 2018 and provided a business update.

“We made significant progress in our key corporate objectives in the first quarter of 2018, including the successful completion of our initial public offering and the listing of our common stock on the NASDAQ Capital Market,” said Mark Pomeranz, CEO of Motus GI. “Looking forward to the remainder of 2018, we remain focused on our clinical and commercial strategy with the execution of a number of studies specifically designed to generate important clinical and health economic data focused on improving the patient flow through the hospital and the quality of the over 4 million in-patient colonoscopy procedures performed annually worldwide. We believe the Pure-Vu® System has the ability to overcome the significant clinical challenges of insufficient bowel prep for colonoscopy which can cause delayed and repeat procedures that may lead to poor clinical outcomes and increased healthcare costs. We are excited to work with key experts and clinical centers in the U.S. and Europe to execute these studies and further secure a platform from which we believe we can successfully build our business for the long-term and create shareholder value.”

Recent Corporate Highlights

- Announced the acceptance of an abstract for presentation at Digestive Disease Week® 2018 (“DDW”), being held June 2-5, 2018 in Washington, DC;
- Appointed Seth A. Gross, MD, FACG, FASGE, AGAF, to Medical Advisory Board;
- 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; and
- Closed \$17.5 million initial public offering and listed common stock on the NASDAQ Capital Market.

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 physicians’ hands so they can gain clear visualization of the wall of the colon to enable a quality exam.



The Pure-Vu® System is currently being introduced on a pilot basis in the U.S. market. The Company is planning to initiate a broader commercial launch in the U.S. and select international markets in 2019, with a focus on the in-patient, hospital-based colonoscopy market, where challenges with bowel prep can delay the time to diagnosis, diminish the quality of care and add significant costs for hospitals. Motus GI plans to continue evaluating the Pure-Vu® System in key U.S. and European clinical centers in post-approval in-patient and out-patient clinical trials which the Company believes will enhance its value proposition over the course of the next 24 months.

Clinical Programs Update

The REDUCE study is a multi-center in-patient 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 a 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 elements of the study include the proportion of patients who receive a successful colonoscopy for the intended indication on the first attempt and the time to successful colonoscopy compared to current care algorithms which have high rates of delayed and repeat procedures, increasing the patient's length of stay and the cost to the hospital. The Company plans to complete the REDUCE study in the fourth quarter of this year.

The clinical studies in the in-patient and high need outpatient settings will 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 system to a successful examination. These studies will include the evaluation of lower GI bleed patients who require accelerated diagnosis and spinal cord injury patients which are very difficult to prep.

Near-Term Milestones Expected to Drive Value

- Initiate the REDUCE (Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement) in-patient study in Q2 2018;
 - Initiate study in the Department of Veterans Affairs for high medical need patient populations in Q3 2018;
 - Launch slim-scope compatible system in Q3 2018;
 - Complete the REDUCE in-patient study in Q4 2018;
 - Continue building 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 for the full market launch of the Pure-Vu System in 2019.
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“We are pleased with the progress of our clinical and commercial plans and look forward to providing continued updates over the course of the year. The initiation of our REDUCE study is the first step toward our goal to establish the Pure-Vu® System as a new standard of care for addressing the critically important in-patient market and providing solutions for patients with high medical needs. We look forward to completing the REDUCE study in the fourth quarter and initiating additional studies throughout the next 24 months,” concluded Mr. Pomeranz.

Financial Results for the Quarter Ended March 31, 2018

For the quarter ended March 31, 2018, Motus GI reported a net loss of approximately \$7.3 million, or a net loss per diluted share of \$0.57, which included a one-time non-cash warrant expense charge of \$3.2 million.

The Company ended the quarter with \$18.6 million in cash and cash equivalents.

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 index, 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>March 31,</u> <u>2018</u> (unaudited)	<u>December 31,</u> <u>2017</u> (*)
ASSETS		
Current assets		
Cash and cash equivalents	\$ 18,629	\$ 6,939
Accounts receivable	11	5
Short-term deposits	—	76
Inventory	21	6
Prepaid expenses and other	938	658
Deferred financing fees	—	602
Total current assets	<u>19,599</u>	<u>8,286</u>
Fixed assets, net	837	783
Long-term deposits	<u>94</u>	<u>99</u>
Total assets	<u>\$ 20,530</u>	<u>\$ 9,168</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 1,515	\$ 1,733
Other current liabilities	<u>80</u>	<u>250</u>
Total current liabilities	<u>1,595</u>	<u>1,983</u>
Contingent royalty obligation	1,740	1,662
Other long-term liabilities	<u>25</u>	<u>—</u>
Total liabilities	<u>3,360</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 March 31, 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 March 31, 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	63,612	44,643
Accumulated deficit	<u>(46,444)</u>	<u>(39,121)</u>
Total shareholders' equity	<u>17,170</u>	<u>5,523</u>
Total liabilities and shareholders' equity	<u>\$ 20,530</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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