

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 9, 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 August 9, 2019, disclosing financial information for its fiscal quarter ended June 30, 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:

Exhibit No.	Description
99.1	Press Release issued by Motus GI Holding, Inc. August 9, 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: August 9, 2019

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by Motus GI Holding, Inc. August 9, 2019



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

– 510(k) clearance from the FDA for GEN2 Pure-Vu[®] System and strong clinical data from REDUCE study sets the stage for commercial launch into the U.S. hospital market

– Pure-Vu[®] System may address unmet need through improved outcomes, greater efficiency and reduced costs for the approximately 1.5 million annual U.S. critical inpatient colonoscopy procedures

– Recent underwritten offering secures funding for commercialization activities for Pure-Vu[®] System

FORT LAUDERDALE, FL, August 9, 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 second quarter ended June 30, 2019 and provided a corporate update.

“This was a productive quarter for Motus GI on multiple fronts. We announced results from our multi-center inpatient REDUCE study, which showed statistically significant improvement in bowel cleanliness after Pure-Vu[®] System use, received 510(k) clearance from the FDA for the GEN2 Pure-Vu[®] System, closed on an important financing that was supported by both existing and new healthcare investors, and continued to fill our pipeline of key market-leading institutions who now have experience with our Pure-Vu[®] System in real world settings,” commented Tim Moran, Chief Executive Officer of Motus GI. “We have been scaling commercial production and gearing up for our launch into the large U.S. hospital market. We expect to be shipping the Pure-Vu[®] System before the end of Q3, allowing us to partner with leading healthcare systems in an effort to improve the inefficient standard of care associated with bowel prep for individuals undergoing inpatient colonoscopy.”

Recent Corporate Highlights

- Presented positive clinical results from the Company’s REDUCE study evaluating the Pure-Vu[®] System at Digestive Disease Week[®] 2019 (“DDW”). Results demonstrated that adequate bowel preparation rate improved to 96% following use of the Pure-Vu[®] system from 38% at baseline.
 - Received 510(k) clearance from the U.S. Food and Drug Administration (“FDA”) for the second-generation Pure-Vu[®] System.
 - Received approximately \$20 million in net proceeds from our underwritten public follow-on offering led by fundamental institutional investors.
 - Bolstered commercial and quality/regulatory expertise with appointments of Steven M. Bosrock as Vice President of Global Marketing & Strategy and George G. Peters as Vice President of Quality & Regulatory Affairs.
 - Strengthened intellectual property estate with the issuance of European patent supporting future international expansion opportunities.
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Clinical Programs Update

Motus GI presented positive clinical results from its REDUCE (Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement) study at Digestive Disease Week® 2019 (“DDW”) in May 2019. The analysis from the REDUCE study showed statistically significant improvement in each colon segment after Pure-Vu® System use. The per segment Boston Bowel Preparation Scale (BBPS) improved from an average baseline of 1.74, 1.74 and 1.5 to 2.89, 2.91 and 2.86, respectively, with a statistically significant p value of .001 for all three segments of the colon. For inpatients that received Pure-Vu® System, adequate bowel preparation improved from a baseline of 38% to 96% in segments evaluated.

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 colonoscopy in inpatient as well high-risk outpatient populations. These clinical studies include EXPEDITE, which will assess the Pure-Vu® System’s ability to minimize the dependency on conventional bowel preparation regimens in order to accelerate the time to a successful colonoscopy. 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

- Commercial launch of the Pure-Vu® System for inpatient colonoscopy in the U.S.;
- Continue to develop strong compendium of clinical data through execution of studies focused on accelerating the time to a successful colonoscopy for inpatients as well as high-risk outpatient populations in premier healthcare institutions;
- Continue to expand field-based sales and clinical resources in key U.S. locations;
- Continue to expand marketing programs to engage hospitals and physician thought leaders to create key reference centers across the US;
- Continue to demonstrate clinical and health economic benefits through peer-reviewed publications;
- File for CE Mark registration of GEN2 Pure-Vu® System;
- Continue building an extensive intellectual property portfolio in key international territories to provide long-term protection for multiple key aspects of the Pure-Vu® System; and
- Participate in key scientific conferences over the remainder of 2019.

Financial Results for the Quarter Ended June 30, 2019

For the three months ended June 30, 2019, Motus GI reported a net loss of approximately \$5.7 million, or a net loss per diluted share of \$0.26, which included non-cash expenses of approximately \$1.1 million principally related to stock based compensation. For the six months ended June 30, 2019, Motus GI reported a net loss of approximately \$12.0 million, or a net loss per diluted share of \$0.56, which included non-cash expenses of approximately \$2.1 million principally related to stock based compensation.

The Company ended the quarter with approximately \$11.0 million in cash, cash equivalents and investments, which did not include approximately \$20 million net proceeds received in our July 2019 underwritten public offerings.



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

	<u>June 30, 2019</u>	<u>December 31, 2018</u>
	(unaudited)	(*)
ASSETS		
Current assets		
Cash and cash equivalents	\$ 7,854	\$ 18,050
Investments	3,104	3,043
Accounts receivable	8	5
Inventory	93	23
Prepaid expenses and other current assets	902	930
Total current assets	<u>11,961</u>	<u>22,051</u>
Fixed assets, net	920	846
Right-of-use assets	908	-
Other non-current assets	13	57
Total assets	<u>13,802</u>	<u>\$ 22,954</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 2,460	\$ 2,140
Operating lease liabilities - current	298	-
Other current liabilities	295	253
Total current liabilities	<u>3,053</u>	<u>2,393</u>
Contingent royalty obligation	2,012	1,953
Operating Lease liabilities - non-current	620	-
Other non-current liabilities	25	91
Total liabilities	<u>5,710</u>	<u>4,437</u>
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 June 30, 2019 and December 31, 2018, respectively	2	2
Additional paid-in capital	81,422	79,893
Accumulated deficit	(73,332)	(61,378)
Total shareholders' equity	<u>8,092</u>	<u>18,517</u>
Total liabilities and shareholder's equity	<u>\$ 13,802</u>	<u>\$ 22,954</u>

(*) 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 first generation of the Pure-Vu[®] System has received CE mark approval in Europe and Motus GI intends to seek CE Mark approval for the second generation system. 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 commercial launch focused on the U.S. hospital market 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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