

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, 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 November 14, 2019, disclosing financial information for its fiscal quarter ended September 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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Motus GI Holding, Inc. November 14, 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: November 14, 2019

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Motus GI Holding, Inc. November 14, 2019

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

- Pure-Vu® System launched in high value U.S. inpatient colonoscopy market with first commercial placements at early adopter hospitals completed in early-October
- Scaled commercial production and expanded the U.S. sales team with additional seasoned medical device sales professionals
- Management to hold an investor conference call today at 8:00 a.m. ET

FORT LAUDERDALE, FL, November 14, 2019 – Motus GI Holdings, Inc., (NASDAQ: MOTS) ("Motus GI" or the "Company"), a medical technology company providing endoscopy solutions that improve clinical outcomes and enhance the cost-efficiency associated with the diagnosis and management of gastrointestinal conditions, today reported its financial results for the third quarter ended September 30, 2019 and provided a corporate update.

"I am excited by the building momentum of the business as we implement our commercial strategy and continued to deliver on several key milestones in the third quarter, including initiating sales and scaling production of the Pure-Vu® System, as well as expanding our U.S. sales team with additional seasoned medical device sales professionals," commented Tim Moran, Chief Executive Officer of Motus GI. "The gastroenterologists and support staff from our initial hospital placements are already reporting positive feedback regarding the Pure-Vu System, along with valuable real-world customer insights that will help us frame our broader U.S. roll-out."

"Our U.S. sales team is actively ramping up their activity, and as a result, our pipeline of high value target accounts is growing. Looking ahead, as the Pure-Vu System builds an installed base, we will rely on our systematic account activation program to drive utilization, which we believe will lead to growing sales of disposable sleeves. We believe that the long-term growth opportunity is centered around the revenue from disposable sleeves, as we gain U.S. customers and commercial utilization of the Pure-Vu System in the coming quarters," concluded Mr. Moran.

Progress Updates

The Company is initially focusing its launch of the Pure-Vu System in the high-value U.S. inpatient colonoscopy market. Inadequate bowel prep in the inpatient market directly affects patient outcomes and impacts the cost of care in a segment that is comprised of approximately 1.5 million annual procedures in the U.S. The Company is currently targeting larger hospital networks, where the average hospital conducts anywhere from 500 to more than 1,000 inpatient colonoscopy procedures per year. In October 2019, Motus GI initiated the first commercial placements of its Pure-Vu System as part of its initial U.S. market launch targeting early adopter hospitals. Since initiating commercial placements of the Pure-Vu System, the system is now being utilized in approximately 10 of the early adopter hospitals. These placements followed the Company scaling of commercial production during the third quarter and receiving 510(k) clearance for the second-generation of the Pure-Vu System (the "GEN2 Pure-Vu System") from the U.S. Food and Drug Administration ("FDA") in June 2019.



To support the commercial roll-out of its Pure-Vu System, the Company continues to strengthen its sales organization with the addition of seasoned medical device sales professionals, strategically expanding its footprint and reach to key target hospital accounts that can become strong reference customers going forward.

In addition, with approximately four million annual in-patient colonoscopy procedures worldwide, the Company believes there are significant opportunities outside the U.S. The Company intends to seek CE Mark approval for the GEN2 Pure-Vu System (GEN1 already received CE Mark) as well as other regulatory approvals in key markets outside the U.S.

Motus GI remains committed to continuing to develop clinical evidence of the benefits of the Pure-Vu System in collaboration with leading investigators at world-class medical centers.

The EXPEDITE Study

In November, the Company announced that the Boston Medical Center has initiated the EXPEDITE study to evaluate the effectiveness of the Pure-Vu System on bowel preparation rates. This study will enroll up to 50 inpatients and 50 outpatients over a 12-month study period. The study will assess the ability of the Pure-Vu System to accelerate time to a successful colonoscopy in a real-world setting.

Near-Term Milestones Expected to Drive Value

- Ramp up commercial sales and marketing activities to engage hospitals and physician thought leaders to create key reference centers across the U.S.
- Announce approval 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
- Support additional sponsored and investigator initiated clinical studies and registries focused on demonstrating the Pure-Vu System's ability to accelerate the time to a successful colonoscopy for inpatients, as well as high-risk outpatient populations at premier healthcare institutions; and
- Demonstrate clinical utility and health economic benefits through new peer-reviewed publications and presentations at key scientific conferences

Financial Results for the Quarter Ended September 30, 2019

For the three months ended September 30, 2019, the Company reported a net loss of approximately \$5.2 million, or a net loss per diluted share of \$0.18, compared to \$5.2 million, or a net loss per diluted share of \$0.33, for the same period last year. The third quarter of 2019 included non-cash expenses of approximately \$0.6 million principally related to stock-based compensation, compared to \$1.4 million of non-cash expenses for the same period of 2018.

For the nine months ended September 30, 2019, the Company reported a net loss of approximately \$17.1 million, or a net loss per diluted share of \$0.72, compared to \$16.7 million, or a net loss per diluted share of \$1.13, for the same period last year. The nine months ended September 30, 2019 included non-cash expenses of approximately \$2.7 million principally related to stock-based compensation, compared to \$5.8 million of non-cash expenses for the same period of 2018.

The Company ended the quarter with approximately \$26.4 million in cash, cash equivalents and investments.



Conference Call:

The Motus GI management team has scheduled a conference call for today at 8:00 a.m. EST to discuss these results. To access the conference call, investors are invited to dial (877) 407-0792 (U.S. and Canada) or (201) 689-8263 (International). The conference ID number is 13696399 . A live audio webcast can be accessed by visiting the investor relations section of the Company's website, www.motusgi.com. A replay of the webcast will be archived on the Motus GI website for 90 days following the event.

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, providing endoscopy solutions that improve clinical outcomes and enhance the cost-efficiency associated with the diagnosis and management of gastrointestinal conditions. 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. 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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Motus GI Holdings, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	September 30,	December 31,
	2019	2018
	(unaudited)	(*)
ASSETS		
Current assets		
Cash and cash equivalents	\$ 15,717	\$ 18,050
Investments	10,657	3,043
Accounts receivable	-	5
Inventory	771	23
Prepaid expenses and other current assets	537	930
Total current assets	27,682	22,051
Fixed assets, net	1,015	846
Right-of-use assets	1,056	-
Other non-current assets	13	57
Total assets	\$ 29,766	\$ 22,954
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 2,733	\$ 2,140
Operating lease liabilities - current	320	-
Other current liabilities	494	253
Total current liabilities	3,547	2,393
Contingent royalty obligation	1,885	1,953
Operating lease liabilities - non-current	748	-
Other non-current liabilities	-	91
Total liabilities	6,180	4,437
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; 28,796,017 and 21,440,148 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	3	2
Additional paid-in capital	102,110	79,893
Accumulated deficit	(78,527)	(61,378)
Total shareholders' equity	23,586	18,517
Total liabilities and shareholders' equity	\$ 29,766	\$ 22,954

(*) Derived from audited consolidated financial statements



Motus GI Holdings, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(In thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue	\$ 3	\$ -	\$ 8	\$ 38
Cost of revenue	62	-	65	56
Gross loss	(59)	-	(57)	(18)
Operating expenses:				
Research and development	2,173	1,770	6,706	4,357
Sales and marketing	1,160	1,215	3,473	2,945
General and administrative	2,028	2,145	7,189	6,021
Total operating expenses	5,361	5,130	17,368	13,323
Operating loss	(5,420)	(5,130)	(17,425)	(13,341)
Warrant expense	-	-	-	(3,156)
Gain (loss) on change in estimated fair value of contingent royalty obligation	127	(85)	68	(244)
Finance income, net	95	44	214	73
Foreign currency gain (loss)	3	1	(6)	(22)
Loss before income taxes	(5,195)	(5,170)	(17,149)	(16,690)
Income tax expense	-	-	-	-
Net loss	\$ (5,195)	\$ (5,170)	\$ (17,149)	\$ (16,690)
Basic and diluted loss per common share	\$ (0.18)	\$ (0.33)	\$ (0.72)	\$ (1.13)
Weighted average number of common shares outstanding, basic and diluted	28,716,213	15,680,750	23,896,843	14,782,285