

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 14, 2020

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 May 14, 2020, disclosing financial information for its fiscal quarter ended March 31, 2020, 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. May 14, 2020

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 14, 2020

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. May 14, 2020



Motus GI Reports First Quarter 2020 Financial Results and Provides Corporate Update

- The Pure-Vu® System approved and placed in 19 major U.S. hospitals since Q4 2019 launch
- More than 75 GI physicians trained on the new Pure-Vu® System technology
- Key regulatory milestone achieved as GEN2 Pure-Vu® System awarded CE mark approval
- Implemented virtual sales support tools to drive activity during unprecedented market conditions related to COVID-19 pandemic

FORT LAUDERDALE, FL, May 14, 2020 – 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 first quarter ended March 31, 2020, and provided a corporate update.

“Our commercialization strategy for the Pure-Vu® System, which is focused on building a strong foundation of leading U.S. hospital systems, continues to build positive momentum with additional placements and evaluations in the first quarter of 2020. We believe that driving adoption and utilization at these prominent national and regional hospitals will provide the reference centers needed to expand our footprint more broadly,” stated Tim Moran, Chief Executive Officer of Motus GI. “While we are faced with unprecedented market challenges associated with the COVID-19 pandemic, including restricted access to hospitals and social distancing guidelines, we have developed remote sales and clinical support capabilities that keep us in active contact with our customers and allow us to engage new hospitals. One of the biggest impacts to the market has been a drop in the number of inpatient colonoscopies performed, as hospitals deferred procedures due to the risks associated with the COVID-19 pandemic. We are now preparing to support our customers as they slowly begin to reactivate their GI labs. For these patients, ensuring the avoidance of unnecessary delays or hospitalizations will be critical and we believe our Pure-Vu System may allow for a successful procedure the first time by improving visualization in patients with poorly prepared colons.”

Progress Updates

Since the first commercial placement of a Pure-Vu® System in October 2019, Motus GI has focused its U.S. sales efforts on early adopter hospitals and larger hospital networks that conduct anywhere from 500 to more than 1,000 inpatient colonoscopy procedures per year. During this time, Motus GI has placed the Pure-Vu® System in 19 of these targeted hospitals. The Company is in the process of gathering positive hospital use cases from these prominent hospitals, which is expected to generate broader industry awareness of the Pure-Vu® System. In addition, Motus GI has engaged a robust pipeline of approximately 150 target hospitals and continues to develop a growing schedule of product evaluations at key hospital systems.

In March, the Company achieved a key regulatory milestone in receiving CE Mark approval for the GEN2 Pure-Vu® System. The Company believes this is a positive step in the commercialization strategy for the system as the Company assesses potential strategic partnership opportunities. As one of the largest markets for inpatient colonoscopies outside of the U.S., the Company believes that Europe offers a significant opportunity to provide patients with improved care.



Subsequent to the end of the first quarter, the Company received notice the U.S. Patent and Trademark Office (USPTO) issued patent No. 10646108, which provides additional protection for the Company's flagship product – the Pure-Vu® System. The patent covers Motus GI's proprietary sensing technology and enhanced suction control systems increasing integrated interactions with other colonoscopy technology.

COVID-19 Pandemic Impact

In the first quarter of 2020, the Company saw a reported reduction of inpatient colonoscopies, as hospitals continue to focus resources on treating COVID-19 patients and cancel or postpone other medical procedures wherever possible. While this disruption within hospitals persists, the Company recognizes there will be an impact on its ability to begin new scheduled evaluations in the sales pipeline.

As announced on March 30, 2020, Motus GI implemented a cost reduction strategy that the Company believes will allow it to successfully navigate the market slowdown as a result of COVID-19, while continuing to advance the commercial and strategic objectives for the Pure-Vu System. The Company is confident that it will reduce its quarterly cash burn by ~50%, or approximately \$3 million per quarter, beginning on July 1, 2020.

The Motus GI management team continues to closely monitor the impact of the COVID-19 pandemic across the U.S. to assess its impact on the Company's business. In a further effort to adjust to the current operating environment, the Company has taken a proactive approach to provide support to the hospitals currently using the Pure-Vu® System. The sales team has maintained continuous contact with customers and is offering remote support for the Pure-Vu® System. This includes enabling the team to virtually conduct in-service assistance to physicians and their staff during procedures, which has already resulted in several Pure-Vu® enabled colonoscopies to be successfully supported remotely. Motus GI also has built the appropriate inventory, of both workstations and disposable sleeves, to supply its customers continued use of the system for the next several months, and its manufacturing partners continue to be fully operational.

Financial Results for the Quarter Ended March 31, 2020

For the three months ended March 31, 2020, the Company reported a net loss of approximately \$6.5 million, or a net loss per diluted share of \$0.23, compared to \$6.3 million, or a net loss per diluted share of \$0.29, for the same period last year. The first quarter of 2020 included approximately \$600,000 in non-cash expenses principally related to stock-based compensation, compared to \$1.0 million of non-cash expenses for the same period of 2019. Implementation of the 2020 cost-cutting plan is tracking as expected and will largely be implemented by the end of the second quarter of 2020, resulting in a significantly reduced cash burn run rate on a go forward basis. The Company expects the total one-time charges associated with the implementation of this program to be between \$1.0 million to \$1.5 million, of which, approximately \$600,000 in related expenses were booked in the first quarter.

The Company reported approximately \$21.5 million in cash, cash equivalents and investments as of March 31, 2020, compared to \$15.3 million for the same period of 2019. The Company believes its cash, cash equivalents and investments will be sufficient to ensure compliance with the Silicon Valley Bank (SVB) liquidity covenant into late fourth quarter 2020 and meet its anticipated cash requirements into 2021.



Conference Call:

The Motus GI management team has scheduled a conference call for today at 4:30 p.m. ET 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 13702032. 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 improve visualization during a colonoscopy while preserving established procedural workflow by irrigating the colon and evacuating debris to provide a better quality exam. 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 enhancing 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 related to the Company's cost reduction plan, the cost savings and the cash expenses related to the implementation of the plan, risks related to the continued impact of the COVID-19 pandemic, 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 30, 2020, 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. and Subsidiaries
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	<u>March 31, 2020</u>	<u>December 31, 2019</u>
	(unaudited)	(*)
ASSETS		
Current assets		
Cash and cash equivalents	\$ 21,457	\$ 20,528
Investments	-	8,203
Accounts receivable	19	65
Inventory	1,232	1,014
Prepaid expenses and other current assets	1,158	339
Related party receivable	4	18
Total current assets	<u>23,870</u>	<u>30,167</u>
Fixed assets, net	1,140	1,056
Right-of-use assets	973	1,021
Other non-current assets	13	13
Total assets	<u>\$ 25,996</u>	<u>\$ 32,257</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 2,948	\$ 2,999
Operating lease liabilities - current	259	321
Other current liabilities	124	270
Term debt, net of debt discount of \$227 and \$246, respectively	7,773	7,754
Total current liabilities	<u>11,104</u>	<u>11,344</u>
Contingent royalty obligation	1,551	1,872
Operating lease liabilities - non-current	720	713
Total liabilities	<u>13,375</u>	<u>13,929</u>
Commitments and contingent liabilities (Note 9)		
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; 28,826,157 and 28,811,087 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	3	3
Additional paid-in capital	103,593	102,789
Accumulated deficit	(90,975)	(84,464)
Total shareholders' equity	<u>12,621</u>	<u>18,328</u>
Total liabilities and shareholders' equity	<u>\$ 25,996</u>	<u>\$ 32,257</u>

(*) Derived from audited consolidated financial statements



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

	Three Months Ended	
	March 31,	
	2020	2019
Revenue	\$ 28	\$ 1
Cost of revenue	30	1
Gross loss	(2)	-
Operating expenses:		
Research and development	1,935	2,404
Sales and marketing	1,863	1,157
General and administrative	2,912	2,797
Total operating expenses	<u>6,710</u>	<u>6,358</u>
Operating loss	(6,712)	(6,358)
Gain on change in estimated fair value of contingent royalty obligation	321	27
Finance income (expense), net	(112)	60
Foreign currency loss	<u>(8)</u>	<u>(2)</u>
Loss before income taxes	(6,511)	(6,273)
Income tax expense	-	-
Net loss	<u>\$ (6,511)</u>	<u>\$ (6,273)</u>
Basic and diluted loss per common share	<u>\$ (0.23)</u>	<u>\$ (0.29)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>28,817,711</u>	<u>21,443,519</u>