

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 13, 2021

**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 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))

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

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 13, 2021, disclosing financial information and operating metrics for its fiscal quarter ended March 31, 2021 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 Holdings, Inc., dated May 13, 2021.

**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 13, 2021

By: /s/ Timothy P. Moran

Name: Timothy P. Moran

Title: Chief Executive Officer



### Motus GI Reports First Quarter 2021 Financial Results and Provides Corporate Update

- Received 510(k) clearance from FDA for Pure-Vu disposable sleeve for Upper GI endoscopies
- Revenue growth of ~40% compared to prior quarter
- Additional prominent U.S. medical centers signed to committed volume contract
- Advanced reimbursement strategy for Pure-Vu® System in both inpatient and outpatient markets

**FORT LAUDERDALE, FL**, May 13, 2021 – 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, 2021, and provided a corporate update.

"Market conditions are steadily improving in hospitals throughout the U.S., and, as a result, our team continues to build important customer relationships as we execute our strategy to build awareness, market acceptance, and utilization of our novel Pure-Vu System. In terms of key performance indicators in the first quarter of 2021, we delivered an almost 40% increase in revenue compared to last quarter. This represented our third consecutive quarter of incremental revenue growth. We are also encouraged to see a steady increase of Pure-Vu procedures conducted this quarter in comparison to the second half of 2020. We attribute this progress to both a rebound in the volume of hospital GI procedures, as well as the additional training we are conducting with targeted physicians as we regain on-site access at most accounts," commented Tim Moran, Chief Executive Officer at Motus GI.

"I am pleased to report that two weeks ago the FDA granted 510(k) clearance for our Pure-Vu disposable sleeve designed to fit on gastroscopes to remove blood, blood clots, and debris during Upper GI endoscopies. This is an exciting new market opportunity with the same customer base as our existing solution, as both use the same Pure-Vu System equipment and technology, and the same GIs perform both procedures, with the only difference being they will either use our disposable sleeve for gastroscopes or our disposable sleeves for colonoscopes. As a result, the commercial activity and customer base we are developing should soon be able to consider using Pure-Vu upper GI sleeves in another clinical application where we believe clearing the field of view during critical inpatient procedures also represents a significant unmet need. Emergent Upper GI procedures, where GI bleeding is the predominant indication, may expand our initial inpatient target market in the U.S. by approximately 25%, thereby allowing us to participate in a larger percentage of procedures performed by our key physicians," continued Mr. Moran.

"During the first quarter we continued to focus on our reimbursement strategy for inpatient and outpatient colonoscopy procedures. Reimbursement may provide an incentive for physicians and facilities to adopt our innovative technology due to favorable additional payments that may enhance the potential economic advantages and savings that Pure-Vu can drive for hospitals. Financial and health economic drivers, of course, complement the superior patient outcomes that we believe the Pure-Vu system delivers today," concluded Mr. Moran.



### First Quarter and Recent Business Highlights

- Reported the third sequential quarter of sales growth, which is attributable to increased disposable sleeve sales for procedures using the Pure-Vu System
- Signed two additional prominent medical centers to 12-month commitment agreements for minimum disposable sleeve purchase orders during the quarter
- Received FDA 510(k) clearance for the new Pure-Vu Upper GI disposable sleeve in April, and currently planning pilot cases with existing Pure-Vu users starting in June 2021
- Advanced the strategy to secure reimbursements for the Pure-Vu System when used during inpatient and traditional outpatient colonoscopies, including several submissions to CMS
- Announced the publication of new data from a sponsored cost effectiveness and resource allocation analysis of the Pure-Vu System® on the outcomes of cost, quality of life, and aversion of colorectal cancers (CRC), as compared to the current standard of care (SOC) for outpatient colonoscopy in the peer-reviewed journal Cost Effectiveness and Resource Allocation
- Continue to enroll patients in the recently announced clinical study at a leading U.S. academic medical center that is using the Pure-Vu System in patients with lower GI bleeding with minimal pre-procedural bowel prep

### Financial Results for the Quarter Ended March 31, 2021

The Company reported revenue of approximately \$51,000 for the first quarter of 2021, compared to approximately \$28,000 for the same period last year. Revenues are generally from new account and site reorder sales of Pure-Vu single-use sleeves.

For the three months ended March 31, 2021, we reported a net loss of \$4.6 million, or \$0.11 per basic and diluted share, compared to a net loss of \$6.5 million, or \$0.23 per basic and diluted share, for the same period last year. The net loss attributable to common shareholders in the first quarter of 2021 was \$10.8 million, or \$0.25 per basic and diluted share, which included a non-cash "deemed dividend from warrant issuance", totaling \$6.1 million, associated with the previously announced issuance of warrants under the warrant exchange agreement executed in January 2021 with an existing institutional investor.

During the first quarter 2021, net cash used in operating activities and for the purchase of fixed assets was \$4.7 million as compared to \$7.2 million for the same period of 2020, a reduction of approximately 35% year-over-year. First quarter 2021 cash expenditures included certain one-time annual outflows associated with compliance and corporate matters, totaling approximately \$1.6 million, which will not recur in future quarters this year.



The Company reported \$27.7 million in cash and cash equivalents as of March 31, 2021. This balance includes the approximately \$11 million raised from our January 2021 warrant exchange agreement, as well as \$8 million from our 2019 term loan agreement with Silicon Valley Bank.

#### Conference Call:

The Motus GI management team has scheduled a conference call for today, May 13<sup>th</sup>, 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 13719304. A live audio webcast can be accessed by visiting the investor relations section of the Company's website, [www.motusgi.com](http://www.motusgi.com) or <http://public.viavid.com/index.php?id=144700>. A replay of the webcast will be archived on the Motus GI website for 90 days following the event.

#### About Motus GI

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.

For more information, visit [www.motusgi.com](http://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 16, 2021, 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.

#### Investor Contact:

Bob Yedid  
LifeSci Advisors  
(646) 597-6989  
[bob@lifesciadvisors.com](mailto:bob@lifesciadvisors.com)



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

	<b>March 31, 2021</b>	<b>December 31, 2020</b>
	<b>(unaudited)</b>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 27,749	\$ 20,819
Accounts receivable	74	35
Inventory	770	805
Prepaid expenses and other current assets	1,221	448
Total current assets	<u>29,814</u>	<u>22,107</u>
Fixed assets, net	1,312	1,178
Right-of-use assets	730	766
Other non-current assets	13	13
Total assets	<u>\$ 31,869</u>	<u>\$ 24,064</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,015	\$ 2,333
Operating lease liabilities - current	243	238
Other current liabilities	4	60
Term debt, net of debt discount of \$19 and \$21, respectively	7,981	7,979
Total current liabilities	<u>10,243</u>	<u>10,610</u>
Contingent royalty obligation	1,697	1,617
Operating lease liabilities - non-current	504	547

Total liabilities	12,444	12,774
Commitments and contingent liabilities (Note 9)		
Shareholders' equity		
Preferred Stock \$0.0001 par value; 10,000,000 shares authorized; zero shares issued and outstanding	-	-
Common Stock \$0.0001 par value; 115,000,000 shares authorized; 46,779,028 and 32,272,309 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	5	3
Additional paid-in capital	127,790	115,008
Accumulated deficit	(108,370)	(103,721)
Total shareholders' equity	19,425	11,290
Total liabilities and shareholders' equity	\$ 31,869	\$ 24,064



**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,	
	2021	2020
Revenue	\$ 51	\$ 28
Operating expenses:		
Costs of revenue - sales	28	30
Research and development	1,345	1,935
Sales and marketing	676	1,863
General and administrative	2,444	2,912
Total costs and expenses	4,493	6,740
<b>Operating loss</b>	(4,442)	(6,712)
Gain (loss) on change in estimated fair value of contingent royalty obligation	(80)	321
Finance expense, net	(117)	(112)
Foreign currency loss	(10)	(8)
Net loss	(4,649)	(6,511)
Deemed dividends from warrant issuance	(6,145)	-
Net loss attributable to common shareholders	\$ (10,794)	\$ (6,511)
Basic and diluted loss per common share:		
Net loss	\$ (0.11)	\$ (0.23)
Net loss attributable to common shareholders	\$ (0.25)	\$ (0.23)
Weighted average number of common shares outstanding, basic and diluted	42,230,001	28,817,711