

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): March 16, 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:

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchanged on Which Registered</u>
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 March 16, 2021, disclosing financial information and operating metrics for its fiscal year ended December 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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Motus GI Holdings, Inc., dated March 16, 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: March 16, 2021

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



### Motus GI Reports Fourth Quarter 2020 Financial Results and Provides Corporate Update

- Signed new 12-month committed volume contracts with two prominent U.S. medical centers
- Reported progress on reimbursement for Pure-Vu System in both inpatient and outpatient markets, starting with CMS submissions
- Preparing to submit a 510(k) application to FDA by Q3 2021 for Pure-Vu System indication expansion for Upper GI endoscopies

**FORT LAUDERDALE, FL**, March 16, 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 fourth quarter ended December 31, 2020, and provided a corporate update.

"We reported a steady increase in commercial momentum during the second half of 2020 compared to the first half of the year. This momentum continued in the fourth quarter despite a resurgence of COVID-19 hospitalizations across much of the United States," stated Tim Moran, Chief Executive Officer of Motus GI. "While our sales team is still encountering limited access at most hospitals as a result of the pandemic, I am pleased by the continued progress we've made expanding our footprint in the market, including the signing of two prominent health systems to new annual agreements that we expect to generate revenues in 2021. We believe that as hospital access returns, GI procedures rebound to pre-pandemic levels and the number of Pure-Vu System placements expand across several hospital networks, our team will be well positioned to drive further Pure-Vu growth over the balance of 2021 and beyond."

"In addition to our commercial efforts, we are executing towards four value creation drivers, including reimbursement, new product innovation, clinical data, and strategic partnerships. Each of these catalysts offer an opportunity for us to enhance our portfolio, broaden our addressable market, scale our organization and unlock long-term shareholder value. We are already making progress with these initiatives, for example, we just announced the initiation of a new study at a leading non-profit academic medical center in the U.S. evaluating the clinical and economic outcomes using the Pure-Vu System in patients with emergent lower gastrointestinal bleeding. In addition, our team presented a request for an ICD-10 code at a Center for Medicare and Medicaid Services (CMS) meeting on March 9<sup>th</sup>, which is part of our broader strategy to obtain reimbursement for certain inpatient and outpatient procedures where Pure-Vu System can help facilitate visualization of inadequately prepared colons in high medical need patients," concluded Mr. Moran.



### Fourth Quarter and Recent Business Highlights

- Reported second sequential quarterly sales growth attributable to disposable sleeve sales for procedures using the Pure-Vu System
- Announced that two prominent medical centers – the University of Texas Medical Center, and NYU Langone – signed 12-month commitments for minimum disposable sleeve purchase orders, effective for 2021
- Initiated product evaluations of the Pure-Vu System at several new accounts, most notably the Mayo Clinic in Phoenix and Mass General Hospital in Boston
- Implemented a strategy to pursue reimbursement for the Pure-Vu System when used during inpatient and traditional outpatient colonoscopies, starting with specific CMS submissions
- Preparing to submit a 510(k) for a new Pure-Vu Upper GI product to FDA by Q3 2021
- Initiated a study at a leading US non-profit academic medical center using the Pure-Vu® System in patients with lower GI bleeding, in order to evaluate the clinical and economic benefits of the system with minimal pre-procedural bowel prep
- Secured an additional U.S. patent for the Pure-Vu System expanding IP portfolio, which includes 31 granted patents and 25 pending patents protecting the Pure-Vu System
- Strengthened the balance sheet, including executing a warrant exercise agreement with an existing institutional investor in January 2021, raising net proceeds of approximately \$11 million dollars that added to the \$20.8 million in cash and cash equivalents reported as of December 31, 2020

### Financial Results for the Quarter and Full Year Ended December 31, 2020

The Company reported revenue of approximately \$36,000 for the fourth quarter of 2020, compared to approximately \$99,000 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 December 31, 2020, we reported a net loss of approximately \$4.4 million, or a net loss per diluted share of \$0.12, compared to \$5.9 million, or a net loss per diluted share of \$0.21, for the same period last year. During the fourth quarter 2020, net cash used in operating activities and for the purchase of fixed assets was \$2.8 million as compared to \$5.6 million for the same period of 2019, a reduction of 50% year-over-year.

For the year ended December 31, 2020, we reported a net loss of approximately \$19.3 million, or a net loss per diluted share of \$0.60, compared to \$23.1 million, or a net loss per diluted share of \$0.92 for the same period last year. Net cash used in operating activities and for the purchase of fixed assets during the year ended December 31, 2020 totaled \$17.1 million as compared to \$20.4 million for the same period of 2019. These decreases were primarily attributable to the Company's cost-cutting measures that were announced on March 30, 2020. These measures reduced the Company's quarterly cash burn by approximately 50% compared to previously forecasted rates for the second half of 2020.

The Company reported approximately \$20.8 million in cash and cash equivalents as of December 31, 2020, compared to cash, cash equivalents and investments of \$28.7 million as of December 31, 2019. In January 2021, the Company executed a warrant exercise agreement with an existing institutional investor, raising net proceeds of approximately \$11 million dollars.



### Conference Call:

The Motus GI management team has scheduled a conference call for today, March 16<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 13714989. 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=142994>. 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 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.

### Investor Contact:

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

	December 31, 2020	December 31, 2019
<b>Asset</b>		
Current assets		
Cash and cash equivalents	\$ 20,819	\$ 20,528
Investments	-	8,203
Accounts receivable	35	65
Inventory	805	1,014
Prepaid expenses and other current assets	448	339
Related party receivable	-	18
Total current assets	22,107	30,167
Fixed assets, net		
Right-of-use assets	1,178	1,056
Other non-current assets	766	1,021
	13	13
Total assets	\$ 24,064	\$ 32,257
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities		
Accounts payable and accrued expenses	\$ 2,333	\$ 2,999
Operating lease liabilities - current	238	321
Other current liabilities	60	270
Term debt, net of debt discount of \$21 and \$246, respectively	7,979	7,754
Total current liabilities	10,610	11,344
Contingent royalty obligation	1,617	1,872

Operating lease liabilities - non-current	547	713
Total liabilities	<u>12,774</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; 115,000,000 and 50,000,000 shares authorized; 32,272,309 and 28,811,087 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	3	3
Additional paid-in capital	115,008	102,789
Accumulated deficit	<u>(103,721)</u>	<u>(84,464)</u>
Total shareholders' equity	11,290	18,328
Total liabilities and shareholders' equity	<u>\$ 24,064</u>	<u>\$ 32,257</u>

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

	<u>3 Months Ended December 31,</u>		<u>Twelve Months Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Revenue	\$ 36	\$ 99	\$ 98	\$ 107
Operating expenses:				
Cost of revenue- sales	23	71	95	136
Cost of revenue - Impairment of Inventory	401	-	401	-
Research and development	1,196	2,307	5,555	9,013
Sales and marketing	578	1,424	3,532	4,897
General and administrative	2,130	2,308	9,562	9,497
Total Cost and Expenses	<u>4,329</u>	<u>6,110</u>	<u>19,145</u>	<u>23,543</u>
<b>Operating loss</b>	<u>(4,293)</u>	<u>(6,011)</u>	<u>(19,047)</u>	<u>(23,436)</u>
Gain on change in estimated fair value of contingent royalty obligation	7	13	255	81
Finance income (expense), net	(116)	59	(464)	273
Foreign currency loss	3	2	(1)	(4)
Loss before income taxes	<u>(4,399)</u>	<u>(5,937)</u>	<u>(19,257)</u>	<u>(23,086)</u>
Net loss	<u>\$ (4,399)</u>	<u>\$ (5,937)</u>	<u>\$ (19,257)</u>	<u>\$ (23,086)</u>
Basic and diluted loss per common share	<u>\$ (0.12)</u>	<u>\$ (0.21)</u>	<u>\$ (0.60)</u>	<u>\$ (0.92)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>37,795,517</u>	<u>28,801,914</u>	<u>32,120,017</u>	<u>25,133,190</u>

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