

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 11, 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 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 12, 2021, disclosing financial information and operating metrics for its fiscal quarter ended June 30, 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 5.07 Submission of Matters to a Vote of Security Holders.**

On August 11, 2021, the Company held its Annual Meeting of Stockholders. The stockholders of the Company acted upon the following proposals at the Annual Meeting: (1) proposal for the election of directors; (2) proposal for the ratification of the appointment of EisnerAmper LLP as the Company's independent registered public accounting firm for the Company's fiscal year ending December 31, 2021; and (3) proposal for an amendment to the Company's certificate of incorporation, as amended, to increase the Company's authorized shares of common stock from 115,000,000 to 165,000,000. The final voting results were as follows:

1. The election of each of Timothy P. Moran, Mark Pomeranz, David Hochman, Darren Sherman, Samuel Nussbaum, Shervin Korangy, Gary J. Pruden and Sonja Nelson as directors to hold office for a term of one year, until their successor is duly elected and qualified or they are otherwise unable to complete their term.

The votes were cast for this matter as follows:

Nominees	Votes For	Votes Withheld	Broker Non-Votes
Timothy P. Moran	11,533,377	255,590	15,225,246
Mark Pomeranz	11,504,166	284,801	15,225,246
David Hochman	8,074,532	3,714,435	15,225,246
Darren Sherman	11,274,354	514,613	15,225,246

Samuel Nussbaum	11,182,789	606,178	15,225,246
Shervin Korangy	11,536,326	252,641	15,225,246
Gary J. Pruden	11,398,225	390,742	15,225,246
Sonja Nelson	11,547,497	241,470	15,225,246

2. The proposal to ratify the appointment of EisnerAmper LLP as the Company's independent registered public accounting firm for the Company's fiscal year ending December 31, 2021 was approved based upon the following votes:

Votes For	Votes Against	Abstentions	Broker Non-Votes
26,766,669	194,582	52,962	0

3. The proposal to approve an amendment to the Company's certificate of incorporation, as amended, to increase the Company's authorized shares of common stock from 115,000,000 to 165,000,000 was not approved based upon the following votes:

Votes For	Votes Against	Abstentions	Broker Non-Votes
20,369,933	6,392,200	252,080	0

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**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) Exhibits

The following exhibits are filed as part of this report:

Exhibit No.	Description
99.1	<a href="#">Press Release issued by Motus GI Holdings, Inc., dated August 12, 2021.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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 12, 2021

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

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

- Reported a 95% revenue increase versus Q1 2021; the fourth consecutive quarter of revenue growth
- Received FDA clearance for Pure-Vu sleeve for Upper GI endoscopies and initiated pilot patient cases
- Announced enrollment in EU clinical study assessing the Pure-Vu® System for outpatient CRC screening
- Secured minimally dilutive \$12.0 million credit financing to support commercial sales growth

**FORT LAUDERDALE, FL**, August 12, 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 second quarter and six months ended June 30, 2021, and provided a corporate update.

“Our team continues to execute our commercial strategy, as we build steady momentum by converting targeted U.S. hospitals into active Pure-Vu customers,” commented Tim Moran, Chief Executive Officer at Motus GI. “The second quarter represented our fourth consecutive quarter of incremental revenue growth and a ~95% increase in revenue compared to the first quarter of 2021. This trend is being driven in part by Pure-Vu disposable sleeve sales as existing customers increase their usage of the Pure-Vu System and we sign additional customers to volume commitment agreements.”

“In addition to our commercial progress, we are executing against our plans to expand our Pure-Vu portfolio through innovative new product launches, seeking to gain reimbursement coverage, generating additional compelling clinical data, and advancing discussions with several potential strategic partners. We believe each of these catalysts have the potential to enhance the enterprise value of the Company,” continued Mr. Moran. “We’ve now commenced initial pilot patient cases of our disposable sleeve for upper GI procedures, which allows for expanded utility of the Pure-Vu System in the GI Lab. This launch is synergistic to the work we are already doing in colonoscopy and will feed right into the upcoming introduction of our third generation Pure-Vu System, which offers even greater ease of use and will support both upper and lower GI procedures. We believe this is an exciting period in our company’s history, and we look forward to keeping everyone updated on our progress.”

### Second Quarter and Recent Business Highlights

- **Revenue Growth** - Reported the fourth sequential quarter of sales growth, which is largely attributable to increased disposable sleeve sales for procedures using the Pure-Vu System.
- **Increased Number of Customer Agreements** – The Company now has five medical centers signed to 12-month committed volume agreements for disposable sleeve purchase orders, which provide for recurring revenues. In addition, the Company completed the capital sale of a Pure-Vu® System to Sinai Hospital of Baltimore, a LifeBridge Health center, in the second quarter of 2021. This represents an important initial customer hospital in a large health system.



- **Initiated pilot cases in Upper GI Product Market** - Commenced initial pilot cases of the Pure-Vu Upper GI product, which is focused on targeted evaluations by existing Pure-Vu accounts currently using the system for colonoscopy. The purpose of these initial series of procedures is to demonstrate clinical utility of the Upper GI product, while also gaining real-world learnings.
- **Inpatient and Outpatient Reimbursement Strategy** - Advancing strategy to secure reimbursement for the Pure-Vu System when used for certain inpatient and outpatient colonoscopies.

In March 2021, we presented a request for an ICD-10 code at a Center for Medicare and Medicaid Services (“CMS”) meeting, which is part of our broader strategy to obtain reimbursement for certain inpatient and outpatient procedures where the Pure-Vu System can help facilitate visualization of inadequately prepared colons in high medical need patients. On August 2, 2021, CMS granted the Pure-Vu System a permanent ICD-10 code which will commence on October 1, 2021. The Pure-Vu System was not selected for the fast-track new technology add-on payment for inpatient procedures. However, the Company does not believe it faces reimbursement headwinds in the hospital inpatient environment.

- **Announced Development of Pure-Vu EVS, 3<sup>rd</sup> Generation Platform** - The development of the ‘Pure-Vu EVS’, the third generation of the Company’s system that will offer continued advancement of the current platform, including enhanced ease-of-use, upper and lower GI capabilities, and a reduced footprint workstation. The Company expects to submit the Pure-Vu EVS System to the FDA for 510K review by the end of 2021.
- **Initiated EU Study Exploring Limited Bowel Prep for CRC Screening** - Enrolled the first patients in the European Union feasibility outpatient study evaluating the clinical outcomes in patients with a history of poor bowel preparation using a low volume preparation with limited diet restrictions and the Pure-Vu System.
- **Progression of U.S. Study for Lower GI with Limited Bowel Prep** - Continuing to successfully enroll patients in the U.S.-based, investigator-initiated clinical study being conducted by a leading U.S. academic medical center to examine using the Pure-Vu System in patients with lower GI bleeding with minimal pre-procedural bowel prep.
- **Peer Reviewed Data Published** - Announced the publication of data from the REDUCE (“Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement”) study in the peer-reviewed journal BMC Gastroenterology. As previously announced, among the important findings from the REDUCE study is that the Pure-Vu System showed a 97% clinical success rate. Also, during the second quarter, the Company announced the peer-reviewed publication of new data from a Company 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, as compared to the current standard of care for outpatient colonoscopy. This data was published in the journal *Cost Effectiveness and Resource Allocation*.
- **Enhanced Financial Stability** – Secured an expanded \$12 million credit financing to support the Company’s commercial sales growth and advancement of its additional value creation drivers, which also replaces the previous \$8.0 million term loan agreement with Silicon Valley Bank and removes the existing \$10.0 million minimum cash balance liquidity covenant.



- **Recent Board Appointment** - Appointed seasoned biotech industry executive, Sonja Nelson, CPA, to the Board of Directors and as Chair of the Audit Committee, who will be a valuable new resource for the management team as the Company continues to ramp up its commercial growth strategy with a goal of building long-term shareholder value.

#### Financial Results for the Quarter Ended June 30, 2021

The Company reported revenue of approximately \$100,000 for the second quarter of 2021, compared to approximately \$1,000 for the same period last year, and approximately \$51,000 for the first quarter of 2021.

For the three months ended June 30, 2021, we reported a net loss of \$4.7 million, or \$0.10 per basic and diluted share, compared to a net loss of \$4.4 million, or \$0.15 per basic and diluted share, for the same period last year.

During the second quarter 2021, net cash used in operating activities and for the purchase of fixed assets was \$3.2 million as compared to \$4.3 million for the same period of 2020, a reduction of approximately 26% year-over-year.

The Company reported \$26.4 million in cash and cash equivalents as of June 30, 2021. This balance includes \$8 million from our 2019 term loan agreement with Silicon Valley Bank. In July 2021, we refinanced this loan and increased our credit facility by 50% up to \$12 million through the execution of a new loan agreement with Kreos Capital. Our current cash balance allows us to continue executing on our value creation drivers and is expected to meet our overall anticipated cash needs through 2022.

#### Conference Call:

The Motus GI management team has scheduled a conference call for today, August 12<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 13720949. 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.viaid.com/index.php?id=145456>. 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:

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

June 30,  
2021

December 31,  
2020

	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 26,379	\$ 20,819
Accounts receivable	73	35
Inventory	706	805
Prepaid expenses and other current assets	859	448
Total current assets	<u>28,017</u>	<u>22,107</u>
Fixed assets, net	1,451	1,178
Right-of-use assets	712	766
Other non-current assets	13	13
Total assets	<u>\$ 30,193</u>	<u>\$ 24,064</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,150	\$ 2,333
Operating lease liabilities – current	261	238
Other current liabilities	7	60
Term debt, net of debt discount of \$17 and \$21, respectively	7,983	7,979
Total current liabilities	<u>10,401</u>	<u>10,610</u>
Contingent royalty obligation	1,734	1,617
Operating lease liabilities - non-current	467	547
Total liabilities	<u>12,602</u>	<u>12,774</u>
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; 48,241,188 and 32,272,309 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	5	3
Additional paid-in capital	130,698	115,008
Accumulated deficit	(113,112)	(103,721)
Total shareholders' equity	<u>17,591</u>	<u>11,290</u>
Total liabilities and shareholders' equity	<u>\$ 30,193</u>	<u>\$ 24,064</u>



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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue	\$ 100	\$ 1	\$ 151	\$ 29
Operating expenses:				
Cost of revenue - sales	42	10	70	40
Research and development	1,508	1,264	2,853	3,199
Sales and marketing	795	582	1,471	2,445
General and administrative	2,345	2,365	4,789	5,277
Total costs and expenses	<u>4,690</u>	<u>4,221</u>	<u>9,183</u>	<u>10,961</u>
<b>Operating loss</b>	(4,590)	(4,220)	(9,032)	(10,932)
Gain (loss) on change in estimated fair value of contingent royalty obligation	(37)	(76)	(117)	245
Finance expense, net	(117)	(119)	(234)	(231)
Foreign currency gain (loss)	2	5	(8)	(3)
Net loss	<u>(4,742)</u>	<u>(4,410)</u>	<u>(9,391)</u>	<u>(10,921)</u>
Deemed dividends from warrant issuance	-	-	(6,145)	-
Net loss attributable to common shareholders	<u>\$ (4,742)</u>	<u>\$ (4,410)</u>	<u>\$ (15,536)</u>	<u>\$ (10,921)</u>
Basic and diluted loss per common share:				
Net loss	\$ (0.10)	\$ (0.15)	\$ (0.21)	\$ (0.38)
Net loss attributable to common shareholders	\$ (0.10)	\$ (0.15)	\$ (0.34)	\$ (0.38)
Weighted average number of common shares outstanding, basic and diluted	<u>47,732,674</u>	<u>28,846,881</u>	<u>45,493,776</u>	<u>28,832,296</u>

