

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 12, 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 November 12, 2021, disclosing financial information and operating metrics for its fiscal quarter ended September 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 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	Press Release issued by Motus GI Holdings, Inc., dated November 12, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

**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 12, 2021

By: /s/ Timothy P. Moran

Name: Timothy P. Moran

Title: Chief Executive Officer



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

- *Reported approximately 40% increase in revenue compared to Q2 2021*
- *On track to file a 510(k) submission to FDA by end of 2021 for Pure-Vu EVS, an advanced, next-generation system that will enhance procedural ease of use and speed of deployment*
- *Designing a multi-center, randomized controlled trial to support reimbursement of Pure-Vu for high need outpatients, a subset of the US market of more than 20 million total annual colonoscopies*

**FORT LAUDERDALE, FL**, November 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 third quarter and nine months ended September 30, 2021, and provided a corporate update.

"I am pleased with our team's ability to drive increased utilization of Pure-Vu® in our initial set of U.S. hospital accounts as well as convert more targeted accounts to active customers. This helped us deliver revenue growth of approximately 40% this quarter over the prior quarter and more than a four-fold increase on a year-over-year basis. Notably, this represents our fifth consecutive quarter of incremental revenue growth, despite continued headwinds from the Covid-19 ongoing pandemic," commented Tim Moran, Chief Executive Officer.

"We are in the process of preparing a 510(k) application for the Pure-Vu EVS, our third generation of the Pure-Vu System, which we expect to submit to the U.S. FDA by the end of this year. The Pure-Vu EVS represents a significant advancement of our technology, including rapid set-up in less than 90 seconds, the ability to load our sleeve on a 'dirty' scope in the procedure room, and improved overall navigation, handling and ease of use. We believe Pure-Vu EVS can accelerate physician interest and adoption of our technology and as such we plan to thoughtfully expand our commercial footprint over the next couple of quarters in anticipation of increased demand, allowing us to have local representation in the major U.S. GI markets," added Mr. Moran.

"Additionally, we continue to report positive new clinical data for the Pure-Vu System. We recently announced the presentation of positive data from an independent single-center study of the Pure-Vu System as an adjunct to colon cleansing in 40 patients with inadequate bowel preparation at the 2021 American College of Gastroenterology (ACG) Annual Scientific Meeting. We are also preparing for the initiation of a large multi-center, randomized control trial to support Pure-Vu reimbursement for the large outpatient colorectal cancer screening and diagnosis market," concluded Mr. Moran.



#### Third Quarter and Recent Business Highlights

- **Procedure Growth** – The Company increased sales of disposable sleeves for procedures using the Pure-Vu System, which resulted in the fifth sequential quarter of revenue growth.
- **New Customer Agreements:**
  - Through the end of the third quarter of 2021, approximately ten key U.S. hospitals have either purchased capital equipment and disposable sleeves or signed a 12 month committed-volume agreement.
  - Completed the capital sale of a Pure-Vu System to Memorial Herman Hospital in Houston in the third quarter of 2021, opening the door to the Memorial Herman Health System, which consists of 17 affiliated hospitals and making this placement an important initial customer hospital in a large health system.
- **510(k) Submission for Pure-Vu EVS to the FDA** - The Company expects to submit a 510(k) application for the Pure-Vu EVS System to the FDA by the end of 2021. In addition, the Company is currently preparing for the commercial launch of the Pure-Vu EVS, pending U.S. FDA clearance. This is the third generation of the Pure-Vu System, which has been under development for the last 18 months.
- **Outpatient Reimbursement Strategy:**
  - The Company is advancing its strategy to secure reimbursement for the Pure-Vu System when used for certain outpatient colonoscopies, including a multi-center, randomized controlled trial.
- **Clinical Data Generation:**
  - Announced positive new data from an independent study at the University of Texas Medical Branch, Galveston that supports use of the Pure-Vu System for screening and emergency colonoscopies for patients with inadequate bowel preparation.
  - Announced the expansion of the EU Clinical study exploring limited bowel prep for CRC screening with enrollment of initial patients at a second clinical site, the GastroZentrum Lippe, one of the top private endoscopy clinics in Germany.
  - Continuing the 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.
- **Exploration of Upper GI Bleed Market** - Commenced initial pilot cases of the Pure-Vu Upper GI product, which is focused on targeted evaluations by existing Pure-Vu accounts already using the system for colonoscopy. The purpose of these initial series of procedures is to demonstrate clinical utility of the Upper GI product and gain real-world learning to support improvements to a future Pure-Vu EVS-based Upper GI system.

- **Enhanced Financial Flexibility** – Secured an expanded \$12.0 million credit facility to support the Company’s commercial sales growth and advancement of its additional value creation drivers, which also replaces the previous \$8 million term loan agreement with Silicon Valley Bank and removes the \$10.0 million minimum cash balance liquidity covenant.



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

The Company reported revenue of approximately \$141,000 for the third quarter of 2021, compared to approximately \$33,000 for the same period last year, and approximately \$100,000 for the second quarter of 2021.

For the three months ended September 30, 2021, the Company reported a net loss of \$4.8 million, or \$0.10 per basic and diluted share, compared to a net loss of \$3.9 million, or \$0.13 per basic and diluted share, for the same period last year.

During the third quarter, net cash used in operating activities and for the purchase of fixed assets was \$3.1 million as compared to \$2.7 million for the same period of 2020.

The Company reported \$23.7 million in cash and cash equivalents as of September 30, 2021. This balance includes \$9.0 million of an up to \$12.0 million credit facility with Kreos Capital, which was put in place during the third quarter. The Company’s current cash balance allows it to continue executing on its value creation drivers and is expected to meet overall anticipated cash needs through 2022.

### Conference Call:

The Motus GI management team has scheduled a conference call for today, November 12<sup>th</sup>, at 8:30 a.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 13723885. 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.viaavid.com/index.php?id=146872>. 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, possible or assumed future results of operations, business strategies, potential growth opportunities, 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)

	September 30, 2021 (unaudited)	December 31, 2020
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 23,652	\$ 20,819
Accounts receivable	181	35
Inventory	515	805

Prepaid expenses and other current assets	530	448
Total current assets	24,878	22,107
Fixed assets, net	1,438	1,178
Right-of-use assets	749	766
Other non-current assets	13	13
Total assets	\$ 27,078	\$ 24,064
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,337	\$ 2,333
Operating lease liabilities - current	300	238
Other current liabilities	9	60
Term debt, net of debt discount of \$0 and \$21, respectively	-	7,979
Total current liabilities	2,646	10,610
Contingent royalty obligation	1,769	1,617
Operating lease liabilities - non-current	457	547
Convertible note, net of unamortized debt discount of \$182 and \$0, respectively	3,818	-
Long-term debt, net of unamortized debt discount of \$480 and \$0, respectively	4,608	-
Total liabilities	13,298	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; 48,241,188 and 32,272,309 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	5	3
Additional paid-in capital	131,711	115,008
Accumulated deficit	(117,936)	(103,721)
Total shareholders' equity	13,780	11,290
Total liabilities and shareholders' equity	\$ 27,078	\$ 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 September 30,		Nine months Ended September 30,	
	2021	2020	2021	2020
Revenue	\$ 141	\$ 33	\$ 292	\$ 62
Operating expenses:				
Cost of revenue - sales	65	32	135	72
Cost of revenue - impairment of inventory	186	-	186	-
Research and development	1,187	1,160	4,040	4,359
Sales and marketing	725	509	2,196	2,954
General and administrative	2,315	2,155	7,104	7,432
Total costs and expenses	4,478	3,856	13,661	14,817
<b>Operating loss</b>	(4,337)	(3,823)	(13,369)	(14,755)
Gain (loss) on change in estimated fair value of contingent royalty obligation	(35)	(3)	(152)	248
Loss on extinguishment of debt	(237)	-	(237)	-
Finance expense, net	(216)	(117)	(450)	(348)
Other income	5	-	5	-
Foreign currency loss	(4)	(1)	(12)	(4)
Net loss	(4,824)	(3,938)	(14,215)	(14,859)
Deemed dividends from warrant issuance	-	-	(6,145)	-
Net loss attributable to common shareholders	\$ (4,824)	\$ (3,938)	\$ (20,360)	\$ (14,859)
Basic and diluted loss per common share:				
Net loss	\$ (0.10)	\$ (0.13)	\$ (0.31)	\$ (0.51)
Net loss attributable to common shareholders	\$ (0.10)	\$ (0.13)	\$ (0.44)	\$ (0.51)
Weighted average number of common shares outstanding, basic and diluted	48,241,188	30,422,265	46,419,643	29,366,154

