

**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 14, 2022

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 November 14, 2022, disclosing financial information and operating metrics for its fiscal quarter ended September 30, 2022 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 November 14, 2022.
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: November 14, 2022

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

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Motus GI Reports Third Quarter 2022 Financial Results and Provides Business Update

- *Pure-Vu EVS approved for use at 25 hospitals since launch in March 2022, resulting in highest quarterly revenue reported in the Company's history*
- *Recently named a Sole Source Supplier by the Department of Veteran's Affairs, with several VA medical centers executing new contracts for Pure-Vu EVS systems under this designation*
- *Presented positive clinical data in three abstracts at the American College of Gastroenterology (ACG) 2022 Annual Scientific Meeting that further illustrate how Pure-Vu EVS is enabling physicians to significantly improve visualization during colonoscopy procedures across different settings and patient populations*

FORT LAUDERDALE, FL, November 14, 2022 – 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 ended September 30, 2022 and provided a corporate update.

“We reported revenue in the third quarter of \$278,000, which represents an approximately 50% increase compared with the second quarter of 2022, and our highest quarterly revenue to date. We continue to drive steady quarterly growth since our launch of Pure-Vu EVS six months ago. We believe our results are driven by an expanded commercial footprint and the positive attributes of the Pure-Vu EVS system,” commented Tim Moran, Chief Executive Officer. “There are approximately 25 hospitals with our system in place, which includes a balanced mix of academic, community, and VA hospitals. While the third quarter represented a solid performance, we did see a few accounts push their purchasing decision to the fourth quarter, which we believe is mainly due to capital budget constraints and continued hospital staffing challenges.”

“Now that we have established a solid base of hospitals with Pure-Vu EVS in use, we are incentivizing our sales team to increase the quarter-on-quarter utilization of Pure-Vu EVS disposable sleeves within each account. We believe that driving consistent repeat utilization is key to our long-term growth and is expected to generate predictable, sustained revenues. Our plan is aimed at going deeper in each metro market, while also strategically expanding to new hospitals,” added Mr. Moran.



Third Quarter and Recent Business Highlights

- Nearly doubled the initial guidance of hospital placements for Pure-Vu EVS, with 25 hospitals currently approved, approximately six months since launch.
- Successful commercial program for the Pure-Vu EVS System continues to drive steady revenue growth, which resulted in highest quarterly revenue in the Company's history.
- Commercial strategy aimed at increasing levels of utilization within existing accounts while strategically expanding to new hospitals. Driving utilization of disposable sleeves is key to the Company's long-term success as it can provide predictable, recurring, and sustained revenue growth.
- **Clinical Data Generation**
 - In October, the Company presented three abstracts featuring positive new clinical data on the Pure-Vu EVS in poster sessions during the American College of Gastroenterology (ACG) 2022 Annual Scientific Meeting. These three presentations showcase how the Pure-Vu System enables physicians to significantly improve visualization during colonoscopy procedures for patients with inadequate bowel preparation across different settings and patient populations.
- **Outpatient Reimbursement Strategy**
 - Continue advancing a multi-pronged strategy to secure reimbursement for the Pure-Vu System procedure by both private and public payers that could accelerate use for certain outpatient colonoscopies, within a market representing approximately 4.7 million targeted outpatient procedures per year.
 - The Company is preparing to initiate a large, multi-center trial designed to show a significant reduction in the number of aborted or poor-quality exams that lead to an early repeat procedure as defined by the Gastroenterology Tri-Society guidelines. The study's aim is to generate data quantifying the percentage of patients with inadequate prep and showing the Pure Vu Systems ability to achieve a substantial clinical improvement in those patients compared to the standard of care in a large multicenter trial. The results from this study are expected to support applications seeking reimbursement of the Pure-Vu System when used in certain outpatient colonoscopies.
- **Product Innovation**
 - On track to launch the Pure Vu EVS Gastro device in the U.S. market in 2023. This device will bring upper GI capabilities to the new Pure-Vu EVS platform through key enhancements, including a larger and more powerful suction channel, more efficient irrigation jets, and a smaller profile distal tip that offers enhanced flexibility during insertion.
 - Upper GI bleeds occurred in the U.S. at a rate of approximately 400,000 cases per year in 2019, according to iData Research Inc. The existence of blood and blood clots in these patients can impair a physician's view, making it difficult to identify the bleed source. Motus believes removing adherent blood clots from the field of view is a significant need in allowing a physician the ability to identify and treat the bleed source. The mortality rate of this condition can reach up to approximately 13%, as noted in Thad Wilkins, MD, et al., American Family Physician (2012).



■ Strategic Partnerships & Collaborations

- The Company continues to pursue various opportunities with strategic partners both in and outside of the U.S. The Company believes the success it's had with the commercial program for the Pure-Vu EVS should provide potential opportunities. The Company's focus in evaluating these opportunities is centered upon accelerating its commercial progress and potentially strengthening its balance sheet.

Financial Results for the Third Quarter Ended September 30, 2022

The Company reported revenue of \$278,000 for the third quarter 2022, compared to \$141,000 for the same period last year. Revenues for this past quarter also represented an approximately 50% increase over the second quarter 2022 and were primarily derived from reorders and new customer orders of disposable sleeves, as well as limited workstation sales and rentals.

For the three months ended September 30, 2022, the Company reported a net loss attributable to common shareholders of \$5.0 million, or \$1.69 per basic and diluted share, compared to a net loss attributable to common shareholders of \$4.8 million, or \$2.00 per basic and diluted share, for the same period last year.

During the third quarter 2022, net cash used in operating activities and for the purchase of fixed assets was \$3.8 million compared to \$3.1 million for the same period of 2021.

The Company reported \$13.3 million in cash and cash equivalents as of September 30, 2022. This balance includes the fully funded credit facility with Kreos Capital. After the third quarter end, the Company sold approximately \$5.5 million worth of shares from its existing at-the-market facility. As a result, the Company's current cash balance allows it to meet anticipated needs through the second quarter 2023.

Motus GI Holdings, Inc. and Subsidiaries Condensed Consolidated Balance Sheets Highlights (unaudited, in thousands)

	As of	
	September 30, 2022	December 31, 2021
Cash	\$ 13,294	\$ 22,563
Working capital	10,020	20,629
Total assets	17,366	26,089
Total shareholders' equity	762	9,657

Conference Call:

The Motus GI management team has scheduled a conference call for today, November 14th, 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 13733811. A live audio webcast can be accessed by visiting the investor relations section of the Company's website, www.motusgi.com or ([click here](#)). 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 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 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 quarterly and annual reports filed with the Securities and Exchange Commission, 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, 2022 <u>(unaudited)</u>	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 13,294	\$ 22,563
Accounts receivable	161	109
Inventory	1,014	496
Prepaid expenses and other current assets	1,018	793
Total current assets	<u>15,487</u>	<u>23,961</u>
Fixed assets, net	1,395	1,428
Right-of-use assets	471	687
Other non-current assets	13	13
Total assets	<u>\$ 17,366</u>	<u>\$ 26,089</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,696	\$ 2,584
Operating lease liabilities - current	248	307
Other current liabilities	70	10
Current portion of long-term debt, net of unamortized debt discount of \$260 and \$271, respectively	2,453	431
Total current liabilities	<u>5,467</u>	<u>3,332</u>
Contingent royalty obligation	1,789	1,760
Operating lease liabilities - non-current	220	385
Convertible note, net of unamortized debt discount of \$123 and \$166, respectively	3,877	3,834
Long-term debt, net of unamortized debt discount of \$176 and \$317, respectively	5,251	7,121
Total liabilities	<u>16,604</u>	<u>16,432</u>
Commitments and contingent liabilities (Note 9)		
Shareholders' equity		
Common stock \$0.0001 par value; 115,000,000 shares authorized; 3,025,502 and 2,416,021 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	-	-
Additional paid-in capital	138,431	132,411
Accumulated deficit	(137,669)	(122,754)
Total shareholders' equity	<u>762</u>	<u>9,657</u>
Total liabilities and shareholders' equity	<u>\$ 17,366</u>	<u>\$ 26,089</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 September 30,		Nine months Ended September 30,	
	2022	2021	2022	2021
Revenue	\$ 278	\$ 141	\$ 483	\$ 292
Operating expenses:				
Cost of revenue - sales	83	65	166	135
Cost of revenue - impairment of inventory	-	186	159	186
Research and development	1,573	1,187	4,261	4,040
Sales and marketing	1,349	725	3,554	2,196
General and administrative	1,978	2,315	6,167	7,104
Total costs and expenses	<u>4,983</u>	<u>4,478</u>	<u>14,307</u>	<u>13,661</u>
Operating loss	(4,705)	(4,337)	(13,824)	(13,369)
Gain (loss) on change in estimated fair value of contingent royalty obligation	34	(35)	(29)	(152)
Loss on extinguishment of debt	-	(237)	-	(237)

Finance expense, net	(310)	(216)	(1,001)	(450)
Other income	-	5	-	5
Foreign currency gain (loss)	<u>17</u>	<u>(4)</u>	<u>(61)</u>	<u>(12)</u>
Net loss	<u>(4,964)</u>	<u>(4,824)</u>	<u>(14,915)</u>	<u>(14,215)</u>
Deemed dividends from warrant issuance	-	-	-	(6,145)
Net loss attributable to common shareholders	<u>\$ (4,964)</u>	<u>\$ (4,824)</u>	<u>\$ (14,915)</u>	<u>\$ (20,360)</u>
Basic and diluted loss per common share:				
Net loss attributable to common shareholders	<u>\$ (1.69)</u>	<u>\$ (2.00)</u>	<u>\$ (5.40)</u>	<u>\$ (8.77)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>2,937,530</u>	<u>2,412,059</u>	<u>2,763,164</u>	<u>2,320,982</u>
