

**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 10, 2023

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 May 10, 2023.
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: May 10, 2023

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



Motus GI Reports First Quarter 2023 Financial Results and Provides Corporate Update

- Oral presentation at the Digestive Disease Week 2023 featured positive clinical data showing a reduction of 33% in incomplete bowel prep (IBP) in just six months after implementation of the Pure-Vu® system at the Minneapolis VA Medical Center
- The Company is advancing its development of Pure-Vu EVS Gastro, designed for Upper GI bleeding procedures - an area of high unmet patient need - and expects submission of the 510(k) to the FDA for this new product line and its next generation Lower GI platform in Q4 2023
- The Company continues its exploration process to target strategic and financing alternatives aimed at accelerating commercialization of the Pure-Vu System and maximizing stockholder value

FORT LAUDERDALE, FL, May 10, 2023 – 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, 2023, and provided a corporate update.

“We continue to advance the development of several potential growth drivers for our business, including R&D efforts to bring Pure-Vu Upper GI, and an enhanced Lower GI platform to market. The planned 510(k) submission to the FDA for the Pure-Vu Gastro Upper GI system and advancements to the overall platform remains on track for the fourth quarter of 2023,” commented Mark Pomeranz, Chief Executive Officer. “While our Pure-Vu technology makes up the backbone of these two new devices, each product provides significant improvements and are designed to potentially open significant new segments of the GI market by introducing new capabilities while also addressing factors that make it easier to work with commercial partners, including minimizing training requirements and reducing the cost of goods by approximately 50%.”

First Quarter and Recent Business Highlights

- Data showing an improved rate of incomplete bowel prep (IBP) after implementation of the Pure-Vu® system at the Minneapolis VA Medical Center (MVA) was selected for an oral presentation during the Digestive Disease Week in May 2023. The data show that six months after the implementation of the Pure-Vu system, MVA noted a lowered rate of IBP by 33% hospital wide to 5.9% compared with 9.3% for the six months prior to implementation of the device, reducing canceled and early repeat procedures, as well as improving examination quality and resource utilization.
- The Company continues to advance the development of the Pure-Vu EVS Gastro device, which is on track to be submitted to the FDA via the 510(k) process before the end of this year. This device brings 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. In addition, several of the design enhancements are expected to result in a significant reduction in cost-of-goods. The Company believes the Upper GI application and removing adherent blood clots from the field of view is a significant need in allowing a physician the ability to identify and treat a GI bleed in a patient population with high mortality rate of ~13%
- The Company is working on incorporating the improvements developed for the Pure-Vu EVS Gastro into the device for the colon. These enhancements are expected to achieve a reduction in the cost-of-goods of approximately 50% and reduce the training requirements for both the sales team and the customer. These improvements along with the Pure-Vu EVS Gastro should better position the company for strategic relationships with the goal to maximizing stockholder value and accelerate commercialization of the Pure-Vu System, however, there can be no assurance that it will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful
- The Company continues to provide sales support and service to hospitals across the United States that have implemented Pure-Vu EVS and is focused on adding targeted new pipeline opportunities in contracted health systems. These efforts include building the Company’s relationship with the Veterans Health Administration (VHA), the largest integrated health care system in the U.S. Several VA hospitals have already implemented Pure-Vu EVS and Motus is currently working with additional VA hospitals to include Pure-Vu EVS in their 2024 budget planning and leveraging Motus GI’s official position as a sole source provider and small business by the VHA.
- To date in 2023, the Company has announced two rounds of cost-cutting measures which are expected to reduce operating expense cash burn by more than 50% in order to aggressively preserve capital. The primary cuts are attributable to reductions in the Company’s executive management, workforce, and clinical expenses. The Company expects to incur certain non-recurring charges related to these cost-cutting measures of approximately \$1.5 million in the first half of 2023.



Financial Results for the Quarter Ended March 31, 2023

The Company reported revenue of \$56,000 for the first quarter 2023, compared to \$20,000 for the same period last year. Revenues for this past quarter were primarily derived from reorders and new customer orders of disposable sleeves.

For the three months ended March 31, 2023, the Company reported a net loss attributable to common shareholders of \$4.4 million, or \$0.92 per basic and diluted share, which includes the impact of restructuring charges of \$1.3 million related to the first quarter strategic restructuring program. This is comparable to a net loss attributable to common shareholders of \$4.8 million, or \$1.86 per basic and diluted share, for the same period last year.

During the first quarter 2023, net cash used in operating activities and for the purchase of fixed assets was \$4.8 million compared to \$5.2 million for the same period of 2022.

The Company reported \$8.6 million in cash and cash equivalents as of March 31, 2023. This balance included the fully funded credit facility with Kreos Capital, which has approximately \$10.6 million due and outstanding.

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:

Troy Williams
LifeSci Advisors
(518) 221-0106
twilliams@lifesciadvisors.com



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

	<u>March 31,</u> <u>2023</u> <u>(unaudited)</u>	<u>December 31,</u> <u>2022</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,648	\$ 14,042
Accounts receivable	52	59
Inventory, current	464	488
Prepaid expenses and other current assets	1,093	781
Total current assets	<u>10,257</u>	<u>15,370</u>
Fixed assets, net	1,237	1,325
Inventory, non-current	334	511
Right-of-use assets	390	428
Other non-current assets	13	13
Total assets	<u>\$ 12,231</u>	<u>\$ 17,647</u>
Liabilities and Shareholders' (Deficiency) Equity		
Current liabilities:		
Current portion of long-term debt, net of unamortized debt discount of \$168 and \$182, respectively	\$ 2,611	\$ 2,532
Accounts payable and accrued expenses	1,472	1,969
Operating lease liabilities - current	248	245
Other current liabilities	47	53
Total current liabilities	<u>4,378</u>	<u>4,799</u>
Convertible note, net of unamortized debt discount of \$94 and \$108, respectively	3,906	3,892
Long-term debt, net of unamortized debt discount of \$104 and \$135, respectively	3,904	4,589
Contingent royalty obligation	992	1,212
Operating lease liabilities - non-current	136	178
Total liabilities	<u>13,316</u>	<u>14,670</u>
Commitments and contingent liabilities (Note 9)		
Shareholders' (deficiency) equity		
Common stock \$0.0001 par value; 115,000,000 shares authorized; 4,778,873 and 4,659,769 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	-	-
Additional paid-in capital	144,652	144,328
Accumulated deficit	(145,737)	(141,351)
Total shareholders' (deficiency) equity	<u>(1,085)</u>	<u>2,977</u>
Total liabilities and shareholders' (deficiency) equity	<u>\$ 12,231</u>	<u>\$ 17,647</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	
	March 31,	
	2023	2022
Revenue	\$ 56	\$ 20
Operating expenses:		
Cost of revenue - sales	9	15
Cost of revenue - impairment of inventory	165	159
Research and development	1,454	1,275
Sales and marketing	842	983
General and administrative	1,945	2,114
Total costs and expenses	<u>4,415</u>	<u>4,546</u>
Loss from Operations	(4,359)	(4,526)
Gain on change in estimated fair value of contingent royalty obligation	220	29
Finance expense, net	(239)	(332)
Foreign currency (loss) gain	(8)	18
Net loss	<u>\$ (4,386)</u>	<u>\$ (4,811)</u>
Basic and diluted loss per common share:	<u>\$ (0.92)</u>	<u>\$ (1.86)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>4,763,210</u>	<u>2,589,712</u>