

**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 14, 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:

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

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 August 11, 2022, disclosing financial information and operating metrics for its fiscal quarter ended June 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 August 14, 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: August 14, 2023

By: /s/ Mark Pomeranz
Name: Mark Pomeranz
Title: Chief Executive Officer

**Motus GI Reports Second Quarter 2023 Financial Results
and Provides Corporate Update**

- *On track to submit planned special 510(k) for Pure-Vu Gen 4 Gastro and Colon to the FDA in Q4 2023;*
- *Received system wide approval in the Banner Medical Hospital Network and installed the first system at the Banner Desert Medical Center in Mesa, Ariz.*
- *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, August 14, 2023 – Motus GI Holdings, Inc., (NASDAQ: MOTS) (“Motus GI” or the “Company”), a medical technology company focused on improving endoscopic outcomes and experiences, today reported its financial results for the second quarter ended June 30, 2023, and provided a corporate update.

Mark Pomeranz, Chief Executive Officer, commented, “We remain on track with the planned submission of a special 510(k) to the FDA in the coming months, which will bring us one step closer to being able to bring our next generation system to the market, expanding upon the Pure-Vu platform’s capabilities into supporting upper GI procedures. The Pure-Vu Gen 4 Gastro and Colon will offer several enhancements compared to our current system, resulting in minimized training requirements and reducing the cost of goods by approximately 50%. In order to support the expected commercial launch of the Pure-Vu Gen 4 Gastro and Colon, pending regulatory clearance, we are working with well-respected research hospitals both in the U.S. and abroad to generate preclinical and clinical data that show the value this system offers patients and hospitals. This includes Dr. Carlos Robles-Medranda, Head of the Endoscopy Service at the Ecuadorian Institute of Digestive Diseases and Director of the Pentax Training Center Ecuador, who recently helped highlight the Pure-Vu Gen 4 Gastro and Colon system during the 9th Ecuadorian Institute of Digestive Diseases (IECED) Live Endoscopy Course 2023.”

Second Quarter and Recent Business Highlights

- The Company continues to advance the development of the Pure-Vu Gen 4 Gastro, which is on track to be submitted to the FDA via the special 510(k) process before the end of this year. A special 510(k), according to FDA guidance, is usually reviewed within 30 days of receipt, rather than the 90 days for a traditional 510(k). Pure-Vu Gen 4 Gastro brings upper GI capabilities to the new Pure-Vu 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, as well as a reduction in the cost-of-goods of approximately 50% and reduction in the training requirements for both the sales team and the customer.
 - The Company is leveraging its Gen 4 technology to enhance the Pure-Vu device in the colon, called Pure-Vu Gen 4 Colon, which is on track to be submitted to the FDA via the special 510(k) process before the end of this year. Both the Pure-Vu Gen 4 Gastro and Colon will utilize the same workstation to create an effective platform to improve visualization in both the upper and lower GI tract to facilitate use in multiple indications.
 - Article published in the July 2023 issue of Gastroenterology & Endoscopy News discussed the clinical data from a 12-month study assessing the Pure-Vu® EVS at the University of Minnesota and Minneapolis VA Medical Center (MVA), which show a hospital-wide improvement in the rate of incomplete bowel prep (IBP) for colonoscopies during. The article is titled, “Intraprocedural Cleansing System Lowers Rate of Inadequate Bowel Prep,” and was authored by Tessa Herman, MD, at the University of Minnesota. Topline data from this study were first presented in an oral presentation during Digestive Disease Week 2023.
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- Pure-Vu Gen 4 Gastro and Colon system featured during the 9th Ecuadorian Institute of Digestive Diseases (IECED) Live Endoscopy Course 2023 at the Pentax Learning Center, which is considered one of the most important digestive medicine annual events held in the Latin American region with over 1,000 physicians registered. During a live case conducted at the event, the Pure-Vu system was used to support an underwater endoscopic mucosal resection (UEMR), which is a polypectomy technique where the colon lumen is filled with distilled water or saline solution instead of air or carbon dioxide as used in a conventional EMR, and resection is then performed without submucosal fluid injection. The Pure-Vu Gen 4 system will have a new mode called “fluid only” that the user can select when needed to support this new use case of UEMR.

The Pure-Vu Gen 4 Gastro, which is designed for use in upper gastrointestinal (GI) procedures, was also featured during the IECED Live Endoscopy Course in a hands-on demonstration area that allowed several hundred physicians to get experience with this next generation system.

- The Company received approval from the Israeli Ministry of Health, Medical Device Division (“AMAR”) to initiate commercial sales of the Pure-Vu EVS System in Israel, one of the largest colonoscopy markets in the Middle East. The Company continues to evaluate potential strategic agreements with medical device companies and distributors who have an existing commercial footprint in Israel and across Europe.
 - In July, the Company announced that Banner Desert Medical Center purchased and initiated the implementation of the Pure-Vu[®] System with the aim of improving efficiencies and clinical outcomes of inpatient colonoscopy procedures for patients who present with inadequate bowel preparation. This is part of the Company’s strategy to get administrative approval in various hospital systems to help advance the roll out of Pure Vu Gastro and Gen 4 Colon and support our strategic initiatives.
 - To date in 2023, the Company has completed two rounds of cost-cutting measures that 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 incurred non-recurring charges related to these cost-cutting measures of approximately \$1.5 million in the first half of 2023.
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Financial Results for the Second Quarter Ended June 30, 2023

The Company reported revenue of \$113,000 for the second quarter 2023, compared to \$185,000 for the same period last year. Revenues for this past quarter were primarily derived from disposable sleeve sales and limited workstation sales.

For the three months ended June 30, 2023, the Company reported a net loss attributable to common shareholders of \$3.0 million, or \$0.40 per basic and diluted share, which includes the impact of restructuring charges of \$0.3 million during the second quarter related to the strategic restructuring program. This is comparable to a net loss attributable to common shareholders of \$5.1 million, or \$1.86 per basic and diluted share, for the same period last year.

During the second quarter 2023, net cash used in operating activities and for the purchase of fixed assets was \$2.6 million compared to \$4.6 million for the same period of 2022.

The Company reported \$8.5 million in cash and cash equivalents as of June 30, 2023. This balance included the fully funded credit facility with Kreos Capital, which has approximately \$10.6 million due and outstanding. The Company believes that its cash and cash equivalents as of June 30, 2023 will be sufficient to allow the Company to fund its commercial, R&D and corporate operations through the first quarter of 2024.

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, statements relating to risks related to market and other conditions, 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, except as required by law.

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

	<u>June 30, 2023</u>	<u>December 31, 2022</u>
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,521	\$ 14,042
Accounts receivable	106	59
Inventory, current	446	488
Prepaid expenses and other current assets	737	781
Total current assets	<u>9,810</u>	<u>15,370</u>
Fixed assets, net	1,209	1,325
Inventory, non-current	377	511
Right-of-use assets	332	428
Other non-current assets	13	13
Total assets	<u>\$ 11,741</u>	<u>\$ 17,647</u>
Liabilities and Shareholders' (Deficiency) Equity		
Current liabilities:		
Current portion of long-term debt, net of unamortized debt discount of \$151 and \$182, respectively	\$ 2,694	\$ 2,532
Accounts payable and accrued expenses	1,470	1,969
Operating lease liabilities – current	243	245
Other current liabilities	44	53
Total current liabilities	<u>4,451</u>	<u>4,799</u>
Convertible note, net of unamortized debt discount of \$80 and \$108, respectively	3,920	3,892
Long-term debt, net of unamortized debt discount of \$70 and \$135, respectively	3,198	4,589
Contingent royalty obligation	1,056	1,212
Operating lease liabilities - non-current	79	178
Total liabilities	<u>12,704</u>	<u>14,670</u>
Commitments and contingent liabilities		
Shareholders' (deficiency) equity		
Common stock \$0.0001 par value; 115,000,000 shares authorized; 5,305,441 and 4,659,769 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	1	-
Additional paid-in capital	147,770	144,328
Accumulated deficit	(148,734)	(141,351)
Total shareholders' (deficiency) equity	<u>(963)</u>	<u>2,977</u>
Total liabilities and shareholders' (deficiency) equity	<u>\$ 11,741</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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue	\$ 113	\$ 185	\$ 169	\$ 205
Operating expenses:				
Cost of revenue - sales	31	68	40	83
Cost of revenue - impairment of inventory	30	-	195	159
Research and development	759	1,413	2,213	2,688
Sales and marketing	337	1,222	1,179	2,205
General and administrative	1,638	2,075	3,583	4,189
Total costs and expenses	<u>2,795</u>	<u>4,778</u>	<u>7,210</u>	<u>9,324</u>
Loss from Operations	(2,682)	(4,593)	(7,041)	(9,119)
Gain (loss) on change in estimated fair value of contingent royalty obligation	(64)	(92)	156	(63)
Finance expense, net	(246)	(359)	(485)	(691)
Foreign currency loss	(5)	(96)	(13)	(78)
Net loss	<u>\$ (2,997)</u>	<u>\$ (5,140)</u>	<u>\$ (7,383)</u>	<u>\$ (9,951)</u>
Basic and diluted loss per common share:	<u>\$ (0.40)</u>	<u>\$ (1.86)</u>	<u>\$ (1.20)</u>	<u>\$ (3.72)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>7,555,903</u>	<u>2,758,457</u>	<u>6,167,271</u>	<u>2,674,536</u>