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): March 31, 2023

MOTUS GI HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-38389	81-4042793
(State or other jurisdiction	(Commission	(IRS Employer
of incorporation)	File Number)	Identification No.)

1301 East Broward Boulevard, 3rd Floor

Ft. Lauderdale, FL

(Address of principal executive offices)

33301

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) П

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. 🗵

(Zip Code)

Item 2.02. Results of Operations and Financial Condition.

Motus GI Holdings, Inc. (the "Company") issued a press release on March 31, 2023, disclosing financial information and operating metrics for its fiscal year ended December 31, 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:

No.	Description
99.1	Press Release issued by Motus GI Holdings, Inc., dated March 31, 2023.
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

Dated.	March	31	2023	
Datou.	watch	51,	2025	

MOTUS GI HOLDINGS, INC.

 By:
 /s/Timothy P. Moran

 Name:
 Timothy P. Moran

 Title:
 Chief Executive Officer



Motus GI Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

- 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
- The Company is actively supporting its existing installed customer base and pipeline opportunities in contracted health systems
- The Company is advancing its development of Pure-Vu EVS Gastro, designed for Upper GI bleeding procedures, and expects submission to FDA by the end of 2023

FORT LAUDERDALE, FL, March 31, 2023 – <u>Motus GI Holdings, Inc.</u>, (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 fourth quarter and year ended December 31, 2022, and provided a corporate update.

"As previously announced, we initiated the ongoing evaluation of strategic and financing alternatives with the goal of identifying opportunities to accelerate our commercialization of the Pure-Vu System while also maximizing shareholder value. In the meantime, we have also implemented a restructuring process to further reduce our costs, while maintaining the ability to support our customers and targeted commercial activities," commented Tim Moran, Chief Executive Officer.

"We remain on track to achieve our previously communicated timeline for submission of our Pure-Vu Gastro Upper GI product to the FDA in the second half of 2023. New enhancements in this device will be incorporated into the current Pure-Vu colon device, which will reduce our overall cost-of-goods by approximately 50%," concluded Mr. Moran.



Fourth Quarter and Recent Business Highlights

- The Company's commercial program continues providing sales and support to hospitals across the United States that have implemented Pure-Vu EVS, as well as pipeline opportunities in contracted health systems.
- The Company recently announced it had initiated a process of exploring a range of strategic and financing alternatives focused on maximizing stockholder value and accelerating commercialization of the Pure-Vu System. Potential strategic alternatives that may be considered by the Company as part of this process include an acquisition, merger, reverse merger, other business combination, sale of assets, licensing, and other strategic transactions. The Company intends to continue to pursue this process, 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.
- In January 2023, the Company began implementing a strategic restructuring program, including a reduction in workforce, with the objective of preserving capital by initially reducing quarterly operating costs by approximately 35% on a go forward basis. The Company expects to incur a non-recurring charge of approximately \$1.0 to 2.0 million in the first quarter of 2023 related to the restructuring.

Product Innovation

- Motus GI continues to advance the development of the Pure-Vu EVS Gastro device, which is on track to be submitted to the FDA before the end of this year via the 510(k) process. 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 will result in a significant reduction in cost-of-goods compared to the EVS colon device that is currently on the market. In parallel the Company is working on incorporating the improvements developed for the Pure-Vu EVS Gastro into the device for the colon, which should achieve approximately a 50% reduction in the cost-of-goods to be better positioned for strategic relationships.
- 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 bleed source. 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. The mortality rate of this condition can reach up to approximately 13%, as noted in Thad Wilkins, MD, et al., American Family Physician (2012).

Outpatient Reimbursement Strategy

The Company has designed 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, a market representing approximately 4.7 million procedures per year.



Financial Results for the Quarter and Year Ended December 31, 2022

The Company reported revenue of \$109,000 for the fourth quarter 2022, compared to \$99,000 for the fourth quarter of 2021. Revenues for the full year 2022 were \$592,000 compared to \$391,000 for the full year 2021. Revenues were primarily derived from reorders and new customer orders of disposable sleeves.

For the three months ended December 31, 2022, the Company reported a net loss attributable to common shareholders of \$3.7 million, or \$0.79 per basic and diluted share, compared to a net loss attributable to common shareholders of \$4.8 million, or \$1.99 per basic and diluted share, for the three months ended December 31, 2021.

For the year ended December 31, 2022, the Company reported a net loss attributable to common shareholders of \$18.6 million, or \$5.74 per basic and diluted share, compared to a net loss attributable to common shareholders of \$25.2 million, or \$10.74 per basic and diluted share, for the year ended December 31, 2021, which included a one-time non-cash deemed dividend from warrant issuance, totaling \$6.1 million, associated with the warrant exchange agreement from the first quarter 2021.

During the fourth quarter of 2022, net cash used in operating activities and for the purchase of fixed assets was \$4.0 million as compared to \$3.9 million for the same period of 2021.

Net cash used in operating activities and for the purchase of fixed assets during the year ended December 31, 2022 totaled \$17.7 million as compared to \$14.9 million for year ended December 31, 2021.

The Company reported \$14.0 million in cash and cash equivalents as of December 31, 2022. This balance included the fully funded credit facility with Kreos Capital, which has approximately \$11.5 million due and outstanding.

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

	A	As of				
	December 31, 2022		December 31, 2021			
Cash	\$ 14,042	\$	22,563			
Working capital	10,571		20,629			
Total assets	17,647		26,089			
Total shareholders' equity	2,977		9,657			



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 grow 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 (Unaudited, in thousands, except share and per share amounts)

	December 31,				
		2022		2021	
Assets					
Current assets:					
Cash and cash equivalents	\$	14,042	\$	22,563	
Accounts receivable		59		109	
Inventory, current		488		496	
Prepaid expenses and other current assets		781		793	
Total current assets		15,370		23,961	
Fixed assets, net		1,325		1,428	
Inventory, non-current		511		-	
Right-of-use assets		428		687	
Other non-current assets		13		13	
Total assets	\$	17,647	\$	26,089	
Liabilities and Shareholders' Equity					
Current liabilities:					
Accounts payable and accrued expenses	\$	1,969	\$	2,584	
Operating lease liabilities - current		245		307	
Other current liabilities		53		10	
Current portion of long-term debt, net of unamortized debt discount of \$182 and \$271, respectively		2,532		431	
Total current liabilities		4,799		3,332	
Contingent royalty obligation		1,212		1,760	
Operating lease liabilities - non-current		178		385	
Convertible note, net of unamortized debt discount of \$108 and \$166, respectively		3,892		3,834	
Long-term debt, net of unamortized debt discount of \$135 and \$317, respectively		4,589		7,121	
Total liabilities		14,670		16,432	
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; 115,000,000 shares authorized; 4,659,769 and 2,416,021 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively		-		-	
Additional paid-in capital		144,328		132,406	
Additional paid-in capital Accumulated deficit		(141,351)		(122,754)	
Total shareholders' equity	*	2,977	*	9,657	
Total liabilities and shareholders' equity	\$	17,647	\$	26,089	



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

	Three Months Ended December 31,			Twelve months Ended December 31,				
		2022		2021		2022		2021
Revenue	\$	109	\$	99	\$	592	\$	391
Operating expenses:								
Cost of revenue - sales		32		46		198		181
Cost of revenue - impairment of inventory		439		257		598		443
Research and development		1,350		1,301		5,611		5,341
Sales and marketing		872		881		4,425		3,077
General and administrative		1,444		2,169		7,611		9,273
Total costs and expenses		4,137		4,654		18,443		18,315
Operating loss		(4,028)		(4,555)		(17,851)		(17,924)
Gain (loss) on change in estimated fair value of contingent royalty obligation		577		9		548		(143)
Loss on extinguishment of debt		-		(267)		-		(237)
Finance expense, net		(251)		(216)		(1,252)		(717)
Other income		-		-		-		5
Foreign currency gain (loss)		19		(5)		(42)		(17)
Net loss		(3,683)		(4,818)		(18,597)		(19,033)
Deemed dividends from warrant issuance				(4,010)		-		(6,145)
Net loss attributable to common shareholders	\$	(3,683)	\$	(4,818)	\$	(18,597)	\$	(25,178)
Basic and diluted loss per common share:								
Net loss attributable to common shareholders	\$	(0.79)	\$	(1.99)	\$	(5.74)	\$	(10.74)
Weighted average number of common shares outstanding, basic and diluted		4,646,834		2,415,315		3,237,952		2,344,759