

**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 12, 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 May 12, 2022, disclosing financial information and operating metrics for its fiscal quarter ended March 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:

Exhibit No. **Description**

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 12, 2022

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



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

- *Pure-Vu EVS approved for use at 11 hospitals since product launch commenced in March 2022; with strong procedural volumes and significant positive feedback*
- *Expansion of US commercial footprint ahead of schedule, with additional investments planned throughout 2022*
- *Designing a large, multi-center trial as part of the strategy to secure reimbursement for the Pure-Vu EVS System for certain outpatient colonoscopies*

FORT LAUDERDALE, FL, May 12, 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 first quarter ended March 31, 2022, and provided a corporate update.

“As we guided at the end of March, our first quarter revenues were impacted by both the surge of Omicron in the US and associated staffing shortages at hospitals, as well as the sunsetting of Pure-Vu Gen2 and initiating our first commercial shipments of Pure-Vu EVS to US hospitals,” commented Tim Moran, Chief Executive Officer.

“During the first quarter, in addition to receiving FDA clearance for the Pure-Vu EVS, we accelerated the expansion of our sales organization as we look to capitalize on what we believe is the right technology to drive broader market adoption. Moreover, we continue to receive positive feedback from both physicians and staff regarding the advancements offered by the all-new Pure-Vu EVS. While it’s early into the commercial launch, we are excited to see physicians performing more procedures than before and, based on the simplicity of the new device, we believe accounts are becoming independent more rapidly. These are important initial indicators that we expect will lead to sustainable, quarterly revenue growth in the US market.”

“It was just six weeks ago that I forecasted we’d have Pure-Vu EVS placed in approximately 12 sites in the near-term. I’m pleased to report that midway through the second quarter, we’re well on track to far exceed that expectation, having Pure-Vu EVS approved for use at 11 hospital accounts since March,” commented Mr. Moran.

First Quarter and Recent Business Highlights

- Received 510(k) clearance from the U.S. FDA for the Pure-Vu EVS System in mid-February 2022.
- March represented a key transitional period for the Company as it completed the sunsetting activities of Pure-Vu Gen2 and began shipments of the all-new Pure-Vu EVS to U.S. customers.
- Company on track with initial guidance of placing Pure-Vu EVS at first 12 sites



■ Clinical Data Generation

- Completed enrollment in the European Union (EU) study of the Pure-Vu System, which is evaluating the clinical outcomes in patients with a history of poor bowel preparation using both a low volume preparation with limited diet restrictions and the Pure-Vu System. The Company expects to announce topline data from the study at a leading scientific conference in May 2022.
- Topline data from the investigator-initiated EU clinical study exploring limited bowel prep for CRC screening at two European health centers expected to be presented during Digestive Disease Week 2022 in May 2022.

■ 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.
- Actively designing a large, multi-center trial that may generate clinical and economic endpoints in the outpatient segment that will support applications seeking reimbursement of the Pure-Vu System.

■ Product Innovation

- Initiated a project to add Upper GI capabilities to the new Pure-Vu EVS platform.
- 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 10%, as noted in Thad Wilkins, MD, et al., *American Family Physician* (2012).
- Key enhancements expected to be featured in the Pure-Vu EVS include a large and powerful suction channel, more efficient irrigation jets, and a smaller profile distal tip that offers enhanced flexibility during insertion.



Financial Results for the First Quarter Ended March 31, 2022

The Company reported revenue of \$20,000 for the first quarter 2022, compared to \$51,000 for the same period last year. The impact of both the Omicron variant early in the first quarter and the controlled phase-out of the Gen 2 System ahead of the EVS launch later in the quarter significantly affected our first quarter results. The Company believes that these specific factors will be less impactful in the second quarter of 2022 and beyond.

For the three months ended March 31, 2022, the Company reported a net loss attributable to common shareholders of \$4.8 million, or \$0.09 per basic and diluted share, compared to a net loss attributable to common shareholders of \$10.8 million, or \$0.25 per basic and diluted share, for the same period last year, which included the impact of a non-cash “deemed dividend from warrant issuance” of \$6.1 million.

During the first quarter 2022, net cash used in operating activities and for the purchase of fixed assets was \$5.2 million as compared to \$4.7 million for the same period of 2021. First quarter 2022 cash expenditures included certain one-time annual outflows associated with compliance and corporate matters, totaling approximately \$1.8 million, which is not expected to recur in future quarters this year.

The Company reported \$20.3 million in cash and cash equivalents as of March 31, 2022. This balance includes the fully funded \$12.0 million credit facility with Kreos Capital. The Company’s current cash balance allows it to continue executing on its upcoming catalysts and is expected to meet overall anticipated cash needs into Q1 2023.

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

	As of	
	March 31, 2022	December 31, 2021
Cash	\$ 20,338	\$ 22,563
Working capital	19,024	20,629
Total assets	24,425	26,089
Total shareholders’ equity	8,607	9,657

Conference Call:

The Motus GI management team has scheduled a conference call for today, May 12th, at 4:30 p.m. ET to discuss these results. To access the conference call, investors are invited to dial (844) 825-9789 (U.S. and Canada) or (412) 317-5180 (International). The conference ID number is 10166381. 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 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
(in thousands, except share and per share amounts)

	<u>March 31,</u> <u>2022</u> <u>(unaudited)</u>	<u>December 31,</u> <u>2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 20,338	\$ 22,563
Accounts receivable	18	109
Inventory	700	496
Prepaid expenses and other current assets	1,347	793
Total current assets	<u>22,403</u>	<u>23,961</u>
Fixed assets, net	1,366	1,428
Right-of-use assets	643	687
Other non-current assets	13	13
Total assets	<u>\$ 24,425</u>	<u>\$ 26,089</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,992	\$ 2,584
Operating lease liabilities - current	296	307
Other current liabilities	8	10
Current portion of long-term debt, net of unamortized debt discount of \$274 and \$271, respectively	1,083	431
Total current liabilities	<u>3,379</u>	<u>3,332</u>
Contingent royalty obligation	1,731	1,760
Operating lease liabilities - non-current	346	385
Convertible note, net of unamortized debt discount of \$153 and \$166, respectively	3,847	3,834
Long-term debt, net of unamortized debt discount of \$268 and \$588, respectively	6,515	7,121
Total liabilities	<u>15,818</u>	<u>16,432</u>
Commitments and contingent liabilities (Note 9)		
Shareholders' equity		
Common stock \$0.0001 par value; 115,000,000 shares authorized; 55,059,891 and 48,320,986 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	5	5
Additional paid-in capital	136,167	132,406
Accumulated deficit	(127,565)	(122,754)
Total shareholders' equity	<u>8,607</u>	<u>9,657</u>
Total liabilities and shareholders' equity	<u>\$ 24,425</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)

	<u>Three Months Ended</u> <u>March 31,</u>	
	<u>2022</u>	<u>2021</u>
Revenue	\$ 20	\$ 51
Operating expenses:		
Cost of Revenue - sales	15	28
Cost of Revenue - impairment of inventory	159	-
Research and development	1,275	1,345
Sales and marketing	983	676
General and administrative	2,114	2,444
Total costs and expenses	<u>4,546</u>	<u>4,493</u>
Operating loss	(4,526)	(4,442)
Gain (loss) on change in estimated fair value of contingent royalty obligation	29	(80)

Finance expense, net		(332)		(117)
Foreign currency gain (loss)		18		(10)
		<u>18</u>		<u>(10)</u>
Net loss	\$	(4,811)	\$	(4,649)
Deemed dividends from warrant issuance		-		(6,145)
Net loss attributable to common shareholders	\$	<u>(4,811)</u>	\$	<u>(10,794)</u>
Basic and diluted loss per common share:				
Net loss attributable to common shareholders	\$	(0.09)	\$	(0.25)
Weighted average number of common shares outstanding, basic and diluted		<u>51,794,258</u>		<u>42,230,001</u>
