

**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 29, 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:

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 March 29, 2022, disclosing financial information and operating metrics for its fiscal year ended December 31, 2021 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 March 29, 2022.](#)

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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: March 29, 2022

By: /s/ Timothy P. Moran

Name: Timothy P. Moran

Title: Chief Executive Officer

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Motus GI Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

- Received FDA clearance in February 2022 to market Pure-Vu EVS, an all new, next-generation system that has been deployed to multiple hospitals in the first few weeks since launch
- Doubled the size of the sales team since November, and plan to continue investing in commercial expansion throughout 2022
- Advancing strategy to secure reimbursement for the Pure-Vu System for certain outpatient colonoscopies, targeting ~4.7M outpatient procedures per year in the U.S.

FORT LAUDERDALE, FL, March 29, 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 fourth quarter and year ended December 31, 2021, and provided a corporate update.

“We are entering an exciting time in the Company’s evolution as we are now armed with the right technology, an expanding commercial team, and a significant backlog of colonoscopy procedures as a result of the pandemic,” commented Tim Moran, Chief Executive Officer. “Over the last 18 months, we’ve delivered on many of the key milestones of our long-term growth strategy. This progress includes building important KOL relationships, gaining key procedural learnings, and advancing our technology, which we expect to provide a solid foundation for commercial growth in the U.S.”

“In February 2022, we received FDA clearance for Pure-Vu EVS, which represents a significant enhancement of our solution, including rapid set-up in approximately 60 seconds, improved navigation capabilities, the ability for bedside loading on a dirty scope, and overall ease of use. This all-new platform is expected to accelerate physician interest and adoption of our technology. To support this anticipated increase in demand, we have doubled the size of our commercial team, now providing local representation in many of the major U.S. GI markets. Looking ahead, our growth strategy includes continued investment in commercial expansion throughout 2022,” added Mr. Moran.

“Additionally, we are currently planning a clinical trial for outpatient procedures, which is expected to provide pivotal data in the outpatient market with clearly identified endpoints. The data generated from this trial is expected to support future reimbursement applications. If we can successfully secure outpatient reimbursement, we believe it can provide additional growth opportunities, as the high medical need segment in outpatient is estimated to represent ~4.7M procedures per year in the United States alone,” concluded Mr. Moran.



Fourth Quarter and Recent Business Highlights

- **FDA Clearance to Market Pure-Vu EVS**
 - Received 510(k) clearance from the U.S. FDA for the Pure-Vu® EVS System, which is intended to improve speed of set-up, enhance navigation capabilities in tortuous anatomy, build upon the excellent cleansing capabilities of prior generations of the Pure-Vu System and enable physicians to rapidly overcome the challenges of poorly prepared colons during a colonoscopy.
- **Outpatient Reimbursement Strategy**
 - 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 ~4.7M targeted outpatient procedures per year.
 - Strategy includes 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.
- **Clinical Data Generation**
 - Fully enrolled the investigator-initiated EU clinical study exploring limited bowel prep for CRC screening at two European health centers; study remains on track for completion in Q2 2022.
 - Incorporating the Pure-Vu EVS platform into an existing investigator-initiated clinical study being conducted by a leading U.S. academic medical center to examine using the Pure-Vu System in patients with lower GI bleeding with minimal pre-procedural bowel prep.
- **Product Innovation**
 - Initiated a project to add Upper GI capabilities to the new Pure-Vu EVS platform.

Financial Results for the Quarter and Year Ended December 31, 2021

The Company reported revenue of \$99,000 for the fourth quarter 2021, compared to \$36,000 for the same period last year. Revenues for the full year 2021 were \$391,000 compared to \$98,000 in 2020. The Omicron variant significantly impacted the Company’s fourth quarter results as delays were encountered with both existing and previously planned new evaluations due to hospital staff shortages and limited sales representative access. These issues have continued to persist into the first quarter 2022.

For the three months ended December 31, 2021, the Company reported a net loss of \$4.8 million, or \$0.10 per basic and diluted share, compared to a net loss of \$4.4 million, or \$0.14 per basic and diluted share, for the same period last year.



For the year ended December 31, 2021, the Company reported a net loss of \$19.0 million compared to \$19.3 million for the same period last year. The net loss attributable to common shareholders was \$25.2 million, 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. This compares to a net loss attributable to common shareholders of \$19.3 million for the year ended December 31, 2020. Net loss per basic and diluted share attributable to common shareholders for the year ended December 31, 2021 was \$0.54 compared to \$0.60 for the same period last year. Excluding the one-time deemed dividend from warrant issuance, the Company's net loss per basic and diluted share for the year ended December 31, 2021, would have been \$0.41 compared to \$0.60 for the prior year. The Company believes this financial measure provides consistent and additional means of evaluating period-over-period operating performance.

During the fourth quarter, net cash used in operating activities and for the purchase of fixed assets was \$4.0 million as compared to \$2.8 million for the same period of 2020.

Net cash used in operating activities and for the purchase of fixed assets during the year ended December 31, 2021 totaled \$14.9 million as compared to \$17.1 million for the same period of 2020.

The Company reported \$22.6 million in cash and cash equivalents as of December 31, 2021. This balance included the fully funded \$12.0 million credit facility with Kreos Capital, which was put in place during the third quarter. The Company's current cash balance allows it to continue executing on its value creation drivers 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	
	December 31, 2021	December 31, 2020
Cash	\$ 22,563	\$ 20,819
Working capital	21,060	11,497
Total assets	26,089	24,064
Total shareholders' equity	26,089	24,064

Conference Call:

The Motus GI management team has scheduled a conference call for today, March 29th, 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 13727501. 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)

	December 31,	
	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 22,563	\$ 20,819
Accounts receivable	109	35
Inventory	496	805
Prepaid expenses and other current assets	793	448
Total current assets	<u>23,961</u>	<u>22,107</u>
Fixed assets, net	1,428	1,178
Right-of-use assets	687	766
Other non-current assets	13	13
Total assets	<u>\$ 26,089</u>	<u>\$ 24,064</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,584	\$ 2,333
Operating lease liabilities - current	307	238
Other current liabilities	10	60
Term debt, net of debt discount of \$0 and \$21, respectively	-	7,979
Total current liabilities	<u>2,901</u>	<u>10,610</u>
Contingent royalty obligation	1,760	1,617
Operating lease liabilities - non-current	385	547
Convertible note, net of unamortized debt discount of \$166 and \$0, respectively	3,834	-
Long-term debt, net of unamortized debt discount of \$588 and \$0, respectively	7,552	-
Total liabilities	<u>16,432</u>	<u>12,774</u>
Shareholders' equity		
Preferred stock \$0.0001 par value; 10,000,000 shares authorized; zero shares issued and outstanding	-	-
Common stock \$0.0001 par value; 115,000,000 shares authorized; 48,320,986 and 32,272,309 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	5	3
Additional paid-in capital	132,406	115,008
Accumulated deficit	(122,754)	(103,721)
Total shareholders' equity	<u>9,657</u>	<u>11,290</u>
Total liabilities and shareholders' equity	<u>\$ 26,089</u>	<u>\$ 24,064</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 December 31,		Twelve Months Ended December 31	
	2021	2020	2021	2020
Revenue	\$ 99	\$ 36	\$ 391	\$ 98
Operating expenses:				
Costs of revenue - sales	46	23	181	95
Costs of revenue - impairment of inventory	257	401	443	401
Research and development	1,301	1,196	5,341	5,555
Sales and marketing	881	578	3,077	3,532
General and administrative	2,169	2,130	9,273	9,562
Total costs and expenses	<u>4,654</u>	<u>4,328</u>	<u>18,315</u>	<u>19,145</u>
Operating loss	(4,555)	(4,292)	(17,924)	(19,047)
Gain (loss) on change in estimated fair value of contingent royalty obligation	(9)	7	(143)	255
Loss on extinguishment of debt	(267)	-	(237)	-
Finance expense, net	(717)	(116)	(717)	(464)

Other income	-	-	5	-
Foreign currency loss	(5)	3	(17)	(1)
Net loss	\$ (4,818)	\$ (4,398)	\$ (19,033)	\$ (19,257)
Deemed dividends from warrant issuance	-	-	(6,145)	-
Net loss attributable to common shareholders	<u>\$ (4,818)</u>	<u>\$ (4,398)</u>	<u>\$ (25,178)</u>	<u>\$ (19,257)</u>
Basic and diluted loss per common share:				
Net loss attributable to common shareholders	<u>\$ (0.10)</u>	<u>\$ (0.14)</u>	<u>\$ (0.54)</u>	<u>\$ (0.60)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>48,306,312</u>	<u>32,261,892</u>	<u>46,895,187</u>	<u>32,120,017</u>
