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# Motus GI Reports Full Year 2018 Financial Results and Provides Business Outlook

*– 2018 marked by strengthening of executive team, expansion of commercial organization, bolstering of clinical and health economic data, and achievement of important regulatory milestones –*

*– REDUCE study per protocol planned interim analysis showed statistical significance in the first 45 patients on the primary endpoint of improvement in bowel cleanliness from baseline –*

*– Market development activities associated with salesforce expansion is driving a robust pipeline of potential customers in support of full commercial launch of the Pure-Vu® System in the U.S. in 2019 –*

FORT LAUDERDALE, Fla.--(BUSINESS WIRE)-- [Motus GI Holdings, Inc.](#), (NASDAQ: MOTS) ("Motus GI" or the "Company"), a medical technology company dedicated to improving clinical outcomes and enhancing the cost-efficiency of colonoscopy, today reported its financial results for the full year ended December 31, 2018 and provided its 2019 business outlook.

"I am pleased with our 2018 accomplishments which reflect significant and sustained progress in several key areas. Since we successfully completed our IPO and began trading on NASDAQ in February 2018, we have attracted key talent in both our executive and commercial leadership roles, bolstered our rapidly expanding compendium of clinical and health economic data, and began execution of our market development program to drive momentum into the full commercial launch of the Pure-Vu® System," commented, [Tim Moran, Chief Executive Officer of Motus GI](#). "The statistically significant interim data from the REDUCE study conducted in real-world settings and generating clinical experience with important thought leaders in our field, solidifies our belief that our revolutionary Pure-Vu® System technology will not only allow physicians to improve the time associated with completing a high quality, successful colonoscopy, but will also provide hospitals with a potential solution for improving the total cost of care."

"From a technology perspective, we are preparing to file a special 510(k) for the second generation of our Pure-Vu® System, which has the same cleansing power of the first generation with a more user-friendly, compact and mobile design. We believe these enhancements will be important to drive market adoption. We also believe that the methodical approach we have taken to commercialization has positioned us for a successful inpatient market launch of the Pure-Vu® System in 2019. We believe 2019 will be a landmark year for Motus GI, and I am excited to lead Motus into our next phase of growth for the Company."

## Recent Corporate Highlights

- Strengthened intellectual property portfolio with issuance of additional patents related

to the Pure-Vu® System to expand global patent estate to support strategic pathway for the Pure-Vu® System to become standard of care.

- Announced that its manuscript titled, “*An intra-procedural endoscopic cleansing device for achieving adequate colon preparation in poorly prepped patients,*” was published in the peer-reviewed Journal of Clinical Gastroenterology and its manuscript titled, “*A novel device for intra-colonoscopy cleansing of inadequately prepared colonoscopy patients – a feasibility study,*” was published in the peer-reviewed journal, Endoscopy.
- Successfully closed a follow-on public offering of 5,750,000 shares of its common stock to help fund commercialization activities, research and development activities, including clinical and regulatory development and the continued development and enhancement of the Pure-Vu® System, and for working capital and other general corporate purposes. Gross proceeds from the offering were approximately \$15.5 million.
- Received special 510(k) clearance from the U.S. Food and Drug Administration (FDA) and announced the first successful clinical cases were completed in late October with the Company’s Pure-Vu® Slim Sleeve, a compatible extension to the Pure-Vu® System for slim colonoscopes. The Pure-Vu® Slim Sleeve further improves ease of use and enables access to the full colonoscopy market where Motus GI estimates, through consultation with colonoscopy manufacturing companies, approximately 30% of U.S. procedures are performed with a slim colonoscopy and growing. The Pure-Vu® Slim Sleeve has been designed to be compatible with smaller diameter and more flexible slim colonoscopes with additional enhancements to the Company’s low friction lubricious coating technology to aid in navigation through the colon and has the same cleansing performance as the standard Pure-Vu® Sleeve and both versions work with the same Pure-Vu® workstation control system.
- Presented positive clinical data from a U.S. prospective investigator-initiated clinical study at the American College of Gastroenterology (ACG) 2018 Annual Meeting demonstrating safety and effectiveness of the Pure-Vu® System in patients who had minimal preparation regimens and who were allowed to consume solid food the day before the procedure. Patients in the study had an average baseline Boston Bowel Preparation Scale (BBPS), a validated and widely used measure with a 0 to 9 point scale, of  $3.67 \pm 2.86$  which was improved to an average of  $8.91 \pm 0.35$  ( $p$  value  $< 0.0001$ ) following use of the Pure-Vu® System. The results were statistically significant and the post-cleansing BBPS score is meaningfully higher than results generally seen with standard liquid diet plus purgative-based bowel prep regimens. Further, the use of the Pure-Vu® System enabled intraprocedural cleansing of the colon and enabled 100% successful completion of all colonoscopies performed. This data gives insight into potential label expansion in the future.

### **Pure-Vu® System Update**

Motus GI plans to submit a Special 510(k) Notice to FDA for the Second-Generation (“Gen 2”) of the Pure-Vu® System in the first half of 2019. The Gen 2 Pure-Vu® System has been designed to improve the mobility and setup logistics of the system and will retain all the same functionality as the current generation of the Pure-Vu® System in terms of colon cleansing.

The Company is currently focused on post-approval clinical trials and market development programs with leading U.S. hospitals that are utilizing the Pure-Vu® System on a pilot basis in preparation for a full commercial launch in the U.S. during 2019. The initial launch will focus on the inpatient colonoscopy market where challenges with insufficient bowel prep slow diagnosis, diminish the quality of care, and add significant costs to hospital systems. Motus GI believes that the Pure-Vu® System may improve quality of care and potentially reduce healthcare costs by reliably and predictably moving patients through the hospital system to a successful examination.

### **Clinical Programs Update**

Motus GI expects to present data from all patients enrolled in the REDUCE (Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement) study at upcoming GI conferences in 2019. The REDUCE study is a multi-center inpatient prospective trial designed to evaluate the Pure-Vu® System's ability to consistently and reliably cleanse the colon to facilitate a successful colonoscopy a timely manner in patients who are indicated for a diagnostic colonoscopy. The primary endpoint of the study is to determine the Pure-Vu® System's rate of improved bowel cleansing level using the BBPS index for all segments examined.

The per protocol planned interim analysis showed statistical significance in the first 45 patients on the primary endpoint of improvement in the BBPS for segments of the colon that were examined. Other key data being collected in the study includes the proportion of patients who receive a successful colonoscopy for the intended indication in the first attempt, which correlates to the quality of the exam as well as hospital length of stay and costs required for the episode of care.

"The positive interim data from the REDUCE study, along with my ongoing experience using the Pure-Vu® System in the inpatient setting gives me confidence that this product can provide an important solution to the significant number of delayed and incomplete procedures associated with inpatients," commented Jason B. Samarasena MD FACP, Associate Clinical Professor of Medicine, Division of Gastroenterology School of Medicine, University of California Irvine. "I truly believe the Pure-Vu® System has the potential to quicken the time to diagnosis, reduce costs and improve bed turnover, all of which are important with the current reimbursement landscape and ultimately will have a transformational positive impact on patients, physicians and the healthcare system."

Over the course of 2019, Motus GI plans to support additional investigator initiated clinical studies, including EXPEDITE, which is a planned feasibility study in hospitalized patients. The EXPEDITE study is designed to assess the Pure-Vu® System's ability to minimize the use of conventional bowel preparation regimens in order to further accelerate the time to a successful colonoscopy in the inpatient population, as well as investigate other difficult to prep populations. Faster diagnosis of critical emergent conditions such as GI bleeding may improve clinical outcomes and potentially reduce costs and complications.

### **Near-Term Milestones Expected to Drive Value**

- Announce results from the REDUCE study at major medical GI conferences beginning in Q2 2019;
- Commence investigator-initiated clinical studies focused on accelerating the time to a

successful inpatient colonoscopy as well as high risk outpatient populations;

- Secure regulatory approval and launch Gen 2 of the Pure-Vu® System that offers enhanced features and superior usability ahead of full commercial launch;
- Continue to expand field-based sales and clinical resources in key U.S. locations;
- Continue to expand market development programs to engage hospitals, physician champions and staff through pilot utilization of the Pure-Vu® System;
- Continue to grow clinical and health economic awareness through peer-reviewed publications;
- Continue to refine in-servicing and training programs in preparation for the full commercial launch;
- Full commercial launch of the Pure-Vu® System in the U.S. for inpatient colonoscopy in the U.S. in 2019;
- Continue building an extensive intellectual property portfolio to provide long-term protection for multiple key aspects of the Pure-Vu® System; and
- Participate in key scientific conferences over the course of 2019.

### Financial Results for the Year Ended December 31, 2018

For the year ended December 31, 2018, Motus GI reported a net loss of approximately \$22.3 million, or a net loss per diluted share of \$1.47, which included a one-time non-cash warrant expense charge of \$3.2 million, compared to a net loss of approximately \$13.2 million or a net loss per diluted share of \$1.28 for the year ended December 31, 2017.

The Company ended the year with cash and cash equivalents, and short-term investments of approximately \$21.1 million.

### Motus GI Holdings, Inc. Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	<u>December 31,</u>	
	<u>2018</u>	<u>2017</u>
<b>ASSETS</b>		
<b><u>Current assets</u></b>		
Cash and cash equivalents	\$ 18,050	\$ 6,939
Short-term investments	3,043	—
Accounts receivable	5	—
Inventory	23	6
Prepaid expenses and other current assets	930	739

Deferred financing fees	—	602
<b>Total current assets</b>	<u>22,051</u>	<u>8,286</u>
Fixed assets, net	846	783
Other non-current assets	<u>57</u>	<u>99</u>
<b>Total assets</b>	<u>\$ 22,954</u>	<u>\$ 9,168</u>

## LIABILITIES AND SHAREHOLDERS' EQUITY

### Current liabilities

Accounts payable and accrued expenses	\$ 2,140	\$ 1,733
Other current liabilities	<u>253</u>	<u>250</u>
<b>Total current liabilities</b>	2,393	1,983
Contingent royalty obligation	1,953	1,662
Other non-current liabilities	<u>91</u>	<u>—</u>
<b>Total liabilities</b>	4,437	3,645

### Shareholders' equity

Preferred stock \$0.0001 par value; 8,000,000 shares authorized; zero shares issued and outstanding	—	—
Preferred Series A stock \$0.0001 par value; 2,000,000 shares authorized; zero and 1,581,128 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively	—	—
Common stock \$0.0001 par value; 50,000,000 shares authorized; 21,440,148 and 10,493,233 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively	2	1
Additional paid-in capital	79,893	44,643
Accumulated deficit	<u>(61,378)</u>	<u>(39,121)</u>
<b>Total shareholders' equity</b>	<u>18,517</u>	<u>5,523</u>
<b>Total liabilities and shareholders' equity</b>	<u>\$ 22,954</u>	<u>\$ 9,168</u>

## About Motus GI and the Pure-Vu® System

Motus GI Holdings, Inc. is a medical technology company, with subsidiaries in the U.S. and Israel, dedicated to improving clinical outcomes and enhancing the cost-efficiency of colonoscopy. The Company's flagship product is the Pure-Vu® System, a U.S. FDA cleared medical device indicated to help facilitate the cleaning of a poorly prepared colon during the colonoscopy procedure. The device integrates with standard and slim colonoscopes to

enable safe and rapid cleansing during the procedure while preserving established procedural workflow and techniques. The Pure-Vu<sup>®</sup> System has received CE mark approval in Europe. The Pure-Vu<sup>®</sup> System is currently being introduced on a pilot basis in the U.S. market, and the Company is planning to initiate a full commercial launch focused on the inpatient colonoscopy market in the U.S. and select international markets in 2019. Challenges with bowel preparation for inpatient colonoscopy represent a significant area of unmet need that directly affects clinical outcomes and increases the cost of care in a market segment that comprises approximately 1.5 million annual procedures in the U.S. and approximately 4 million annual procedures worldwide. Motus GI believes the Pure-Vu<sup>®</sup> System may improve outcomes and lower costs for hospitals by reducing the time to successful colonoscopy, minimizing delayed and incomplete procedures, and improving the quality of an exam. In clinical studies to date, the Pure-Vu<sup>®</sup> System significantly increased the number of patients with an adequate cleansing level, according to the Boston Bowel Preparation Scale Score, a validated assessment instrument.

For more information, visit [www.motusgi.com](http://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 inherent in the development and commercialization of potential products, 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 Form 10-K filed on March 26, 2019, 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.

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