UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2018
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 001-38389

Motus GI Holdings, Inc.
(Exact name of registrant as specified in its charter)

DELAWARE **(State or other jurisdiction of incorporation or organization)**	**81-4042793** **(I.R.S. Employer Identification No.)**
1301 East Broward Boulevard, 3rd Floor **Ft. Lauderdale, FL** **(Address of principal executive offices)**	**33301** **(Zip code)**

(954) 541-8000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.0001 per share	**NASDAQ Capital Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of June 29, 2018, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately $72,750,742, based on the closing price of the registrant's Common Stock on June 29, 2018.

The number of shares outstanding of the registrant's Common Stock, par value of $0.0001 per share, as of March 21, 2019 was 21,450,877.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Motus GI Holdings, Inc.
ANNUAL REPORT ON FORM 10-K

For the Year Ended December 31, 2018

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report on Form 10-K contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our limited operating history;
- our history of operating losses in each year since inception and expectation that we will continue to incur operating losses for the foreseeable future;
- our current and future capital requirements to support our development and commercialization efforts for the Pure-Vu System and our ability to satisfy our capital needs;
- our dependence on the Pure-Vu System, our sole product candidate, which is still in development;
- our ability to obtain approval from regulatory agents in different jurisdictions for the Pure-Vu System;
- our Pure-Vu System and the procedure to cleanse the colon in preparation for colonoscopy are not currently reimbursable through private or governmental third-party payors;
- our lack of a developed sales and marketing organization and our ability to commercialize the Pure-Vu System;
- our dependence on third-parties to manufacture the Pure-Vu System;
- our ability to maintain or protect the validity of our patents and other intellectual property;
- our ability to retain key executives and medical and science personnel;
- our ability to internally develop new inventions and intellectual property;
- interpretations of current laws and the passages of future laws;
- acceptance of our business model by investors;
- the accuracy of our estimates regarding expenses and capital requirements; and
- our ability to adequately support growth.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipate in our forward-looking statements. Please see "Part I—Item 1A—Risk Factors" for additional risks which could adversely impact our business and financial performance.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and we believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

ITEM 1. BUSINESS

Overview

We have developed the Pure-Vu System (the "Pure-Vu System"), a medical device that has received 510(k) clearance from the U.S. Food and Drug Administration (the "FDA") and CE mark approval in the European Economic Area. The Pure-Vu System is 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 by irrigating the colon and evacuating the irrigation fluid (water), feces and other bodily fluids and matter. 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 for a hospital in a market segment where most of the reimbursement is under a bundle payment based on a Diagnostic Related Group (a "DRG"), comprising of approximately 1.5 million annual inpatient colonoscopy procedures in the U.S. and approximately 3.8 million annual inpatient colonoscopy procedures worldwide. The Pure-Vu System does not currently have a unique reimbursement code with any private or governmental third-party payors in any country. To date, as part of our limited pilot launch in the U.S. market, we have focused on collecting additional clinical and health economic data, as exemplified by the recently initiated Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement Study (the "REDUCE Study"), along with garnering valuable experience in key hospitals on the use of the Pure-Vu System to support a planned full launch of the Pure-Vu System in the United States inpatient colonoscopy market in 2019. We do not expect to generate significant revenue from product sales unless and until we expand our commercialization efforts.

Market Overview

Colonoscopies are one of the most frequently performed medical procedures with over 15 million colonoscopies performed in the U.S. every year and close to 30 million worldwide. In the U.S., approximately 90% of the 15 million colonoscopies are performed as outpatient procedures (13.5 million) at an ambulatory endoscopy center, or AEC, and/or hospital outpatient departments, or HOPD, and 10% as inpatient procedures (1.5 million) in hospitals. The veteran population represents approximately 250,000 colonoscopies performed annually. Approximately 60% of colonoscopies are performed to detect and prevent colorectal cancer, or CRC, which is the second leading cause of cancer related deaths in the U.S. with approximately 140,000 new cases diagnosed and 50,000 deaths every year. Over the past few decades, CRC has been demonstrated to be one of the most preventable cancers through the use of colonoscopies. The remaining 40% of colonoscopies are performed to help diagnose and treat other gastrointestinal, or GI, conditions including irritable bowel syndrome, or IBS, inflammatory bowel disease, or IBD, anemia and lower GI bleeding.

Despite the pervasiveness and effectiveness of colonoscopy, a key ongoing clinical challenge of the procedure is that patients are required to undergo a potent pre-procedure bowel preparation regimen to try to ensure that the colon is fully cleansed to enable clear visualization of the tissue. The regimens can be highly disruptive and uncomfortable for many patients. In fact, approximately 57% of patients cite not wanting to take the bowel preparation as the number one deterrent for the procedure. Further, it has been widely reported that approximately 23% of outpatients, and approximately 45% of inpatients present with inadequately prepped colons, resulting in a number of colonoscopies that yield poor diagnostic accuracy or failed colonoscopies that must be repeated. It has also been widely reported that patients requiring frequent colonoscopies, such as CRC survivors and other surveillance patients, account for approximately 21% of the outpatient colonoscopies performed annually in the U.S., and that patients with lower GI bleeding or poorly prepared colons represent approximately 45% of inpatient colonoscopies performed annually in the U.S. Another key problem is that approximately 35% of eligible patients are not current with their CRC screening in the U.S. based on current guidelines.

Successful bowel preparation is one of the most important factors in delivering a thorough, high quality exam and is well documented to have a direct impact on the adenoma detection rate (ADR) (the rate of detecting pre-cancer anomalies in the colon tissue), which in turn predicts a decrease in CRC risk. The preparation regimen typically requires patients to be on a liquid diet for over 24 hours, drink up to four liters of a purgative, spend up to 12 hours prior to the exam periodically going to the bathroom to empty their bowels, and disrupting their daily activities, which could include missing work or other activities. The cleansing process is well known to be inconvenient and uncomfortable for many patients resulting in approximately twenty three percent (23%) of patients arriving for their colonoscopy inadequately cleansed. An inadequately prepared colon can impact the diagnostic accuracy of the procedure and can lead to procedures having to be repeated earlier than the medical guidelines advise or can lead to failed procedures especially in the inpatient setting. Rescheduling the procedure is inconvenient to the patient (and many patients fail to come for their follow-up), creates inefficiencies in the provider's workflow, and increases the length of hospital stay for the inpatient, each of which results in increased healthcare costs.

Our Pure-Vu Solution

To address this unmet need, we have developed the Pure-Vu System, a medical device that has received 510(k) clearance from the U.S. Food and Drug Administration (the "FDA") and CE mark approval in the European Economic Area. The Pure-Vu System is 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 by irrigating the colon and evacuating the irrigation fluid (water), feces and other bodily fluids and matter. We believe that the technology may be useful in the future as a tool to help reduce user dependency on conventional pre-procedural bowel prep regimens.

Our system consists of a workstation controller and a single-use, disposable sleeve that fits over most standard-size commercial colonoscopes. Together with the colonoscope, the Pure-Vu System performs rapid, effective and efficient intra-procedural cleaning without compromising procedural workflow and techniques. The over-sleeve has an umbilical section that connects to a cartridge that mounts to the workstation and serves as the interface between the disposable over-sleeve and the workstation. The workstation, through a series of peristaltic pumps activated by foot pedals, delivers an irrigation medium of air and water that creates a pulsed vortex inside the colon to break up fecal matter while simultaneously evacuating the colon content into waste receptacles already used in a standard colonoscopy procedure. The proprietary evacuation system in the device has sensors built in that can detect the formation of a blockage and automatically clear it allowing the physician to remove significant debris from the patient. We filed for and received special 510(k) clearance from the FDA in the fourth quarter of 2017 to adjust our labeling to simplify the process of removing the Pure-Vu System from a colonoscope and to support minor enhancements to the manufacturing of the system. The Pure-Vu System has been clinically demonstrated to be capable of cleaning poorly prepared colons in minutes. We are building an extensive intellectual property portfolio designed to protect key aspects of the system, including the pulsed vortex irrigation and auto-purge functions.

The First Generation Pure-Vu System:

Pure-Vu Slim Sleeve

We have additionally received special 510(k) clearance from FDA for the Pure-Vu Slim Sleeve (the "Pure-Vu Slim Sleeve"), a compatible extension to the Pure-Vu System for slim colonoscopes. The Pure-Vu Slim Sleeve design allows the Pure-Vu System access to the full range of procedures in the colonoscopy market as we estimate, through consultation with colonoscope manufacturing companies, approximately 30% of procedures are performed with a slim colonoscope. The Pure-Vu Slim Sleeve has the same cleansing performance as the standard Pure-Vu System sleeve, and both versions work with the same Pure-Vu workstation control system. The Pure-Vu Slim Sleeve has been designed to be compatible with smaller diameter and more flexible slim colonoscopes with additional enhancements to our low friction lubricious coating technology to aid in navigation through the colon. The first successful clinical cases using the Pure-Vu Slim Sleeve were completed in October 2018.

Second Generation of Pure-Vu System

We expect to submit a Special 510(k) Notice to FDA in the first half of 2019 for the Second-Generation ("Gen 2") of the Pure-Vu System. This premarket notification is a premarket submission used to review with FDA modifications to our devices that can be validated within our Quality Systems and which do not affect the device's intended use or alter the device's fundamental scientific technology.

The Gen 2 Pure-Vu System has been designed to improve the mobility and logistics in the setup of the system and will retain all the same functionality as the current generation of the Pure-Vu System in terms of how it cleanses the colon. The Gen 2 Pure-Vu System Workstation will have a reduced footprint and be mounted on a roll stand to allow nursing staff to easily move the Gen 2 Pure-Vu System to different procedure rooms or to the ICU as needed. The Gen 2 Pure-Vu System also has improvements that reduce the number of steps to set up the system and simplifies the loading process onto the colonoscope.

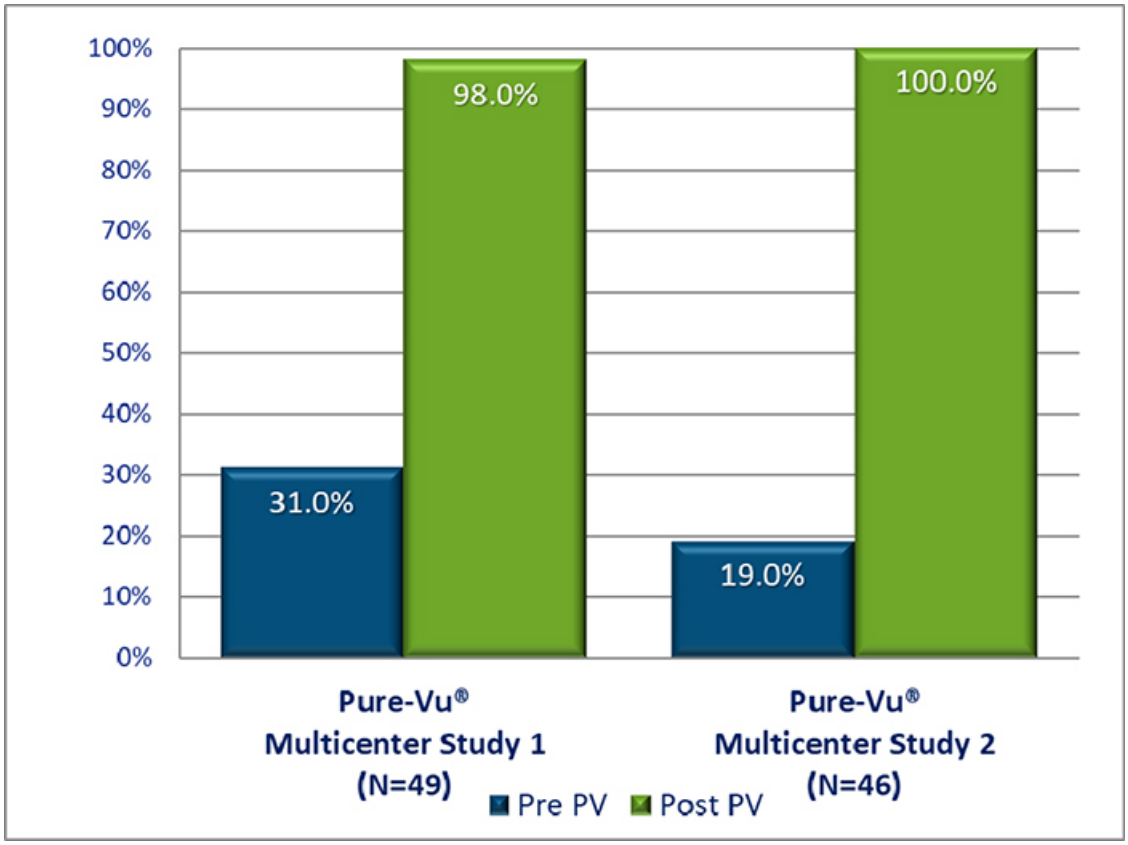
Inpatient Opportunity: improving efficiencies and shortening time to complete a successful colonoscopy

Inpatient colonoscopy is usually performed to diagnose the source of various gastrointestinal conditions such as lower GI bleeding or bowel pain. For an inpatient hospital stay, the Centers for Medicare and Medicaid Services, or CMS, uses a prospective payment system, or PPS, based upon DRG, to pay for hospital services with the goal of encouraging providers to minimize their costs. The DRG assignment is influenced by a combination of factors such as a patient's sex, diagnosis at the time of discharge and procedures performed. Based on patient specific information, all hospital expenses for their care during an inpatient stay are packaged and assigned to one of over 500 MS-DRGs ("Medical Severity - Diagnostic Related Groups"). According to Decision Driver Analytics, a reimbursement consulting agency, when a colonoscopy is performed as the primary procedure (no other procedures or complicating diagnosis), DRGs 395, 394 or 393 would apply which pay between $3,861 (without complications or major comorbidities) and $9,421 (with major complications and comorbidities). The National Inpatient Sample ("NIS") and other literature sources note that the cost for a standard hospital bed averages $2,298 and the cost for an intensive care unit ("ICU") bed averages $6,546 per day in the U.S, so reducing the length of stay can save the hospital significant expense.

An inpatient colonoscopy is more problematic than an outpatient procedure due primarily to poorer quality bowel prep which can lead to lower rates of successful completion of the procedure and a higher frequency of repeat procedures. Inpatients are difficult to prep as exemplified by inadequate bowel prep rates. Published studies have found that the inpatient population experiences rates of insufficiently prepped colons at the time of colonoscopy as high as 55%. This has been shown to lead directly to significantly longer hospital stays and other additional costs due to the need for repeated preps, repeated colonoscopies and additional diagnostic procedures. This is exemplified in a recently published study from Northwestern University Hospital System which showed an average hospital stay extension of two days and cost increase of as much as $8,000 per patient as a result of challenges associated with bowel preparation. We believe the Pure-Vu System may improve outcomes and lower costs for hospitals by reducing the time to a successful colonoscopy, minimizing delayed and incomplete procedures, and improving the quality of an exam.

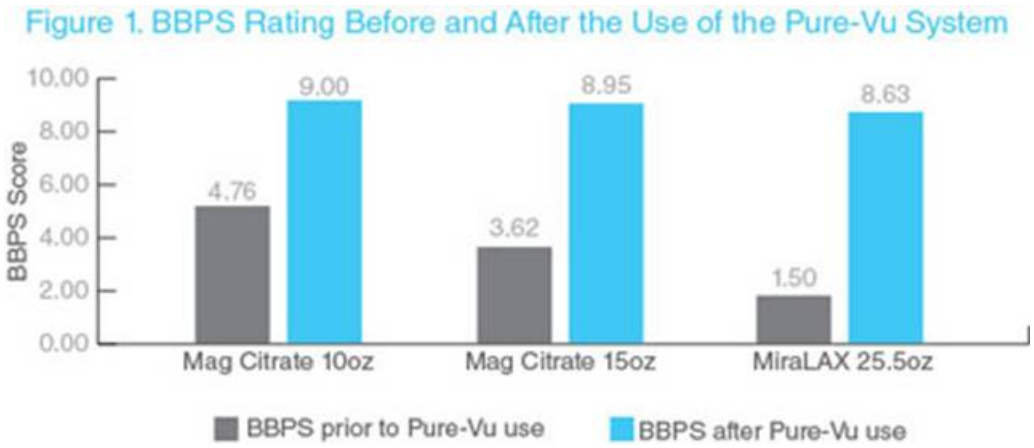
Pre-Clinical and Clinical Data & Safety

The Pure-Vu System has been studied in multiple clinical trials in patients receiving a reduced prep regime. The Pure-Vu System was used in two multi-center clinical studies in the EU and Israel, and most recently a single center study in the US. The first study involved 49 patients and was completed in the second quarter of 2016. The second study was completed in June 2017 and involved 46 patients. Patients in these studies had a restricted diet for 18-24 hours and received a split dose of 20mg of over-the-counter Dulcolax® (bisocodyl). Patients did not take any liquid purgative traditionally prescribed for bowel preparation. The clinical data showing performance of the Pure-Vu System in these studies using the BBPS, is shown below. The clinical results from the 2016 study were presented at United European Gastroenterology Week ("UEGW") in October 2016. The clinical results from the 2017 study were presented at the UEGW in October 2017, showing similar results, as shown below. This study has recently been published in *Endoscopy* one of the top peer reviewed journals in the EU.



In a recent clinical study completed in the third quarter of 2018 performed in the United States, the Pure-Vu System demonstrated safe and effective colonic cleaning in the per protocol analysis of 46 patients receiving a reduced prep regimen. The study was initially designed to compare two different minimal bowel preparation regimens. Initially patients were randomized to receive one of two minimal bowel preparations: three doses of 17 gr. MiraLAX each mixed in 8.5 oz. of clear liquids or two doses of 7.5 oz. magnesium citrate (MgC) each taken with 19.5 oz. of clear liquid. A study amendment early on replaced the MiraLAX arm, due to obvious inferior Boston Bowel Preparation Scale ("BBPS"), a validated assessment instrument, scoring from the outset. The replacement arm consisted of two doses of 5 oz. MgC taken with 16 oz. of clear liquid. All patients were allowed to eat a low residue diet on the day prior and were asked to avoid seeds and nuts for five days prior to their procedure. Study objectives evaluated for each study arm included: (1) improvement of colon cleansing from presentation baseline to completion of the procedure (as assessed by the BBPS) through the use of the Pure-Vu System, (2) time required to reach the cecum, (3) total procedure time, and (4) safety. No significant differences were found between the three groups with regard to demographics or indication for colonoscopy. No serious adverse events related to the device were reported. The use of the Pure-Vu System enabled successful intraprocedural cleansing of the colon and ensured successful completion of all colonoscopies performed (100% success rate). Although there were only 46 patients in the study, there was a highly significant difference in the study population (p value <0.0001) between the baseline preparation and that seen post cleansing with the Pure-Vu System. The use of the Pure-Vu System added some time to the procedure, but the total procedure time was approximately 25 minutes in this study.

The clinical data showing performance of the Pure-Vu System in this study using the BBPS is shown below. The clinical results from the study were presented at the 2018 American College of Gastroenterology ("ACG") Annual Meeting in October 2018.



REDUCE Study

On May 23, 2018, we announced the initiation of the Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement Study (the "REDUCE Study"). 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 in a timely manner in patients who are indicated for a diagnostic colonoscopy. The study is designed to enroll up to 100 subjects in at least five hospital centers in the United States and Europe.

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. We expect to present REDUCE Study detailed results at upcoming GI conferences in 2019.

Additional Clinical Studies

We expect to initiate several Investigator Initiated Studies in 2019. This includes the EXPEDITE Study (the "EXPEDITE Study") which is a planned feasibility study in hospitalized patients which will be designed to analyze the Pure-Vu System's ability to minimize the preparation in order to shorten the time to a successful colonoscopy in the inpatient population. We are also working with key centers to generate clinical data on outpatient populations that have difficulty with the pre-procedural preparation to study the Pure-Vu System's ability to allow these patients to have a successful exam. This data is expected to lay the ground work for future expansion into high need outpatient populations.

Intellectual Property

Our IP position comprises a highly innovative portfolio covering technologies rooted in systems and methods for cleaning body cavities with or without the use of an endoscope. Currently we have eight granted or allowed patents in the U.S., eight patents in Asia, six patents in the EU, which extended patent protection until at least 2035 in the U.S. In addition, we have 26 pending patent applications in various regions of the world with a focus on the U.S., EU and Japan. We have registered trademarks for Motus GI and for Pure-Vu in the US, EU and other international jurisdictions. We also have a pending trademark application in the US to MICRO-PREP.

Our patent application portfolio focuses on cleaning body cavities in a safe and efficient manner, insertion and movement and steering of an endoscopic device within the body cavity in a predetermined direction, coordinated positioning of an endoscope with a suction device and cleaning systems with automatic self-purging features. Our applications cover critical aspects of our system that we believe are key to effectively and efficiently clean the colon or other cavities in the body. These areas include cleansing jet methodologies, sensing and control of evacuation to avoid clogging, designs for easy attachment to endoscopes and cleaning segments under water.

Our commercial success depends in part on our ability to obtain and maintain patent and other proprietary protection for Pure-Vu and to operate without infringing the proprietary right of others and to prevent others from infringing our proprietary rights. We strive to protect our intellectual property through a combination of patents, and trademarks as well as through the confidentiality provisions in our contracts. With respect to the Pure-Vu System, we endeavor to obtain and maintain patent protection in the United States and internationally on all patentable aspects of the system. We cannot be sure that the patents will be granted with respect to any patent applications we may own or license in the future, nor can we be sure that our existing patents or any patents we may own or license in the future will be useful in protecting our technology.

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, significant aspects of our proprietary technology platform are based on unpatented trade secrets and know-how. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We also plan to continue to seek trademark protection in the United States and outside of the United States where available and when appropriate. We intend to use these registered marks in connection with our research and development as well as our product candidates.

Competition

We do not believe that there are currently any direct competitors in the market, nor any known competing medical device under development, using similar technology to our technology. Currently the major colonoscope manufacturers (i.e., Olympus, Pentax, Fuji) sell an irrigation pump that can pump fluid through the working channel of a colonoscope. Potentially competitive intra-procedural devices such as Cantel Medical's Jet Prep, and another similar product in development Medjet Ltd.'s MedJet, go through the working channel of a scope and are used mostly for spot cleaning a small amount of debris and do not have the capability to fully clean the colon of large amounts of fecal matter. The Jet Prep and MedJet products also require the physician to remove it from the working channel during the procedure if they need to remove polyps or take a biopsy, impacting the workflow of the procedure. The competitive products mentioned are not currently reimbursed by private or government payors. There are over ten different preparation regimens used prior to colonoscopy today. Some are prescription medications and others are over-the-counter. Typically, the over-the-counter regimens are not indicated for colonoscopy prep but for issues of motility, such as constipation, but are still widely prescribed by physicians for colonoscopy prep. Depending on the insurance a patient has, the prescription prep may be covered in part but many of them require the patient to pay out-of-pocket.

The medical device and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have indirect competitors in a number of jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Currently, the colonoscopy market is dominated by Olympus, who controls a majority of the market, with Pentax and FujiFilm taking most of the rest of the U.S. colonoscope market. Boston Scientific, Medtronic US Endoscopy, Cantel Medical and other smaller players sell ancillary devices and accessories into the marketplace as well. These established competitors may invest heavily to quickly discover and develop novel devices that could make our Pure-Vu System obsolete or uneconomical. There are also capsule endoscopy systems such as the PillCam™ from Medtronic and the Endocapsule 10 from Olympus. These systems, however, require at least the same level of prep as conventional colonoscopies, cannot remove polyps, and therefore, cannot be used to obtain biopsies to detect cancer, so may be less useful for colonoscopy as compared to visualization of the small bowel. Another visualization technique is the virtual colonoscopy, where a radiologist uses a CT scan to obtain 2D and 3D images of the colon. Virtual colonoscopies may require the same level of prep as conventional colonoscopies and if a polyp or abnormality is detected, the patient may still need to undergo a colonoscopy. Other screening tests for colon cancer specifically include fecal occult blood tests and DNA stool tests such as the Cologuard test from Exact Sciences. However, Cologuard is not a replacement for diagnostic colonoscopies or surveillance colonoscopies in high risk individuals and has a lower specificity than standard colonoscopies. While none of these testing alternatives may ever fully replace the colonoscopy, over time, they may take market share away from conventional colonoscopies for specific purposes and may lower the potential market opportunity for us.

Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, cost, convenience, tolerability and safety to be commercially successful. Other competitive factors, including new competitive entrants, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to the Pure-Vu System. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

Research and Development

We have research and development capabilities in electrical and mechanical engineering with laboratories in our facility in Israel for development and prototyping, and electronics design and testing. We also use consultants and third party design houses to complement our internal capabilities.

We have received, and may receive in the future, grants from the Government of the State of Israel through the Israeli National Authority for Technological Innovation (the "IIA") (formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry (the "OCS")), for the financing of a portion of our research and development expenditures pursuant to the Israeli Law for the Encouragement of Research, Development and Technological Innovation in Industry 5744-1984 (the "Research Law"), and the regulations previously promulgated thereunder, as well as the IIA's rules and benefit tracks which apply to companies receiving IIA funding (collectively, including the Research Law, the "IIA Regulations").

As of December 31, 2018, we had received grants from the IIA in the aggregate amount of $1.332 million, and had a contingent obligation to the IIA up to an aggregate amount of approximately $1.383 million (assuming no increase, per the IIA Regulations, as described below). As of December 31, 2018, we paid a minimal amount to the IIA. We may apply for additional IIA grants in the future. However, as the funds available for IIA grants out of the annual budget of the State of Israel are subject to the pre-approval of the IIA and have been reduced in the past and may be further reduced in the future, we cannot predict whether we will be entitled to – or approved for – any future grants, or the amounts of any such grants (if approved).

In exchange for these grants, we are required to pay royalties to the IIA of 3% to 3.5% (which may be increased under certain circumstances) from our revenues generated (in any fashion) from know-how developed using IIA grants, up to an aggregate of 100% (which may be increased under certain circumstances) of the U.S. dollar-linked value of the grant, plus interest at the rate of 12-month LIBOR.

The IIA Regulations also require that certain amounts of products developed with IIA grants be manufactured in Israel and that certain technology developed thereunder may not be transferred outside of Israel (including by way of certain licenses), unless prior approval is received from the IIA, which we intend to apply for but may not be granted. Even if such approval is granted, the transfer outside of Israel of manufacturing which is connected with the IIA-funded knowhow may result in increased royalties (up to three times the aggregate amount of the IIA grants plus interest thereon), as well as in a higher royalty repayment rate. In addition, the transfer outside of Israel of IIA-funded knowhow may trigger additional payments to the IIA (up to six times the aggregate amount of the IIA grants plus interest thereon). Even following the full repayment of any IIA grants, we must nevertheless continue to comply with the requirements of the IIA Regulations. The foregoing restrictions and requirements for payment may impair our ability to transfer or sell our technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any IIA-funded know-how outside of Israel.

Furthermore, companies that receive IIA funding are required to ensure that all rights in the IIA-backed product are retained by them. This means that all know-how which is derived from the research and development conducted pursuant to an IIA approved plan, and every right derived from it, must be owned by the recipient of the IIA funding from the date such know-how is generated. Companies that receive IIA funding are further subject to reporting requirements and other technical requirements, which are intended to allow the IIA to ensure that the IIA Regulations are being complied with.

If we fail to comply with any of the conditions and restrictions imposed by the IIA Regulations, or by the specific terms under which we received the grants, we may be required to refund any grants previously received together with interest and penalties, and, in certain circumstances, may be subject to criminal charges.

For additional information, see "Part I—Item 1A—Risk Factors—Risks Related to Our Operations in Israel."

Manufacturing and Supply

We have established relationships with research facilities, contract manufacturing organizations, or CMO's, and our collaborators to manufacture and supply our product for our limited pilot launch in the U.S. market and for commercialization. Currently, the workstation component of our Pure-Vu System is manufactured by Sanmina Corporation at their facilities in Israel and the loading fixture is made by the RMS Company in Minnesota. We may enter into formal supply agreements for the manufacture of the workstation component and loading fixture of our Pure-Vu System with Sanmina Corporation or RMS Company respectively, as we continue to establish higher volume capabilities and our commercialization efforts grow. The disposable portion of our Pure-Vu System is manufactured by Polyzen, Inc., at their facilities in North Carolina, U.S., pursuant to a supply agreement we entered into with Polyzen, Inc. in September 2017. A critical component supplier for the disposable manufactured by Polyzen, Inc. is EG Gilero. These manufacturing suppliers have extensive experience in medical devices and dealing with regulatory bodies. These suppliers have ISO 13485 approved quality systems. We have an agreement in place with a third party logistics provider in the U.S. who is ISO 13485 certified and specializes in medical devices and equipment. They will provide warehousing, shipping and back office support to meet our commercial needs.

For additional information, see "Part I—Item 1—Business—Research and Development" above, and "Part I—Item 1A—Risk Factors—Risks Related to Our Operations in Israel."

U.S. Market Entry Strategy

We have been actively conducting a limited pilot launch in the U.S. market during 2018 and into the first quarter of 2019. Our evaluation cases have been performed, to date, at twenty centers showing cleansing capabilities similar to our clinical trial experience. This pilot phase is expected to continue to run until our planned full launch of the Pure-Vu System in the United States inpatient colonoscopy market in 2019 with the primary objectives of expanding our clinical evidence, developing a practice integration model and creating key reference centers in the hospital inpatient settings. In connection with our planned full launch of the Pure-Vu System in the United States inpatient colonoscopy market in 2019 we will initially focus on validating our clinical and economic value proposition within key US hospitals and integrated delivery networks ("IDN's"). Our focus will be on building clinical champions amongst key Gastroenterologists, and other GI and nursing floor leadership and staff. Additionally, we will articulate the clinical and economic value of the Pure-Vu System technology to key members of hospital administration. After a pre-defined product evaluation period, we will work within the Value Analysis Committee approval process, currently utilized within most U.S. hospitals and IDN's. We will support our customers with robust training on the effective use of our Pure-Vu System technology through our training and in-servicing programs.

We are working with a third party logistics provider specializing in medical devices to provide front and back office support to successfully fulfill customer orders. Additionally our commercial organization has implemented a robust customer relationship management tool to track account progress and help provide accurate forecasting for operations. We anticipate the sales cycle to be in the range of six to twelve months. During our limited pilot launch in the U.S. market, we have continued to refine our commercialization strategy and tactics prior to our planned full launch of the Pure-Vu System in the United States inpatient colonoscopy market in 2019. Our planned full launch of the Pure-Vu System in the United States inpatient colonoscopy market will focus on launching Gen 2 of the Pure-Vu System platform (see Part I—Item 1—Business —Second Generation of Pure-Vu System), growing the top line revenues and scaling the commercial organization. We expect to develop strategic relationships to pursue OUS marketing opportunities and to initiate sales in the EU, Japan, China and other Asian markets in the future.

Market Expansion Opportunities

Our resources are currently focused on the planned full launch of the Pure-Vu System in the United States inpatient colonoscopy market in 2019. However, we have identified two follow-on market expansion opportunities we may explore in the future. These include the inpatient upper gastrointestinal bleed ("Upper GI") endoscopy market and the outpatient high need colonoscopy market. In the Upper GI bleed endoscopy market, we believe the Pure-Vu System has the potential to be used during endoscopy procedures to remove clots and debris to provide a clear field of view for the endoscopist. Separately, the outpatient high need colonoscopy market presents a large potential commercial market opportunity for the Pure-Vu System, as close to 26 million outpatient colonoscopy procedures are performed worldwide. Based on published literature in several peer reviewed journals from 2010 to 2015 and surveys of physicians conducted in 2015, approximately 23% of such colonoscopy patients can have an inadequate preparation, which may lead to repeat procedures earlier than the medical guidelines suggest. We believe use of the Pure-Vu System has the potential to reduce the need for such repeat procedures if used in the outpatient high need colonoscopy market. Additionally, if we choose to explore either market, we may be able to leverage our existing hospital and doctor relationships developed through our inpatient colonoscopy sales force to facilitate such expansion.

Employees

As of December 31, 2018, we had 44 full time employees. All of our employees are engaged in administration, finance, clinical, research and development, engineering, regulatory or sales and marketing functions. We believe our relations with our employees are good. We anticipate that the number of employees will grow as we scale our commercial capabilities. In addition, we utilize and will continue to utilize consultants, clinical research organizations and third parties to perform our pre-clinical studies, clinical studies, manufacturing and regulatory functions.

Under Israeli law, we and our employees in Israel are subject to Israeli protective labor provisions, including the length of the workday, minimum wages for employees, annual leave, sick pay, determination of severance pay and advance notice of termination of employment, as well as procedures for hiring and dismissing employees and equal opportunity and anti-discrimination laws. While none of our employees in Israel is party to any collective bargaining agreements, orders issued by the Israeli Ministry of Economy and Industry may make certain industry-wide collective bargaining agreements applicable to us. These agreements affect matters such as the length of the workday and week, recuperation pay, travel expenses and pension rights. We have never experienced labor-related work stoppages and believe that our relationships with our employees are a significant part of our operations and that we maintain a good and positive relationship with our employees.

Israeli law generally requires the payment of severance compensation by employers upon the retirement, death or dismissal of an employee. We fund our ongoing Israeli severance obligations by making monthly payments to insurance policies. All of our current employees in Israel have agreed that, upon termination of their employment, they will be entitled to receive only the amounts accrued in the insurance policies with respect to severance pay.

Furthermore, Israeli employees and employers are required to pay predetermined sums to the National Insurance Institute, which is similar to the U.S. Social Security Administration. These amounts also include payments for national health insurance.

Regulatory Matters

Government Regulation

Our business is subject to extensive federal, state, local and foreign laws and regulations, including those relating to the protection of the environment, health and safety. Some of the pertinent laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations. In addition, these laws and their interpretations are subject to change, or new laws may be enacted.

Both federal and state governmental agencies continue to subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. We believe that we have structured our business operations and relationships with our customers to comply with all applicable legal requirements. However, it is possible that governmental entities or other third parties could interpret these laws differently and assert otherwise. We discuss below the statutes and regulations that are most relevant to our business.

U.S. Food and Drug Administration regulation of medical devices.

The FDCA and FDA regulations establish a comprehensive system for the regulation of medical devices intended for human use. Our products include medical devices that are subject to these, as well as other federal, state, local and foreign, laws and regulations. The FDA is responsible for enforcing the laws and regulations governing medical devices in the United States.

The FDA classifies medical devices into one of three classes (Class I, Class II, or Class III) depending on their level of risk and the types of controls that are necessary to ensure device safety and effectiveness. The class assignment is a factor in determining the type of premarketing submission or application, if any, that will be required before marketing in the United States.

- Class I devices present a low risk and are not life-sustaining or life-supporting. The majority of Class I devices are subject only to "general controls" (e.g., prohibition against adulteration and misbranding, registration and listing, good manufacturing practices, labeling, and adverse event reporting. General controls are baseline requirements that apply to all classes of medical devices.)

- Class II devices present a moderate risk and are devices for which general controls alone are not sufficient to provide a reasonable assurance of safety and effectiveness. Devices in Class II are subject to both general controls and "special controls" (e.g., special labeling, compliance with performance standards, and post market surveillance. Unless exempted, Class II devices typically require FDA clearance before marketing, through the premarket notification (510(k)) process.)

- Class III devices present the highest risk. These devices generally are life-sustaining, life-supporting, or for a use that is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury. Class III devices are devices for which general controls, by themselves, are insufficient and for which there is insufficient information to determine that application of special controls would provide a reasonable assurance of safety and effectiveness. Class III devices are subject to general controls and typically require FDA approval of a premarket approval ("PMA") application before marketing.

Unless it is exempt from premarket review requirements, a medical device must receive marketing authorization from the FDA prior to being commercially marketed, distributed or sold in the United States. The most common pathways for obtaining marketing authorization are 510(k) clearance and PMA.

510(k) pathway

The 510(k) review process compares a new device to a legally marketed device. Through the 510(k) process, the FDA determines whether a new medical device is "substantially equivalent" to a legally marketed device (i.e., predicate device) that is not subject to PMA requirements. "Substantial equivalence" means that the proposed device has the same intended use as the predicate device, and the same or similar technological characteristics, or if there are differences in technological characteristics, the differences do not raise different questions of safety and effectiveness as compared to the predicate, and the information submitted in the 510(k) demonstrates that the proposed device is as safe and effective as the predicate device.

To obtain 510(k) clearance, a company must submit a 510(k) application containing sufficient information and data to demonstrate that its proposed device is substantially equivalent to a legally marketed predicate device. These data generally include non-clinical performance testing (e.g., software validation, animal testing electrical safety testing), but may also include clinical data. Typically, it takes three to twelve months for the FDA to complete its review of a 510(k) submission; however, it can take significantly longer and clearance is never assured. During its review of a 510(k), the FDA may request additional information, including clinical data, which may significantly prolong the review process. After completing its review of a 510(k), the FDA may issue an order, in the form of a letter, that finds the device to be either (i) substantially equivalent and states that the device can be marketed in the United States, or (ii) not substantially equivalent and states that device cannot be marketed in the United States. Depending upon the reasons for the not substantially equivalent finding, the device may need to be approved through the PMA pathway (discussed below) prior to commercialization.

After a device receives 510(k) clearance, any modification that could significantly affect the safety or effectiveness of the device, or that would constitute a major change in its intended use, including significant modifications to any of our products or procedures, requires submission and clearance of a new 510(k) or approval of a PMA. The FDA relies on each manufacturer to make and document this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. Modifications meeting certain conditions may be candidates for a streamlined FDA review known as Special 510(k) review, which the FDA intends to process within 30 days of receipt. If a device modification requires the submission of a 510(k), but the modification does not affect the intended use of the device or alter the fundamental technology of the device, then summary information that results from the design control process associated with the cleared device can serve as the basis for clearing the application. A Special 510(k) allows a manufacturer to declare conformance to design controls without providing new data. When a modification involves a change in material, the nature of the "new" material will determine whether a traditional or Special 510(k) is necessary. An Abbreviated 510(k) is another type of 510(k) that is intended to streamline the review of data through the reliance on one or more FDA-recognized consensus standards, special controls established by regulation, or FDA guidance documents. In most cases, an Abbreviated 510(k) includes one or more declarations of conformity to an FDA-recognized consensus standard. We may also make minor product enhancements that we believe do not require new 510(k) clearances. If the FDA disagrees with our determination regarding whether a new 510(k) clearance was required for these modifications, we may need to cease marketing and/or recall the modified device. The FDA may also subject us to other enforcement actions, including, but not limited to, issuing a warning letter or untitled letter to us, seizing our products, imposing civil penalties, or initiating criminal prosecution.

Premarket approval pathway

Unlike the comparative standard of the 510(k) pathway, the PMA approval process requires an independent demonstration of the safety and effectiveness of a device. PMA is the most stringent type of device marketing application required by the FDA. PMA approval is based on a determination by the FDA that the PMA contains sufficient valid scientific evidence to ensure that the device is safe and effective for its intended use(s). A PMA application generally includes extensive information about the device including the results of clinical testing conducted on the device and a detailed description of the manufacturing process.

After a PMA application is accepted for review, the FDA begins an in-depth review of the submitted information. FDA regulations provide 180 days to review the PMA and make a determination; however, in reality, the review time is normally longer (e.g., 1-3 years). During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the data supporting the application and provide recommendations to the FDA as to whether the data provide a reasonable assurance that the device is safe and effective for its intended use. In addition, the FDA generally will conduct a preapproval inspection of the manufacturing facility to ensure compliance with QSR, which imposes comprehensive development, testing, control, documentation and other quality assurance requirements for the design and manufacturing of a medical device.

Based on its review, the FDA may (i) issue an order approving the PMA, (ii) issue a letter stating the PMA is "approvable" (e.g., minor additional information is needed), (iii) issue a letter stating the PMA is "not approvable," or (iv) issue an order denying PMA. A company may not market a device subject to PMA review until the FDA issues an order approving the PMA. As part of a PMA approval, the FDA may impose post-approval conditions intended to ensure the continued safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution, and requiring the collection of additional clinical data. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including withdrawal of the approval.

Most modifications to a PMA approved device, including changes to the design, labeling, or manufacturing process, require prior approval before being implemented. Prior approval is obtained through submission of a PMA supplement. The type of information required to support a PMA supplement and the FDA's time for review of a PMA supplement vary depending on the nature of the modification.

Clinical trials

Clinical trials of medical devices in the United States are governed by the FDA's Investigational Device Exemption ("IDE") regulation. This regulation places significant responsibility on the sponsor of the clinical study including, but not limited to, choosing qualified investigators, monitoring the trial, submitting required reports, maintaining required records, and assuring investigators obtain informed consent, comply with the study protocol, control the disposition of the investigational device, submit required reports, etc.

Clinical trials of significant risk devices (e.g., implants, devices used in supporting or sustaining human life, devices of substantial importance in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health) require FDA and Institutional Review Board ("IRB") approval prior to starting the trial. FDA approval is obtained through submission of an IDE application. Clinical trials of non-significant risk ("NSR"), devices (i.e., devices that do not meet the regulatory definition of a significant risk device) only require IRB approval before starting. The clinical trial sponsor is responsible for making the initial determination of whether a clinical study is significant risk or NSR; however, a reviewing IRB and/or FDA may review this decision and disagree with the determination.

An IDE application must be supported by appropriate data, such as performance data, animal and laboratory testing results, showing that it is safe to evaluate the device in humans and that the clinical study protocol is scientifically sound. There is no assurance that submission of an IDE will result in the ability to commence clinical trials. Additionally, after a trial begins, the FDA may place it on hold or terminate it if, among other reasons, it concludes that the clinical subjects are exposed to an unacceptable health risk.

As noted above, the FDA may require a company to collect clinical data on a device in the post-market setting.

The collection of such data may be required as a condition of PMA approval. The FDA also has the authority to order, via a letter, a post-market surveillance study for certain devices at any time after they have been cleared or approved.

Pervasive and continuing FDA regulation

After a device is placed on the market, regardless of its classification or premarket pathway, numerous additional FDA requirements generally apply. These include, but are not limited to:

- Establishment registration and device listing requirements;
- Quality System Regulation ("QSR"), which governs the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of finished devices;

- Labeling requirements, which mandate the inclusion of certain content in device labels and labeling, and generally require the label and package of medical devices to include a unique device identifier ("UDI"), and which also prohibit the promotion of products for uncleared or unapproved, i.e., "off-label," uses;

- Medical Device Reporting ("MDR") regulation, which requires that manufacturers and importers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and

- Reports of Corrections and Removals regulation, which requires that manufacturers and importers report to the FDA recalls (i.e., corrections or removals) if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health; manufacturers and importers must keep records of recalls that they determine to be not reportable.

The FDA enforces these requirements by inspection and market surveillance. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include, but is not limited to, the following sanctions:

- Untitled letters or warning letters;

- Fines, injunctions and civil penalties;

- Recall or seizure of our products;

- Operating restrictions, partial suspension or total shutdown of production;

- Refusing our request for 510(k) clearance or premarket approval of new products;

- Withdrawing 510(k) clearance or premarket approvals that are already granted; and

- Criminal prosecution.

We are subject to either announced or unannounced device inspections by the FDA, as well as other regulatory agencies overseeing the implementation of and compliance with applicable state public health regulations. These inspections may include our suppliers' facilities.

International

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. In order to market our products in other countries, we must obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ. The European Union/European Economic Area (the "EU/EEA"), requires a CE conformity mark, or CE Mark, in order to market medical devices. Many other countries, such as Australia, India, New Zealand, Pakistan and Sri Lanka, accept CE or FDA clearance or approval, although others, such as Brazil, Canada and Japan require separate regulatory filings.

In the EU and the EEA, devices are required to comply with the essential requirements of the EU Medical Devices Directive. Compliance with these requirements would entitle us to affix the CE conformity mark to our medical devices, without which they cannot be commercialized in the EU and EEA. To demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity mark we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I), where the manufacturer can issue a CE Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the Medical Devices Directive, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization accredited at the European Commission to conduct conformity assessments. The Notified Body would typically audit and examine the quality system for the manufacture, design and final inspection of our devices before issuing a certification demonstrating compliance with the essential requirements. Based on this certification we can draw up a CE Declaration of Conformity which allows us to affix the CE Mark to our products.

Further, the advertising and promotion of our products in the EU and the EEA is subject to the laws of individual EU and EEA Member States implementing the EU Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other EU and EEA Member State laws governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the Department of Health and Human Services, the Department of Justice, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of medical device products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of medical device products.

Third-Party Payor Coverage and Reimbursement

Our Pure-Vu System and the procedure to cleanse the colon in preparation for colonoscopy are not currently reimbursable through private or governmental third-party payors in any country. Significant uncertainty exists as to whether coverage and reimbursement of the Pure-Vu System will develop; but we intend to seek reimbursement through private or governmental third-party payors in the future. In both the United States and foreign markets, our ability to commercialize the Pure-Vu System successfully, and to attract commercialization partners for the Pure-Vu System, depends in part on the availability of adequate financial coverage and reimbursement from third-party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Medicare is a federally funded program managed by the CMS, through local contractors that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured, and it is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations or other guidelines that govern its individual program. Each payor, whether governmental or private, has its own process and standards for determining whether it will cover and reimburse a procedure or particular product. Private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. The competitive position of the Pure-Vu System will depend, in part, upon the extent of coverage and adequate reimbursement for such product and for the procedures in which such product is used. Prices at which we or our customers seek reimbursement for the Pure-Vu System can be subject to challenge, reduction or denial by the government and other payors.

In the event we do receive approval for third-party or government reimbursement for our product, the marketability of such product may suffer if the government and commercial third-party payors fail to provide adequate coverage and reimbursement. An emphasis on cost containment measures in the United States has increased and we expect it will continue. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

State and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

In addition, in some foreign countries, the proposed pricing for a medical device must be approved before it may be lawfully marketed. The requirements governing medical device pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medical devices for which their national health insurance systems provide reimbursement and to control the prices of medical devices. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of our medical devices to other available therapies in order to obtain or maintain reimbursement or pricing approval. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be priced significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our medical devices is unavailable or limited in scope or amount, our revenues from sales by us or our strategic partners and the potential profitability of any of our medical devices in those countries would be negatively affected.

Other Healthcare Laws and Compliance Requirements

Healthcare providers, physicians, and third party payors will play a primary role in the recommendation and use of any products for which we obtain marketing approval. Our future arrangements with third party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any device for which we obtain marketing approval. In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the CMS, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. The applicable laws and regulations include the federal health care program Anti-Kickback Statute, the federal Civil False Claims Act, and the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).

- The federal health care programs Anti-Kickback Statute (“AKS”) makes it illegal for any person, including a device manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, or order of a particular device, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to ten years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it.

- The Federal Civil False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $11,463 and $22,927 (adjusted annually for inflation) for each separate false claim and the potential for exclusion from participation in federal healthcare programs. Conduct that violates the False Claims Act also may implicate various federal criminal statutes. The government may deem manufacturers to have “caused” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute also are deemed false or fraudulent claims for purposes of the False Claims Act. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product and any future product candidates, are subject to scrutiny under this law.

- HIPAA which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and its implementing regulations, also imposes certain obligations, including contractual terms and technical safeguards, with respect to maintaining the privacy, security and transmission of individually identifiable health information.

- HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA privacy and security rules and seek attorneys' fees and costs associated with pursuing federal civil actions.

- The Federal Physician Payments Sunshine Act within the Affordable Care Act, and its implementing regulations, which requires that certain manufacturers of devices and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

- Analogous state and foreign fraud and abuse laws and regulations, such as anti-kickback and false claims laws, which may apply to sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts. Such laws are generally broad and are enforced by various state agencies and private actions.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information, which are applicable to "business associates"—independent contractors or agents of HIPAA covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity.

EU Member States and other jurisdictions where we operate have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the General Data Protection Regulation (GDPR) which became applicable on May 25, 2018, replacing the EU Data Protection Directive, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical investigations and safety reporting.

Switzerland has adopted similar restrictions. These obligations and restrictions concern, in particular, the consent of the individuals to whom the personal data relate, the information provided to the individuals, the transfer of personal data out of the EEA or Switzerland, security breach notifications, security and confidentiality of the personal data, as well as substantial potential fines for breaches of the data protection obligations.

Data protection authorities from the different EU Member States may interpret the GDPR and applicable related national laws differently and impose requirements additional to those provided in the GDPR. In addition, guidance on implementation and compliance practices may be updated or otherwise revised, which adds to the complexity of processing personal data in the EU. When processing personal data of subjects in the EU, we must comply with the applicable data protection laws. In particular, when we rely on third party services providers processing personal data of subjects in the EU we must enter into suitable agreements with these providers and receive sufficient guarantees that the providers meet the requirements of the applicable data protection laws, particularly the GDPR which imposes specific and relevant obligations.

Although there are legal mechanisms to allow for the transfer of personal data from the EEA to the US, a decision of the European Court of Justice in the Schrems case (Case C-362/14 Maximillian Schrems v. Data Protection Commissioner) that invalidated the safe harbor framework has increased uncertainty around compliance with EU privacy law requirements. As a result of the decision, it was no longer possible to rely on the safe harbor certification as a legal basis for the transfer of personal data from the EU to entities in the US. On February 29, 2016, however, the European Commission announced an agreement with the United States Department of Commerce (DOC) to replace the invalidated Safe Harbor framework with a new EU-US "Privacy Shield." On July 12, 2016, the European Commission adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the requirements set out by the European Court of Justice in its ruling by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DOC and Federal Trade Commission, and making commitments on the part of public authorities regarding access to information. US companies have been able to certify to the US Department of Commerce their compliance with the privacy principles of the Privacy Shield since August 1, 2016.

On September 16, 2016, an Irish privacy advocacy group brought an action for annulment of the EC decision on the adequacy of the Privacy Shield before the European Court of Justice (Case T-670/16). In October 2016, a further action for annulment was brought by three French digital rights advocacy groups (Case T-738/16). Case T-670/16 was declared inadmissible. Case T-738/16 is still pending before the European Court of Justice. The United States was admitted as an intervener in the action on September 4, 2018. If the European Court of Justice invalidates the Privacy Shield, it will no longer be possible to rely on the Privacy Shield certification to support transfer of personal data from the EU to entities in the US. Adherence to the Privacy Shield is not, however, mandatory. US-based companies are permitted to rely either on their adherence to the Privacy Shield or on the other authorized means and procedures to transfer personal data provided by the GDPR. If we or our vendors fail to comply with applicable data privacy laws, or if the legal mechanisms we or our vendors rely upon to allow for the transfer of personal data from the EEA or Switzerland to the US (or other countries not considered by the European Commission to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions and significant penalties against us, and our business could be adversely impacted if our ability to transfer personal data outside of the EEA or Switzerland is restricted, which could adversely impact our operating results.

Current and future legislation

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

With the current Administration and Congress, there may be additional administrative or legislative changes, including modification, repeal, or replacement of all, or certain provisions of, the Affordable Care Act, which may impact reimbursement for medical devices. On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress has attempted several times to repeal and replace the Affordable Care Act, yet to date no complete repeal has occurred. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the Affordable Care Act Numerous insurers have filed suits to obtain unpaid cost-sharing subsidy payments. In several of the cases, district courts have held that insurers are entitled to unpaid subsidies but litigation and appeals are ongoing. Litigation and legislation over the Affordable Care Act are likely to continue, with unpredictable and uncertain results.

Additional laws and regulations governing international operations

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Our business activities outside of the U.S. are also subject to anti-bribery or anti-corruption laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct or rules of other countries in which we operate, including the U.K. Bribery Act of 2010.

Interactions between medical devices manufacturers and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct developed at both EU level and in the individual EU Member States. The provision of benefits or advantages to physicians to induce or encourage the recommendation, endorsement, purchase, supply, order or use of medical devices is prohibited in the EU. Breach of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States also must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, their competent professional organization, and/or the competent authorities of the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Post-Marketing Regulations

Following clearance or approval of a new product, a company and the product are subject to continuing regulation by the FDA and other foreign, federal and state regulatory authorities, including, among other things, monitoring and recordkeeping activities, reporting to applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting for uses or in patient populations not described in the product's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the products or labeling or changes of site of manufacture are often subject to the approval of the FDA and other regulators or subject of review by a notified body in the EU, which may or may not be received or may result in a lengthy review process.

Initial Public Offering

On February 16, 2018, we completed our initial public offering of 3,500,000 shares of our Common Stock, par value $0.0001 per share (the "Common Stock"), at a public offering price of $5.00 per share, with gross proceeds of $17.5 million (the "IPO"). Simultaneously with the closing of our IPO, all 1,581,128 previously outstanding shares of our convertible preferred stock, par value $0.0001 (the "Series A Convertible Preferred Stock"), were converted, on a one-to-one basis, into an aggregate of 1,581,128 shares of our Common Stock. No shares of our Series A Convertible Preferred Stock remain outstanding as a result of such conversion. Additionally, at the closing of our IPO, we issued warrants to certain of our former Series A Convertible Preferred Stock holders, pursuant to an amendment to our registration rights agreement (the "Registration Rights Agreement") entered into with the investors in the private placement offering of units we conducted from December 2016 to February 2017 (the "2017 Private Placement") and an amendment to our Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (the "Certificate of Designation") to purchase 1,095,682 shares of our Common Stock (the "Ten Percent Warrants"). The Ten Percent Warrants are exercisable for our Common Stock at an exercise price of $5.00. The Ten Percent Warrants are currently exercisable, have a five year term, and provide for cashless exercise. Certain related parties received Ten Percent Warrants, see "Part III—Item 13—Certain Relationships and Related Transactions, and Director Independence—Ten Percent Warrants – Related Party Participation." Certain related parties purchased shares of our Common Stock in our IPO, see "Part III—Item 13—Certain Relationships and Related Transactions, and Director Independence—Participation in Initial Public Offering."

On March 12, 2018, we completed the sale of an additional 56,000 shares of our Common Stock at a price of $5.00 per share, pursuant to a partial exercise of the underwriters 30-day option to purchase up to an additional 525,000 shares of our Common Stock in connection with the IPO (the "Partial IPO Over-Allotment Exercise"), with gross proceeds of $280,000.

Follow On Public Offering

On December 24, 2018, we completed a follow on public offering of 5,750,000 shares of our Common Stock at a public offering price of $2.70 per share (the "Follow On Offering"), inclusive of 750,000 shares issued pursuant to the full exercise of the underwriters option to purchase up to an additional 750,000 shares of our Common Stock in connection with the offering. Gross proceeds from the Follow On Offering were approximately $15.5 million. Certain related parties purchased shares of our Common Stock in our Follow On Offering, see "Part III—Item 13—Certain Relationships and Related Transactions, and Director Independence—Participation in Follow On Offering."

Implications of Being an Emerging Growth Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and, for as long as we continue to be an "emerging growth company," we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, (the "Sarbanes-Oxley Act"), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an "emerging growth company" for up to five years from the date of our initial public offering in February 2018, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our Common Stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three-year period. We intend to take advantage of these reporting exemptions described above until we are no longer an "emerging growth company." Under the JOBS Act, "emerging growth companies" can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

Corporate and Available Information

We are a Delaware corporation formed in September 2016 under the name Eight-Ten Merger Corp. In November 2016, we changed our name to Motus GI Holdings, Inc. We are the parent company of Motus GI Medical Technologies Ltd., an Israeli corporation, and Motus GI, Inc. a Delaware corporation.

Our principal executive offices are located at 1301 East Broward Boulevard, 3rd Floor, Ft. Lauderdale, FL 33301. Our phone number is (954) 541-8000 and our web address is www.motusgi.com. Our website and the information contained on, or that can be accessed through, our website will not be deemed to be incorporated by reference into this Annual Report on Form 10-K or any other report we file with or furnish to the SEC.

We make available free of charge on or through the Investor Relations link on our website, www.motusgi.com, access to press releases and investor presentations, as well as all materials that we file electronically with the SEC, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after electronically filing such materials with, or furnishing them to, the SEC. During the period covered by this Form 10-K, we made all such materials available through our website as soon as reasonably practicable after filing such materials with the SEC. The SEC maintains an Internet website, www.sec.gov, that contains reports, proxy and information statements and other information that we file electronically with the SEC.

"Motus GI," "Pure-Vu," and our other registered or common law trademarks, service marks or trade names appearing herein are the property of Motus GI Holdings, Inc. Some trademarks referred to in this report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

ITEM 1A. RISK FACTORS

Risks Related to Our Financial Position and Need for Capital

There is substantial doubt about our ability to continue as a going concern, which will affect our ability to obtain future financing and may require us to curtail our operations.

Our financial statements as of December 31, 2018 were prepared under the assumption that we will continue as a going concern. The independent registered public accounting firm that audited our 2018 financial statements, in their report, included an explanatory paragraph referring to our recurring losses since inception and expressing substantial doubt in our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our ability to continue as a going concern depends on our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. We cannot assure you, however, that we will be able to achieve any of the foregoing.

We have incurred substantial operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future. We may never become profitable or, if achieved, be able to sustain profitability.

We expect to incur substantial expenses without corresponding revenues unless and until we expand our commercialization efforts. To date, as part of our limited pilot launch in the U.S. market, we have generated limited revenue from our Pure-Vu System, but we do not expect to generate significant revenue from product sales unless and until we expand our commercialization efforts, which is subject to significant uncertainty. We expect to incur significant marketing expenses in the United States, Europe and elsewhere, and there can be no assurance that we will generate significant revenues or ever achieve profitability. Our net loss for the years ended December 31, 2018 and December 31, 2017 was approximately $22.3 million and $13.2 million, respectively. As of December 31, 2018, we had an accumulated deficit of approximately $61.4 million.

Our cash, cash equivalents or short-term investments will only fund our operations for a limited time and we will need to raise additional capital to support our development and commercialization efforts.

We are currently operating at a loss and expect our operating costs will increase significantly as we incur costs associated with commercialization activities related to our Pure-Vu System. Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern in their report on our financial statements. At December 31, 2018, we had a cash and cash equivalents, and short-term investments balance of approximately $21.1 million. Based on our current business plan, we believe our cash, cash equivalents and short-term investments balance as of December 31, 2018, will be sufficient to meet our anticipated cash requirements through the fourth quarter of 2019.

If our available cash balances are insufficient to satisfy our liquidity requirements, including due to risks described herein, we may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. We will need to raise additional capital, and we may also consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities, or for other reasons, including to:

- fund development and efforts of any future products;
- acquire, license or invest in technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- our revenue growth rate and ability to generate cash flows from operating activities;
- our sales and marketing and research and development activities;

- costs of and potential delays in product development;
- changes in regulatory oversight applicable to our products; and
- costs related to international expansion.

We do not currently have any arrangements or credit facilities in place as a source of funds, and there can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, or at all, and if we are not successful in raising additional capital, we may not be able to continue as a going concern. We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, that could increase our expenses and require that our assets secure such debt. Equity financing, if obtained, could result in dilution to our then existing stockholders and/or require such stockholders to waive certain rights and preferences. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of business opportunities and our operations and financial condition may be materially adversely affected. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all. In addition, if we are unable to secure sufficient capital to fund our operations, we might have to enter into strategic collaborations that could require us to share commercial rights to the Pure-Vu System with third parties in ways that we currently do not intend or on terms that may not be favorable to us. If we choose to pursue additional indications and/or geographies for the Pure-Vu System or otherwise expand more rapidly than we presently anticipate, we may also need to raise additional capital sooner than expected.

Future capital raises may dilute our existing stockholders' ownership and/or have other adverse effects on our operations.

If we raise additional capital by issuing equity securities, our existing stockholders' percentage ownership will be reduced and these stockholders may experience substantial dilution. If we raise additional funds by issuing debt securities, these debt securities would have rights senior to those of our Common Stock and the terms of the debt securities issued could impose significant restrictions on our operations, including liens on our assets. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or products, or to grant licenses on terms that are not favorable to us.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Effective on December 1, 2016, Motus G.I. Medical Technologies LTD, and the holders of all issued and outstanding shares of capital stock of Motus G.I. Medical Technologies LTD (the "LTD Stockholders"), entered into a share exchange agreement (the "Share Exchange Agreement") with us. Pursuant to the terms of the Share Exchange Agreement, as a condition of and contemporaneously with the initial closing (the "Initial Closing") of the 2017 Private Placement, the LTD Stockholders sold to us, and we acquired, all of the issued and outstanding shares of capital stock of Motus G.I. Medical Technologies LTD (the "Share Exchange Transaction") and Motus G.I. Medical Technologies LTD became our direct wholly-owned subsidiary As a result of the Share Exchange Transaction, our ability to utilize our federal net operating loss, carryforwards and federal tax credit may be limited under Sections 382 of the Internal Revenue Code of 1986, as amended (the "Code"). The limitations apply if an "ownership change," as defined by Section 382, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect "five percent shareholders" increases by more than 50 percentage points over their lowest ownership percentage at any time during the applicable testing period (typically three years). In addition, future changes in our stock ownership, which may be outside of our control, may trigger an "ownership change" and, consequently, Section 382 limitations. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

U.S. federal income tax reform could adversely affect us.

On December 22, 2017, President Trump signed into law the statute originally named the "Tax Cuts and Jobs Act" (the "2017 Tax Act") which enacts a broad range of changes to the Code. The 2017 Tax Act, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating losses, allows for the expensing of certain capital expenditures, and puts into effect a number of changes impacting operations outside of the United States including, but not limited to, the imposition of a one-time tax on accumulated post-1986 deferred foreign income that has not previously been subject to tax, and modifications to the treatment of certain intercompany transactions. As of December 31, 2018, we have completed our accounting for the tax effects of the 2017 Tax Act. We have revalued our net deferred tax assets and liabilities at the newly enacted U.S. corporate tax rate, resulting in a write-down of our gross deferred tax assets of approximately $0.4 million as of December 31, 2017. We continue to examine the impact this tax legislation, as well as any additional regulatory guidance that may be issued, may have on our business. The impact of this tax legislation on holders of our Common Stock is uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our Common Stock.

Risks Related to Government Regulation and Third-Party Reimbursement

We are subject to complex and costly regulation.

Our product, and any products we may develop in the future, are subject to regulation by the FDA and other national, supranational, federal and state governmental authorities. It can be costly and time-consuming to obtain regulatory clearance and/or approval to market a new or modified medical device or other product. Clearance and/or approval might not be granted on a timely basis, if at all. Regulations are subject to change as a result of legislative, administrative or judicial action, which may further increase our costs or reduce sales. Unless an exception applies, the FDA requires that the manufacturer of a new medical device or a new indication for use of, or other significant change in, an existing medical device obtain either FDA 510(k) pre-market clearance or pre-market approval before that product can be marketed or sold in the United States. Modifications or enhancements to a product that could significantly affect its safety or effectiveness, or that would constitute a major change in the intended use of the device, technology, materials, labeling, packaging, or manufacturing process may also require a new 510(k) clearance or possibly premarket approval. The FDA has indicated that it intends to continue to enhance its pre-market requirements for medical devices. Although we cannot predict with certainty the future impact of these initiatives, it appears that the time and cost to get medical devices to market could increase significantly.

In addition, we are subject to regulations that govern manufacturing practices, product labeling and advertising, and adverse-event reporting that apply after we have obtained clearance or approval to sell a product. Our failure to maintain clearance for our Pure-Vu System, to obtain clearance or approval for new or modified products, or to adhere to regulations for manufacturing, labeling, advertising or adverse event reporting could adversely affect our results of operations and financial condition. Further, if we determine a product manufactured or marketed by us does not meet our specifications, published standards or regulatory requirements, we may seek to correct the product or withdraw the product from the market, which could have an adverse effect on our business. Many of our facilities and procedures, and those of our suppliers are subject to ongoing oversight, including periodic inspection by governmental authorities. Compliance with production, safety, quality control and quality assurance regulations can be costly and time-consuming.

The sales and marketing of medical devices is under increased scrutiny by the FDA and other enforcement bodies. If our sales and marketing activities fail to comply with FDA regulations or guidelines, or other applicable laws, we may be subject to warnings or enforcement actions from the FDA or other enforcement bodies.

We may be unable to obtain or maintain governmental approvals to market our Pure-Vu System outside the United States and the European Union countries.

To be able to market and sell our Pure-Vu System in other countries, we must obtain regulatory approvals and comply with the regulations of those countries. These regulations, including the requirements for approvals and the time required for regulatory review, vary from country to country. Many non-European markets, including major markets in South America and Asia Pacific, have allowed for expedited regulatory review and approval based on an existing CE Mark. We have affixed a CE Mark to our Pure-Vu System in the EU in February 2018, and intend to target countries with a regulatory approval process with similar requirements to CE Mark. However, obtaining and maintaining foreign regulatory approvals are complex and expensive and subject to delays, and management cannot be certain that we will receive and be able to maintain regulatory approvals in any foreign country in which we plan to market our Pure-Vu System or in the time frame in which we expect.

Modifications to our product may require new 510(k) clearance or may require us to cease marketing or recall the modified products until approvals are obtained.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new clearance or possibly premarket approval. Changes that do not rise to this level of significance, including certain manufacturing changes, may be made without FDA clearance upon documentation in the manufacturer's files of the determination of the significance of the change. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with the manufacturer's determination. If the FDA disagrees with any determination that we may make in the future and requires us to seek new 510(k) clearance for modifications to any previously approved or cleared products for which we have concluded that new approvals are unnecessary, we may be required to cease marketing or distribution of our products or to recall the modified product until we obtain approval, and we may be subject to significant regulatory fines or penalties. In the future we may seek to expand the indication for which the Pure-Vu System is cleared or approved to allow us to actively promote the product and a less-prep regimen to patients. This would require us to perform one or more clinical trials to facilitate the approval of such expanded labeling, however, if such trials are unsuccessful or the FDA denies our expanded labeling, our revenues may be adversely affected.

In the European Union/European Economic Area (the "EU/EEA"), we will be required to inform the Notified Body that carried out the conformity assessment of the medical devices we market or sell in the EEA of any planned changes to our quality system or changes to our devices which could affect compliance with the essential requirements set forth in the EU Medical Devices Directive or the devices' intended purpose. The Notified Body will then assess the changes and verify whether they affect the products' conformity with the essential requirements set forth in the EU Medical Devices Directive or the conditions for the use of the device. If the assessment is favorable, the Notified Body will issue a new CE Certificate of Conformity or an addendum to the existing CE Certificate of Conformity attesting compliance with the essential requirements set forth in the EU Medical Devices Directive. If it is not, we may not be able to market and sell the product in the EEA.

If our product malfunctions, or causes or contributes to a death or a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our product also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results. Similar strict regulatory requirements concerning safety reporting and post-market surveillance obligations apply in the EU.

Our Pure-Vu System may in the future be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, including a third-country authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. A government-mandated or voluntary recall by us or a distributor could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. A recall of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our product in a cost-effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or another third-country competent authority. We may initiate voluntary recalls that we determine do not require notification of the FDA or another third-country competent authority. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls.

We are also required to follow detailed recordkeeping requirements for all firm-initiated medical device corrections and removals. In addition, in October 2014, the FDA issued guidance intended to assist the FDA and industry in distinguishing medical device recalls from product enhancements. Per the guidance, if any change or group of changes to a device addresses a violation of the Federal Food, Drug and Cosmetic Act (the "FDCA"), that change would generally constitute a medical device recall and require submission of a recall report to the FDA. Similar strict regulatory requirements concerning medical device recall and related reporting obligations apply in the EU.

Our Pure-Vu System is not currently reimbursable through private or governmental third-party payors, which could limit market acceptance.

Our Pure-Vu System and the procedure to cleanse the colon in preparation for colonoscopy are not currently reimbursable through private or governmental third-party payors in any country. We intend to seek reimbursement through private or governmental third-party payors in the future, however coverage and reimbursement may not be available for any product that we commercialize and, even if available, the level of reimbursement may not be satisfactory. The commercialization of our Pure-Vu System depends on prospective patients' ability to cover the costs of the procedure, and/or physician willingness to subsidize all or some of the costs of the procedure. We believe that a substantial portion of individuals who are candidates for the use of the Pure-Vu System worldwide do not have the financial means to cover its cost. Moreover, healthcare providers may be reluctant to make the initial investment in the system. A general regional or worldwide economic downturn could negatively impact demand for our Pure-Vu System. In the event that medically eligible patients deem the costs of our procedure to be prohibitively high or consider alternative treatment options to be more affordable, or healthcare providers deem the cost of the system to be too high, our business, results of operations and financial condition would be negatively impacted.

If we or our sales personnel or distributors do not comply with fraud and abuse laws, including anti-kickback laws for any products approved in the U.S., or with similar foreign laws where we market our products, we could face significant liability.

There are numerous federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws, false claims, and physician transparency laws. Our relationships with physicians and surgeons, hospitals and our independent distributors are subject to scrutiny under these laws. Violations of these laws are punishable by criminal and civil sanctions, including significant fines, damages and monetary penalties and in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid and Veterans Administration health programs.

Many foreign countries have enacted similar laws addressing fraud and abuse in the healthcare sector. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance requirements in multiple jurisdictions increases the possibility that a healthcare company may run afoul of one or more of the requirements.

We may become liable for significant damages or be restricted from selling our products if we engage in inappropriate promotion of our Pure-Vu System.

Our promotional materials and training methods for our Pure-Vu System must comply with FDA and other foreign applicable laws and regulations, including the prohibition of the promotion of the "off-label" use of our Pure-Vu System, including by using our Pure-Vu System in a way not approved by the FDA or not consistent with the intended purpose for which Pure-Vu System is CE marked in the EU. The Pure-Vu System is currently indicated to connect to standard colonoscopes to facilitate intra-procedural cleaning of a poorly prepared colon by irrigating or cleaning the colon and evacuating the irrigated fluid, feces and other bodily fluids and matter. We do not currently promote a particular prep regimen as this is left up to the discretion of the physician since our current indication does not reference any preparation protocol. Healthcare providers may use our products off-label, as the FDA or the competent authorities in the EU Member States do not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA or a competent authority in an EU Member State determines that our promotional materials, training or marketing efforts constitute promotion of an off-label use, it could request that we modify our training or promotional materials or marketing efforts or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties. Although we do not intend to engage in any activities that may be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged, directly or indirectly, in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could result in substantial damage awards against us and harm our reputation.

Our financial performance may be adversely affected by medical device tax provisions in the healthcare reform laws.

The Patient Protection and Affordable Care Act (the "Affordable Care Act") imposes, among other things, an excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, although this tax has been suspended for calendar years 2016, 2017, 2018 and 2019. It is unclear at this time if the moratorium will be further extended. We anticipate that primarily all of our sales of our Pure-Vu System in the United States will be subject to this 2.3% excise tax after December 31, 2019. Additionally, Congress could terminate the moratorium or further change the law related to the medical device tax in a manner that could adversely affect us.

Risks Related to Our Business Operations

Our Pure-Vu System is currently our sole product and we are completely dependent on the successful marketing and sale of this product. There is no assurance that we will be able to develop any additional products.

Our Pure-Vu System, inclusive of the Pure-Vu Slim Sleeve and Gen 2, is currently our sole product and we are completely dependent on the success of this product. We may fail to successfully commercialize our product. Successfully commercializing medical devices such as ours is a complex and uncertain process, dependent on the efforts of management, distributors, outside consultants, physicians and general economic conditions, among other factors. Any factors that adversely impact the commercialization of our Pure-Vu System, including, but not limited to, competition or acceptance in the marketplace, will have a negative impact on our business, results of operations and financial condition. We cannot assure you that we will be successful in developing or commercializing any potential enhancements to our Pure-Vu System or any other products. Our inability to successfully commercialize our Pure-Vu System and/or successfully develop and commercialize additional products or any enhancements to our Pure-Vu System which we may develop would have a material adverse effect on our business, results of operations and financial condition.

We are a medical technology company with a limited operating history.

We are a medical technology company with a limited operating history. We received clearance from the FDA, and CE Mark approval in Europe, for our Pure-Vu System and are preparing for a planned full launch of the Pure-Vu System in the United States inpatient colonoscopy market in 2019. We expect that sales of our Pure-Vu System will account for substantially all of our revenue for the foreseeable future. However, we have limited experience in selling our products and we may be unable to successfully commercialize our Pure-Vu System for a number of reasons, including:

- market acceptance of our Pure-Vu System by physicians and patients will largely depend on our ability to demonstrate its relative safety, efficacy, cost-effectiveness and ease of use;
- our inexperience in marketing, selling and distributing our products;
- we may not have adequate financial or other resources to successfully commercialize our Pure-Vu System;
- we may not be able to manufacture our Pure-Vu System in commercial quantities or at an acceptable cost;
- the uncertainties associated with establishing and qualifying a manufacturing facility;
- patients will not generally receive reimbursement from third-party payors for the use of our Pure-Vu System for colon cleansing, which may reduce widespread use of our Pure-Vu System;
- the introduction and market acceptance of competing products and technologies; and
- rapid technological change may make our Pure-Vu System obsolete.

Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we cannot assure you that we will be able to:

- successfully execute our current business plan for the commercialization of our Pure-Vu System, or that our business plan is sound;
- successfully contract for and establish a commercial supply of our product;
- achieve market acceptance of our Pure-Vu System; and
- attract and retain an experienced management and advisory team.

If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment will be adversely affected.

The Pure-Vu System may not be accepted by physicians and patients.

Our Pure-Vu System for use during colonoscopy screenings to clean the colon through irrigation and evacuation of bowel contents is a new technology and may be perceived as more invasive than current colonoscopy screening procedures, and patients may be unwilling to undergo the procedure. Moreover, patients may be unwilling to depart from the current standard of care. In addition, physicians tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products. Physicians may not recommend or prescribe our Pure-Vu System until there is long-term clinical evidence to convince them to alter their existing treatment methods, there are recommendations from prominent physicians that our Pure-Vu System is safe and efficient and reimbursement or insurance coverage is available. We cannot predict when, if ever, physicians and patients may adopt the use of our Pure-Vu System. If our Pure-Vu System does not achieve an adequate level of acceptance by patients, physicians and healthcare payors, we may not generate significant product revenue and we may not become profitable.

If we are not able to successfully commercialize our Pure-Vu System, the revenue that we generate from its sales, if any, may be limited.

The commercial success of our Pure-Vu System will depend upon its acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance of our Pure-Vu System will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience, burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe the Pure-Vu System and of the target patient population to try new procedures;

- efficacy of our Pure-Vu System compared to competing procedures;
- the introduction of any new products and procedures that may in the future become available for colonoscopy preparation may be approved;
- pricing and cost-effectiveness;
- the inclusion or omission of our Pure-Vu System in applicable treatment guidelines;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in FDA-approved labeling;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement.

If our Pure-Vu System does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our Pure-Vu System may require significant resources and may never be successful.

We currently have a limited sales and marketing organization. If we are unable to secure a sales and marketing partner and/or establish satisfactory sales and marketing capabilities, we may not successfully commercialize our Pure-Vu System.

At present, we have limited sales or marketing personnel. In order to commercialize devices that are approved for commercial sales, we must either collaborate with third parties that have such commercial infrastructure and/or continue to develop our own sales and marketing infrastructure. If we are not successful entering into appropriate collaboration arrangements, recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty successfully commercializing our Pure-Vu System, which would adversely affect our business, operating results and financial condition.

We may not be able to enter into collaboration agreements on terms acceptable to us or at all. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties. If we elect to establish a sales and marketing infrastructure we may not realize a positive return on this investment. In addition, we will have to compete with established and well-funded medical device companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize our Pure-Vu System without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to use our Pure-Vu System;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Our Pure-Vu System may cause adverse side effects that prevent its widespread adoption or that may necessitate its withdrawal from the market.

Our Pure-Vu System is currently believed to have the same side effects as a standard colonoscopy, such as inducing trauma to the colon's mucosa or, in rare cases, perforation of the colon. With more extensive use, the Pure-Vu System may be found to cause additional undesirable and unintended side effects or show a higher rate of side effects than a standard colonoscopy that may prevent or limit its commercial adoption and use. Even upon receiving clearance from the FDA and other regulatory authorities, our products may later exhibit adverse side effects that prevent widespread use or necessitate withdrawal from the market. The manifestation of such side effects could cause our business to suffer.

If we do not convince gastroenterologists that our products are attractive alternatives to the currently marketed medical devices and suitable for use in addressing bowel preparation or cleansing, we will not be commercially successful.

If we are not successful in convincing gastroenterologists of the merits of our products or educating them on the use of our products, they may not use our products and we will be unable to fully commercialize our products or reach profitability. Gastroenterologists may be hesitant to change their medical treatment practices for the following reasons, among others:

- lack of experience with our products and concerns regarding potential side effects;
- lack of clinical data currently available to support the safety and effectiveness of our products;
- lack or perceived lack of evidence supporting additional patient benefits;
- perceived liability risks generally associated with the use of new products and procedures; and
- the time commitment that may be required for training.

In addition, we believe recommendations and support of our products by influential gastroenterologists are important for market acceptance and adoption. If we do not receive support from such gastroenterologists or long term data does not show the benefits of using our products, gastroenterologists may not use our products. In such circumstances, we may not be able to grow our revenues or achieve profitability**.**

If we are unable to train gastroenterologists and their clinical staff on the safe and appropriate use of our products, we may be unable to achieve revenue growth or profitability.

An important part of our sales process includes the ability to train gastroenterologists and their clinical staff on the safe and appropriate use of our products. We have very limited experience in training and retaining qualified independent gastroenterologists to perform the colon cleansing procedure using our Pure-Vu System. If we are unable to attract gastroenterologists to our training programs, it may lead to a higher rate of injury, negative publicity and an increased risk of product liability, which would adversely affect our growth or profitability.

There is a learning process involved in gastroenterologists and their clinical staff becoming proficient in the use of our products. It is critical to the success of our commercialization efforts to train a sufficient number of gastroenterologists and to provide them with adequate instruction in the use of our Pure-Vu System. This training process may take longer than expected and may therefore affect our ability to increase sales. Following completion of training, we expect to rely on the trained gastroenterologists to advocate the benefits of our products in the broader marketplace. Convincing gastroenterologists to dedicate the time and energy necessary for adequate training is challenging, and we cannot assure you we will be successful in these efforts. If gastroenterologists and their clinical staff are not properly trained, they may misuse or ineffectively use our products. Such uses may result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us, any of which would have a material adverse effect on our business, results of operations and financial condition.

We may face competition from other medical device companies in the future and our operating results will suffer if we fail to compete effectively.

The medical device industries are intensely competitive and subject to rapidly evolving technology and intense research and development efforts. We have competitors in a number of jurisdictions that have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Established competitors may invest heavily to quickly discover and develop novel devices or procedures that could make our Pure-Vu System obsolete or uneconomical. Any new product that competes with a cleared medical device may need to demonstrate compelling advantages in efficacy, cost, convenience, tolerability and safety to be commercially successful. Other competitive factors could force us to lower prices or could result in reduced sales, including increased use of alternatives to colonoscopies such as capsule endoscopy systems, virtual colonoscopies using a CT scan, and other similar screening tests for colon cancer. While none of these testing alternatives may ever fully replace the colonoscopy, over time, they may take market share away from conventional colonoscopies for specific purposes and may lower the potential market opportunity for us. In addition, new devices developed by others could emerge as competitors to our Pure-Vu System. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

Our products face the risk of technological obsolescence, which, if realized, could have a material adverse effect on our business.

The medical device industry is characterized by rapid and significant technological change. There can be no assurance that third parties will not succeed in developing or marketing technologies and products that are more effective than ours or that would render our technology and products obsolete or noncompetitive. Additionally, new, less invasive surgical procedures and medications could be developed that replace or reduce the importance of current procedures that use or could use our products. Accordingly, our success will depend in part upon our ability to respond quickly to medical and technological changes through the development of new products. Product development involves a high degree of risk, and we cannot assure you that our new product development efforts will result in any commercially successful products.

If defects are discovered in our products, we may incur additional unforeseen costs, hospitals may not purchase our products and our reputation may suffer.

Our products incorporate mechanical parts, any of which can contain errors or failures, especially when first introduced. In addition, new products or enhancements may contain undetected errors or performance problems that, despite testing, are discovered only after commercial shipment. Because our products are designed to be used to perform medical procedures, we expect that our customers will have an increased sensitivity to such defects. We cannot provide any assurances that our products will not experience component aging, errors or performance problems in the future. If we experience flaws or performance problems, any of the following could occur:

- delays in product shipments;
- loss of revenue;
- delay in market acceptance;
- diversion of our resources;
- damage to our reputation;
- product recalls;
- regulatory actions;
- increased service or warranty costs; or
- product liability claims.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize our Pure-Vu System in foreign markets for which we intend to rely on collaborations with third parties. If we commercialize our Pure-Vu System in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our Pure-Vu System in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our Pure-Vu System could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs, any of which may adversely affect our results of operations.

We are, and will be, completely dependent on third parties to manufacture our Pure-Vu System, and our commercialization of our Pure-Vu System could be halted, delayed or made less profitable if those third parties fail to obtain or maintain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our Pure-Vu System device components or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture our Pure-Vu System, as well as the other related device components for high volume commercial purposes. We do have capability to produce limited units for use in our clinical trials, if required. As a result, we are obligated to rely on contract manufacturers for the commercial supply of our product. We currently rely on several manufacturing partners, however we anticipate engaging additional manufacturers for the production of the components of our Pure-Vu System as we expand our commercialization efforts.

The facilities used by our contract manufacturers to manufacture the Pure-Vu System must be compliant with FDA Quality System Regulation requirements and registered with the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with current Good Manufacturing Practices ("cGMPs") for manufacture of medical devices, as issued in the Quality System Regulation (21 CFR Part 820). These cGMPs regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to the Pure-Vu System. If our contract manufacturers cannot successfully manufacture products that conform to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our products or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to maintain regulatory approval for or market the Pure-Vu System.

Our contract manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to market the Pure-Vu System, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we will not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to maintain regulatory approval for or market our Pure-Vu System.

If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers, or any alternate manufacturers, experience any significant difficulties in their respective manufacturing processes for our product or should cease doing business with us, we could experience significant interruptions in supply or may not be able to create or maintain a commercial supply. Were we to encounter manufacturing issues, our ability to produce sufficient commercial supply might be negatively affected. Our inability to coordinate the efforts of our third party manufacturing partners or the lack of capacity available at our third party manufacturing partners, could impair our ability to supply our Pure-Vu System at required levels. If we face these or other difficulties with our manufacturing partners we could experience significant interruptions in the supply of our products if we decided to transfer the manufacture to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical components and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of our Pure-Vu System, increase our cost of goods sold and result in lost sales.

The manufacture of our Pure-Vu System, and the technology developed thereunder, is subject to certain Israeli government regulations which may impair our ability to outsource or transfer development or manufacturing activities with respect to any product or technology outside of Israel.

We have received, and may receive in the future, grants from the Government of the State of Israel through the IIA for the financing of a portion of our research and development expenditures pursuant to the IIA Regulations.

The terms of the IIA Regulations also require that products developed with IIA grants be manufactured in Israel at a rate (scope) which will not be less than the rate of manufacturing and added value in Israel that were included in the grant application submitted to the IIA. Furthermore, the IIA Regulations additionally require that the knowhow resulting from research and development according to an IIA-approved plan, not being the product developed within the framework of such approved plan, and any right deriving therefrom may not be transferred outside of Israel (including by way of certain licenses), unless prior approval is received from the IIA, which we intend to apply for but may not be granted. Even if such approval is granted, the transfer outside of Israel of manufacturing which is connected with the IIA-funded know-how may result in increased royalties (up to three times the aggregate amount of the IIA grants plus interest thereon), as well as in a higher royalty repayment rate. In addition, the transfer outside of Israel of IIA-funded know-how may trigger additional payments to the IIA (up to six times the aggregate amount of the IIA grants plus interest thereon). Even following the full repayment of any IIA grants, we must nevertheless continue to comply with the requirements of the IIA Regulations. The foregoing restrictions and requirements for payment may impair our ability to transfer or sell our technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any IIA-funded product or technology outside of Israel.

Furthermore, companies that receive IIA funding are required to ensure that all rights in the IIA-backed product are retained by them. This means that all knowhow which is derived from the research and development conducted pursuant to an IIA approved plan, and every right derived from it, must be owned by the recipient of the IIA funding from the date such knowhow is generated. Companies that receive IIA funding are further subject to reporting requirements and other technical requirements, which are intended to allow the IIA to ensure that the IIA Regulations are being complied with.

If we fail to comply with any of the conditions and restrictions imposed by the IIA Regulations, or by the specific terms under which we received the grants, we may be required to refund any grants previously received together with interest and penalties, and, in certain circumstances, may be subject to criminal charges.

For additional information, see "Part I—Item 1A—Risk Factors—Risks Related to Our Operations in Israel."

Risks Relating to Our Intellectual Property Rights

We may be unable to protect our intellectual property rights or may infringe on the intellectual property rights of others.

We rely on a combination of patents, trademarks, copyrights, trade secrets and nondisclosure agreements to protect our proprietary intellectual property. Our efforts to protect our intellectual property and proprietary rights may not be sufficient. We cannot be sure that our pending patent applications will result in the issuance of patents to us, that patents issued to or licensed by us in the past or in the future will not be challenged or circumvented by competitors or that these patents will remain valid or sufficiently broad to preclude our competitors from introducing technologies similar to those covered by our patents and patent applications. In addition, our ability to enforce and protect our intellectual property rights may be limited in certain countries outside the United States, which could make it easier for competitors to capture market position in such countries by utilizing technologies that are similar to those developed or licensed by us.

Competitors also may harm our sales by designing products that mirror the capabilities of our products or technology without infringing our intellectual property rights. If we do not obtain sufficient protection for our intellectual property, or if we are unable to effectively enforce our intellectual property rights, our competitiveness could be impaired, which would limit our growth and future revenue.

We may in the future be a party to patent litigation and administrative proceedings that could be costly and could interfere with our ability to sell our Pure-Vu System.

Litigation related to infringement and other intellectual property claims, with or without merit, is unpredictable, can be expensive and time consuming and can divert management's attention from our core business. If we lose this kind of litigation, a court could require us to pay substantial damages, and prohibit us from using technologies essential to our Pure-Vu System, any of which would have a material adverse effect on our business, results of operations and financial condition. If relevant patents are upheld as valid and enforceable and we are found to infringe, we could be prevented from selling our Pure-Vu System unless we can obtain a license to use technology or ideas covered by such patents or are able to redesign our Pure-Vu System to avoid infringement. We do not know whether any necessary licenses would be available to us on satisfactory terms, if at all, or whether we could redesign our Pure-Vu System or processes to avoid infringement.

Competing products may also appear in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, we could be prevented from marketing our Pure-Vu System in one or more foreign countries.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is commonplace in our industry, we employ and plan to employ individuals who were previously employed at other medical device companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non-competition or non-solicitation obligations) or claims that our employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

General Company-Related Risks

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2018, we had 44 full time employees. As our marketing and commercialization plans and strategies develop, we will need to expand the size of our employee and consultant base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize the Pure-Vu System and any other future product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage our future growth.

Our success will depend in part on our ability to manage our operations as we advance our product candidates through clinical trials and to expand our development or regulatory capabilities or contract with third parties to provide these capabilities for us. Failure to achieve any of these goals could have a material adverse effect on our business, financial condition or results of operations.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of certain key employees would adversely impact our business prospects.

We depend on key members of our management team. The loss of the services of Tim Moran, our Chief Executive Officer, Mark Pomeranz, our President and Chief Operating Officer, Andrew Taylor, our Chief Financial Officer or any member of our senior management team, could harm our ability to execute our commercial strategy for our Pure-Vu System and the strategic objectives for our company. We entered into employment agreements with our Chief Executive Officer, President and Chief Operating Officer, and Chief Financial Officer, but these agreements are terminable by the employees on short or no notice at any time without or with limited penalty. In addition, we do not maintain, and have no current intention of obtaining, "key man" life insurance on any member of our management team.

Recruiting and retaining qualified scientific and commercial personnel, including sales and marketing executives and field personnel, is also critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous medical device and pharmaceutical companies for similar personnel and based on our company profile. We also experience competition for the hiring of scientific personnel from universities and research institutions. If we fail to recruit and then retain these personnel, we may not be able to effectively execute our commercial strategy for the Pure-Vu System.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of the Pure-Vu System.

We are, and may be in the future, subject to product liability claims and lawsuits, including potential class actions, alleging that our products have resulted or could result in an unsafe condition or injury. Any product liability claim brought against us, with or without merit, could be costly to defend and could result in settlement payments and adjustments not covered by or in excess of insurance. In addition, we may not be able to obtain insurance on terms acceptable to us or at all because insurance varies in cost and can be difficult to obtain. Our failure to successfully defend against product liability claims or maintain adequate insurance coverage could have an adverse effect on our results of operations and financial condition.

Exchange rate fluctuations between the U.S. dollar and the Israeli New Shekel (the "NIS") and inflation may negatively affect our earnings and we may not be able to hedge our currency exchange risks successfully.

The U.S. dollar is our functional and reporting currency. However, a portion of our operating expenses, including personnel and facilities related expenses, are incurred in NIS. As a result, we are exposed to the risks that the NIS may appreciate relative to the U.S. dollar, or, if the NIS instead devalues relative to the U.S. dollar, that the inflation rate in Israel may exceed such rate of devaluation of the NIS, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected. Given our general lack of currency hedging arrangements to protect us from fluctuations in the exchange rates of the NIS and other foreign currencies in relation to the U.S. dollar (and/or from inflation of such foreign currencies), we may be exposed to material adverse effects from such movements. We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the NIS against the U.S. dollar.

We may acquire other businesses or form joint ventures or make investments in other companies or technologies that could negatively affect our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

We may pursue acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our intellectual property and industry experience to expand our offerings or distribution. We have no history of acquiring other companies or with forming strategic partnerships. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in the issuance of equity securities, incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a material adverse effect on our financial condition, results of operations, and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that we would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations and financial condition. We may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, or joint venture.

To finance any acquisitions or joint ventures, we may choose to issue shares of our Common Stock as consideration, which would dilute the ownership of our stockholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our Common Stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration.

Risks Related to our Capital Stock

Our officers, directors, and principal stockholders exercise significant control over our Company, and will control our company for the foreseeable future, including the outcome of matters requiring stockholder approval.

Our officers, directors, entities controlled by our officers and directors, and principal stockholders who beneficially own more than 5% of our Common Stock, in the aggregate, beneficially own shares representing approximately 62.72% of our outstanding capital stock as of March 1, 2019. As a result, such entities and individuals have the ability, acting together, to control the election of our directors and the outcome of corporate actions requiring stockholder approval, such as: (i) a merger or a sale of our company, (ii) a sale of all or substantially all of our assets, and (iii) amendments to our certificate of incorporation and bylaws. This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other stockholders and be disadvantageous to our stockholders with interests different from those entities and individuals. These individuals also have significant control over our business, policies and affairs as officers and directors of our company.

Our quarterly operating results may be subject to significant fluctuations.

To date, as part of our limited pilot launch in the U.S. market, we have generated limited revenue from our Pure-Vu System, but we do not expect to generate significant revenue from product sales unless and until we expand our commercialization efforts, which is subject to significant uncertainty, and accordingly we may experience significant fluctuations in our quarterly operating results in the future. The rate of market acceptance of our Pure-Vu System could contribute to this quarterly variability. Our limited operating history complicates our ability to project quarterly revenue and any future revenue generated from sales of our Pure-Vu System may fluctuate from time to time. In addition, our expense levels are based, in part, on expectation of future revenue levels. A shortfall in expected revenue, if any, could, therefore, result in a disproportionate decrease in our net income. As a result, our quarterly operating results may be subject to significant fluctuations.

An active trading market for our Common Stock may not be sustained.

Prior to the closing of our IPO on February 16, 2018, there had been no public market for our Common Stock. Although our Common Stock is listed on the NASDAQ Capital Market, the market for our shares has demonstrated varying levels of trading activity. Furthermore, the current level of trading may not be sustained in the future. The lack of an active market for our Common Stock may impair investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the fair market value of their shares and may impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration.

A sale of a substantial number of shares of our Common Stock in the public market could cause the market price of our Common Stock to drop significantly, even if our business is doing well.

Our stock price could decline as a result of sales of a large number of shares of our Common Stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

In addition, in the future, we may issue additional shares of Common Stock or other equity or debt securities convertible into Common Stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our Common Stock, the price of our Common Stock could decline.

The trading market for our Common Stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our Common Stock could decline if one or more equity analysts downgrade our Common Stock or if analysts issue other unfavorable commentary or cease publishing reports about us or our business.

Our share price may be volatile, which could subject us to securities class action litigation and our stockholders could incur substantial losses.

The market price for our Common Stock may be volatile and subject to wide fluctuations in response to factors including the following:

- actual or anticipated fluctuations in our quarterly or annual operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares; additions or departures of key management or other personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our Common Stock by us, our insiders or our other stockholders; and
- general economic, market or political conditions in the United States or elsewhere.

In particular, the market prices of early commercial-stage companies like ours have been highly volatile due to factors, including, but not limited to:

- any delay or failure to conduct a clinical trial for our product or receive approval from the FDA and other regulatory agents;
- developments or disputes concerning our product's intellectual property rights;
- our or our competitors' technological innovations;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies or patents;
- failure to complete significant transactions or collaborate with vendors in manufacturing our product; and
- proposals for legislation that would place restrictions on the price of medical therapies.

These and other market and industry factors may cause the market price and demand for our Common Stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of Common Stock and may otherwise negatively affect the liquidity of our Common Stock. In addition, the stock market in general, and NASDAQ Capital Markets and emerging growth companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

Pursuant to the terms of our outstanding Royalty Payment Rights Certificates and our outstanding Placement Agent Royalty Payment Rights Certificates, we may be obligated to pay significant royalties.

Pursuant to the terms of the Royalty Payment Rights Certificates (as defined in "Part III—Item 13—Certain Relationships and Related Transactions, and Director Independence— Royalty Payment Rights Certificates - Related Party Participation") which were issued in connection with the conversion of all of our outstanding shares of Series A Convertible Preferred Stock upon the consummation of our IPO, we may be required to make certain royalty payments. After we generate sales of the current and potential future versions of the Pure-Vu System, including disposables, parts, and services, in excess of $20 million since our inception, then we will be required to pay to the holders of our Royalty Payment Rights Certificates a royalty equal to (i) three percent (3%) of our net sales, if any, in any calendar year, not in excess of $30 million per year. Additionally, after we receive any proceeds from the licensing of the current and potential future versions of the Pure-Vu System in excess of $3.5 million since our inception, then we will be required to pay to the holders of the Royalty Payment Rights Certificates a royalty equal to 5% of our licensing proceeds, if any, in any calendar year, not in excess of $30 million per year. The royalties will be payable up to the later of (i) the latest expiration date for our current patents (which is currently November 2034), or (ii) the latest expiration date of any pending patents as of the date of the initial closing of the 2017 Private Placement that may be issued in the future.

Pursuant to the terms of our Placement Agent Royalty Payment Rights Certificates issued in connection with the 2017 Private Placement, we will be required to pay the holders of the Placement Agent Royalty Payment Rights Certificates, in the aggregate, 10% of the amount of payments paid to the holders of the Royalty Payment Rights Certificates.

We are an "emerging growth company," and will be able take advantage of reduced disclosure requirements applicable to "emerging growth companies," which could make our Common Stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act and, for as long as we continue to be an "emerging growth company," we intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an "emerging growth company" for up to five years from the date of our initial public offering in February 2018, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our Common Stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period.

We intend to take advantage of these reporting exemptions described above until we are no longer an "emerging growth company." Under the JOBS Act, "emerging growth companies" can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

We cannot predict if investors will find our Common Stock less attractive if we choose to rely on these exemptions. If some investors find our Common Stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

We will incur significantly increased costs and devote substantial management time as a result of operating as a public company particularly after we are no longer an "emerging growth company."

As a newly public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. For example, we are required to comply with certain of the requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as amended, as well as rules and regulations subsequently implemented by the SEC, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time consuming and costly. In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act. In addition, after we no longer qualify as an "emerging growth company," as defined under the JOBS ACT we expect to incur additional management time and cost to comply with the more stringent reporting requirements applicable to companies that are deemed accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. We have not yet completed the process of compiling the system and processing documentation needed to comply with such requirements. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. In that regard, we currently do not have an internal audit function, and we will need to hire or contract for additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs.

There may be limitations on the effectiveness of our internal controls, and a failure of our control systems to prevent error or fraud may materially harm our company.

Proper systems of internal controls over financial accounting and disclosure controls and procedures are critical to the operation of a public company. As we have a limited operating history, we only have 5 employees, and 5 contractors in our finance and accounting functions, which may result in a lack of segregation of duties and are at the very early stages of establishing, and we may be unable to effectively establish such systems, especially in light of the fact that we expect to operate as a publicly reporting company. This would leave us without the ability to reliably assimilate and compile financial information about our company and significantly impair our ability to prevent error and detect fraud, all of which would have a negative impact on our company from many perspectives.

Moreover, we do not expect that disclosure controls or internal control over financial reporting, even if established, will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Failure of our control systems to prevent error or fraud could materially adversely impact us.

We identified a material weakness in our internal control over financial reporting. If we are not able to remediate the material weakness and otherwise maintain an effective system of internal control over financial reporting, the reliability of our financial reporting, investor confidence in us and the value of our Common Stock could be adversely affected.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. A material weakness is defined as a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

In connection with the review of our third quarter 2018 financial statements and the audit of our annual consolidated financial statements, we identified a material weakness in our internal control over financial reporting related to the accounting for non-routine complex transactions. Management did not appropriately identify the proper accounting treatment related to contingent payments and stock awards owed to a non-employee. Management has begun remediation by engaging a third party firm with technical accounting specialists to review the accounting for non-routine complex transactions on a prospective basis.

In light of the material weakness, we performed additional analyses and other post-closing procedures to ensure our consolidated financial statements are prepared in accordance with U.S. GAAP. Accordingly, our CEO and CFO have certified that, based on their knowledge, the consolidated financial statements, and other financial information included in this Form 10-K, fairly present in all material respects our financial condition, results of operations and cash flows as of, and for, the periods presented in this Form 10-K.

If our steps are insufficient to successfully remediate the material weakness and otherwise establish and maintain an effective system of internal control over financial reporting, the reliability of our financial reporting, investor confidence in us and the value of our Common Stock could be materially and adversely affected. Effective internal control over financial reporting is necessary for us to provide reliable and timely financial reports and, together with adequate disclosure controls and procedures, are designed to reasonably detect and prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations.

We may have additional material weaknesses in our internal control over financial reporting. In addition, because of our status as an emerging growth company, our independent registered public accountants are not required to provide an attestation report as to our internal control over financial reporting for the foreseeable future.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting, as well as, if applicable, a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting.

We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective.

If we are unable to assert that our internal control over financial reporting is effective, or, if applicable, our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our Common Stock to decline, and we may be subject to investigation or sanctions by the SEC. We will also be required to disclose changes made in our internal control and procedures on a quarterly basis.

However, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the date we are no longer an “emerging growth company” as defined in the JOBS Act, if we take advantage (as we expect to do) of the exemptions contained in the JOBS Act. We will remain an “emerging growth company” for up to five years from the date of our initial public offering in February 2018, although if the market value of our Common Stock that is held by non-affiliates exceeds $700 million as of any June 30th before that time, we would cease to be an “emerging growth company” as of the following December 31st. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in our internal control over financial reporting in the future.

Any of the foregoing occurrences, should they come to pass, could negatively impact the public perception of our company, which could have a negative impact on our stock price.

We do not currently intend to pay dividends on our Common Stock in the foreseeable future, and consequently, any gains from an investment in our Common Stock will likely depend on appreciation in the price of our Common Stock.

We have never declared or paid cash dividends on our Common Stock and do not anticipate paying any cash dividends to holders of our Common Stock in the foreseeable future. Consequently, investors must rely on sales of their Common Stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that shares of our Common Stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

Upon dissolution of our company, our stockholders may not recoup all or any portion of their investment.

In the event of a liquidation, dissolution or winding-up of our company, whether voluntary or involuntary, the proceeds and/or assets of our company remaining after giving effect to such transaction, and the payment of all of our debts and liabilities and distributions required to be made to holders of any outstanding preferred stock will then be distributed to the stockholders of our Common Stock on a pro rata basis. There can be no assurance that we will have available assets to pay to the holders of our Common Stock, or any amounts, upon such a liquidation, dissolution or winding-up of our company.

Our certificate of incorporation, as amended, allows for our board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our Common Stock.

Our board of directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our board of directors has the authority to issue up to 10 million shares of our preferred stock without further stockholder approval. As a result, our board of directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation and the right to receive dividend payments before dividends are distributed to the holders of our Common Stock. In addition, our board of directors could authorize the issuance of a series of preferred stock that has greater voting power than our Common Stock or that is convertible into our Common Stock, which could decrease the relative voting power of our Common Stock or result in dilution to our existing stockholders.

Our certificate of incorporation, as amended, designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against us, and our directors and officers.

Our certificate of incorporation, as amended, provides that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty; (iii) any action asserting a claim against us, or any of our officers or directors, arising pursuant to, or a claim against us, or any of our officers or directors, with respect to the interpretation or application of any provision of the Delaware General Corporation Law, our certificate of incorporation, as amended, or our bylaws; or (iv) any action asserting a claim governed by the internal affairs doctrine. However, if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, the action may be brought in another state court sitting in the State of Delaware.

Risks Related to Our Operations in Israel

Our research and development facilities and some of our suppliers are located in Israel and, therefore, our business, financial condition and results of operation may be adversely affected by political, economic and military instability in Israel.

Our research and development facilities are located in northern Israel. In addition, most of our employees are residents of Israel. Accordingly, political, economic and military conditions in Israel may directly affect our business. Since the State of Israel was established in 1948, the State of Israel and its economy has experienced significant growth and expansion, coupled with an increase in the standard of living, and has developed one of the most advanced high-tech industries in the world. However, it continues to face many geo-political and other challenges that may affect companies located in Israel, such as ours. For example, a number of armed conflicts have occurred between Israel and its Arab neighbors. Although Israel has entered into various peace agreements with Egypt and Jordan as well as comprehensive agreements with the Palestinian Authority, there continues to be unrest and terrorist activity in Israel with varying levels of severity, as well as ongoing hostilities and armed conflicts between Israel and the Palestinian Authority and other groups in the West Bank and Gaza Strip, recent unrest was due to the United States' relocation of its embassy from Tel Aviv to Jerusalem. The effects of these hostilities and violence on the Israeli economy and our operations are unclear, and we cannot predict the effect on us of a further increase in these hostilities or any future armed conflict, political instability or violence in the region. We could be harmed by any major hostilities involving Israel, the interruption or curtailment of trade between Israel and its trading partners, boycotts or a significant downturn in the economic or financial condition of Israel. The impact of Israel's relations with its Arab neighbors in general, or on our operations in the region in particular, remains uncertain. The establishment of new fundamentalist Islamic regimes or governments more hostile to Israel could have serious consequences for the stability in the region, place additional political, economic and military confines upon Israel, materially adversely affect our operations and limit our ability to sell our products to countries in the region.

Additionally, several countries, principally in the Middle East, still restrict doing business with Israel and Israeli companies, and additional countries and groups have imposed or may impose restrictions on doing business with Israel and Israeli companies if hostilities in Israel or political instability in the region continues or increases. These restrictions may limit our ability to sell our products to companies in these countries. Furthermore, the Boycott, Divestment and Sanctions Movement, a global campaign attempting to increase economic and political pressure on Israel to comply with the stated goals of the movement, may gain increased traction and result in a boycott of Israeli products and services. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or significant downturn in the economic or financial condition of Israel, could adversely affect our business, results of operations and financial condition.

Our commercial insurance policy does not cover losses associated with armed conflicts and terrorist attacks. Although the Israeli government in the past covered the reinstatement value of certain damages that were caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained, or if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business.

Our operations could also be disrupted by the obligations of personnel to perform military service. Some of our employees in Israel may be called upon to perform up to 54 days in each three year period (and in the case of military officers, up to 84 days in each three year period) of military reserve duty until they reach the age of 40 (and in some cases, depending on their specific military profession up to 45 or even 49 years of age) and, in certain emergency circumstances, may be called to immediate and unlimited active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists and it is possible that there will be similar large-scale military reserve duty call-ups in the future. Our operations could be disrupted by the absence of a significant number of employees related to military service, which could materially adversely affect our business and results of operations.

Pursuant to the terms of the Israeli government grants we received for research and development expenditures, we are obligated to pay certain royalties on our revenues to the Israeli government. The terms of the grants require us to satisfy specified conditions and to make additional payments in addition to repayment of the grants upon certain events.

We have received, and may receive in the future, grants from the IIA for the financing of a portion of our research and development expenditures pursuant to the IIA Regulations.

As of December 31, 2018, we had received grants from the IIA in the aggregate amount of $1.332 million, and had a contingent obligation to the IIA up to an aggregate amount of approximately $1.383 million (assuming no increase, per the IIA Regulations, as described below). As of December 31, 2018, we paid a minimal amount to the IIA. We may apply for additional IIA grants in the future. However, as the funds available for IIA grants out of the annual budget of the State of Israel are subject to the pre-approval of the IIA and have been reduced in the past and may be further reduced in the future, we cannot predict whether we will be entitled to – or approved for – any future grants, or the amounts of any such grants (if approved).

In exchange for these grants, we are required to pay royalties to the IIA of 3% to 3.5% (which may be increased under certain circumstances) from our revenues generated (in any fashion) from knowhow developed using IIA grants, up to an aggregate of 100% of all such grants (which may be increased under certain circumstances) of the U.S. dollar-linked value of the grant, plus interest at the rate of 12-month LIBOR.

The IIA Regulations also require that certain amounts of products developed with IIA grants be manufactured in Israel and that certain technology developed thereunder may not be transferred outside of Israel (including by way of certain licenses), unless prior approval is received from the IIA, which we intend to apply for but may not be granted. Even if such approval is granted, the transfer outside of Israel of manufacturing which is connected with the IIA-funded know-how may result in increased royalties (up to three times the aggregate amount of the IIA grants plus interest thereon), as well as in a higher royalty repayment rate. In addition, the transfer outside of Israel of IIA-funded know-how may trigger additional payments to the IIA (up to six times the aggregate amount of the IIA grants plus interest thereon). Even following the full repayment of any IIA grants, we must nevertheless continue to comply with the requirements of the IIA Regulations. The foregoing restrictions and requirements for payment may impair our ability to transfer or sell our technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any IIA-funded know-how outside of Israel.

Furthermore, companies that receive IIA funding are required to ensure that all rights in the IIA-backed product are retained by them. This means that all know-how which is derived from the research and development conducted pursuant to an IIA approved plan, and every right derived from it, must be owned by the recipient of the IIA funding from the date such know-how is generated. Companies that receive IIA funding are further subject to reporting requirements and other technical requirements, which are intended to allow the IIA to ensure that the IIA Regulations are being complied with.

If we fail to comply with any of the conditions and restrictions imposed by the IIA Regulations, or by the specific terms under which we received the grants, we may be required to refund any grants previously received together with interest and penalties, and, in certain circumstances, may be subject to criminal charges.

It may be difficult to enforce a judgment of a U.S. court against us in Israel or the United States to assert U.S. securities laws claims in Israel or to serve process on these experts.

Motus GI Medical Technologies Ltd., our wholly owned subsidiary, is incorporated in Israel. Our Israeli experts reside in Israel, and substantially all of our technology and intellectual property assets are located in Israel. Therefore, a judgment obtained against us, or any of such persons may not be collectible in the United States and may not be enforced by an Israeli court. It also may be difficult for you to effect service of process on such persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws on the grounds that Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proven as a fact by expert witnesses, which can be a time consuming and costly process. Certain matters of procedure would also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above. As a result of the difficulty associated with enforcing a judgment against us in Israel, you may not be able to collect any damages awarded by either a U.S. or foreign court.

We may become subject to claims for payment of compensation for assigned service inventions by our current or former employees, which could result in litigation and adversely affect our business.

Under the Israeli Patents Law, 5727-1967, or the Patents Law, inventions conceived by an employee during the scope of his or her employment are regarded as "service inventions" and are owned by the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Patents Law also provides that if no such agreement between an employer and an employee exists, which prescribes whether, to what extent, and on what conditions the employee is entitled to remuneration for his or her service inventions, then such matters may, upon application by the employee, be decided by a government-appointed compensation and royalties committee established under the Patents Law. A significant portion of our intellectual property has been developed by our employees in Israel in the course of their employment. Such employees have agreed to waive and assign to us all rights to any intellectual property created in the scope of their employment with us, and most of our current employees, including all those involved in the development of our intellectual property, have agreed to waive economic rights they may have with respect to service inventions.

However, despite such contractual obligations, we cannot assure you that claims will not be brought against us by current or former employees demanding remuneration in consideration for assigned alleged service inventions or any other intellectual property rights. If any such claims were filed, we could potentially be required to pay remuneration to our current or former employees for such assigned service inventions or any other intellectual property rights, or be forced to litigate such claims, which could negatively affect our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We currently rent 7,836 square feet of space in Tirat Carmel, Israel. This facility is used for office space as well as laboratories for product development. We entered the lease on January 1, 2015, and the lease is for a period of five-years. Annual rent is $82 thousand per year.

On April 13, 2017, we entered into a lease for a facility in Fort Lauderdale, Florida, which we began occupying in October 2017. On December 20, 2017, we entered into a lease amendment upon remeasurement of the lease space. The facility currently consists of 4,554 square feet, which will increase to 6,496 square feet by the second year of the lease. The term will run for seven years and two months from September 2017. Annual base rent was amended to $159 thousand per year, subject to annual increases of 2.75%. This facility will be used for office space as well as laboratories for both quality assurance and product development.

We believe our facilities are adequate for our foreseeable needs.

ITEM 3. LEGAL PROCEEDINGS

We are not currently subject to any material legal proceedings; however, we may from time to time become a party to various legal proceedings arising in the ordinary course of our business. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this report, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our Common Stock trades on the NASDAQ Capital Market under the symbol "MOTS". Trading of our Common Stock commenced on February 14, 2018 in connection with our IPO. Prior to that time, there was no established public trading market for our Common Stock.

Holders of Record

As of March 21, 2019, we had approximately 164 holders of record of our Common Stock. This number does not include beneficial owners whose shares were held in street name. The actual number of holders of our Common Stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees.

Use of Proceeds from Registered Securities

On February 13, 2018, our registration statement on Form S-1 (Registration No. 333-222441) was declared effective by the SEC for our IPO pursuant to which we sold an aggregate of 3,500,000 shares of our Common Stock at a price to the public of $5.00 per share, for an aggregate offering of approximately $17.5 million. Piper Jaffray & Co. acted as the sole book-running manager and Oppenheimer& Co. acted as lead manager for the offering. On February 16, 2018, we closed the sale of 3,500,000 shares, resulting in net proceeds to us of $15 million after deducting underwriting discounts and commissions and other offering expenses. On March 12, 2018 we closed the sale of an additional 56,000 shares pursuant to the Partial IPO Over-Allotment Exercise, resulting in net proceeds to us of approximately $258,000 after deducting underwriting discounts and commissions. No payments were made by us to directors, officers or persons owning ten percent or more of our Common Stock or to their associates, or to our affiliates. There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on February 15, 2018 pursuant to Rule 424(b).

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION.

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and the related notes and the other financial information included elsewhere in this report. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this report, particularly those under "Risk Factors."

Overview

We have developed the Pure-Vu System, a medical device that has received 510(k) clearance from the FDA and CE mark approval in the European Economic Area. The Pure-Vu System is 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 by irrigating the colon and evacuating the irrigation fluid (water), feces and other bodily fluids and matter. 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 for a hospital in a market segment where most of the reimbursement is under a bundle payment based on a DRG, comprising of approximately 1.5 million annual inpatient colonoscopy procedures in the U.S. and approximately 3.8 million annual inpatient colonoscopy procedures worldwide. The Pure-Vu System does not currently have a unique reimbursement code with any private or governmental third-party payors in any country. To date, as part of our limited pilot launch in the U.S. market, we have focused on collecting additional clinical and health economic data, as exemplified by the recently initiated REDUCE Study, along with garnering valuable experience in key hospitals on the use of the Pure-Vu System to support a planned full launch of the Pure-Vu System in the United States inpatient colonoscopy market in 2019. We do not expect to generate significant revenue from product sales unless and until we expand our commercialization efforts.

Financial Operations Overview

We are a development stage company and have not generated any significant revenues from the sale of products. We have never been profitable and our accumulated deficit as of December 31, 2018 was approximately $61.4 million. Our net loss for the years ended December 31, 2018 and 2017 was approximately $22.3 million and $13.2 million, respectively. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase significantly in connection with our ongoing activities to commercialize and market the Pure-Vu System. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need additional financing to support our continuing operations. We will seek to fund our operations through public or private equity or debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- Initiate our planned full launch of the Pure-Vu System in the United States inpatient colonoscopy market in 2019;
- contract with third parties to scale up the manufacture of the workstation and the disposable portion of Pure-Vu System;
- develop a second generation system to improve user interface, optimize ease of use and reduce the cost structure;
- raise sufficient funds in the capital market to effectuate our business plan, including commercialization activities related to our Pure-Vu System and our research and development activities, including clinical and regulatory development and the continued development and enhancement of our Pure-Vu System; and
- operate as a public company.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

On an ongoing basis, we evaluate our estimates and judgments for all assets and liabilities, including those related to fair value calculations for equity securities, assessing contingent liabilities, establishing valuation allowances for deferred taxes, and the recovery of deferred costs. We base our estimates and judgments on historical experience, current economic and industry conditions and on various other factors that are believed to be reasonable under the circumstances. This forms the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that full consideration has been given to all relevant circumstances that we may be subject to, and the consolidated financial statements accurately reflect our best estimate of the results of operations, financial position and cash flows for the periods presented.

Revenue

To date, as part of our limited launch, we have generated limited revenue from the sales of products. We do not expect to generate significant revenue from product sales unless and until we expand our commercialization efforts for the Pure-Vu System, which is subject to significant uncertainty.

Research and Development

We incurred expenses of approximately $6.0 million and $4.3 million, respectively, during the years ended December 31, 2018 and 2017 for research and development activities. These expenses include cash and non-cash expenses relating to the advancement of our development and clinical programs for the Pure-Vu System. We have research and development capabilities in electrical and mechanical engineering with laboratories in our facility in Israel for development and prototyping, and electronics design and testing. We also use consultants and third-party design houses to complement our internal capabilities.

Sales and Marketing

We incurred expenses of approximately $4.3 million and $2.4 million, respectively, during the years ended December 31, 2018 and 2017 for sales and marketing activities. These expenses include cash and non-cash expenses relating to the development of our sales and marketing infrastructure for the Pure-Vu System. We have hired limited sales and marketing personnel in the U.S. as part of our limited pilot launch in the U.S. market to develop our policies and procedures, as well as to spearhead the pilot phase of our market penetration.

General and Administrative Expenses

We incurred expenses of approximately $8.5 million and $6.3 million, respectively, during the years ended December 31, 2018 and 2017 for general and administrative activities. General and administrative expenses consist primarily of payroll and professional services, which include accounting, legal services, investor relations services, and expenses associated with obtaining and maintaining patents. We anticipate that our general and administrative expenses will increase significantly during 2019 and in the future as we increase our headcount and other activities to support continued development and commercialization of our Pure-Vu System. We also anticipate increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations and communication costs associated with being a public company. Additionally, commencing in 2017, we began to compensate our outside directors.

Stock-Based Compensation

Stock options are granted with an exercise price at no less than fair market value at the date of the grant. The stock options normally expire ten years from the date of grant. Stock option awards vest upon terms determined by our board of directors.

We recognize compensation costs resulting from the issuance of stock-based awards to employees, members of our Board of directors and non-employees. The fair value of each option or warrant grant was estimated as of the date of grant or reporting period using the Black-Scholes option-pricing model or other appropriate option pricing model. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. Due to our limited operating history and limited volume of sales of our Common Stock, we estimated our volatility in consideration of a number of factors, including the volatility of comparable public companies. The expected term of options granted to employees under our stock plans is based on the average of the contractual term (generally 10 years) and the vesting period (generally 36 months). The expected term of options granted under the 2016 Plan, all of which qualify as “plain vanilla” per SEC Staff Accounting Bulletin 107, is based on the average of the 5.8 years. For non-employee awards, the expected term is the contractual term and awards granted to non-employees are revalued at the end of each reporting period until vested and changes in their fair value are recorded as adjustments to expense over the related vesting period. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the expected term of the award. We have never paid dividends on our Common Stock and do not anticipate paying dividends on our Common Stock in the foreseeable future. Accordingly, we have assumed no dividend yield for purposes of estimating the fair value of our share-based compensation.

The following weighted-average assumptions were used to estimate the fair value of stock options granted during the year ended December 31, 2018 using the Black-Scholes option pricing model:

Fair value of Common Stock	$	4.16
Expected volatility		68.72%
Dividend yield		0%
Risk-free interest		3.01%
Expected life of up to (years)		5.8

Emerging Growth Company Status

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Results of Operations

Comparison of Year Ended December 31, 2018 and 2017

To date, as part of our limited launch, we have generated limited revenue from the sales of products. We do not expect to generate significant revenue from product sales unless and until we expand our commercialization efforts for the Pure-Vu System, which is subject to significant uncertainty.

Research and Development

Research and development expenses for the year ended December 31, 2018 totaled approximately $6.0 million, an increase of $1.7 million over the $4.3 million recorded for the year ended December 31, 2017. The increase in fiscal year 2018 compared to fiscal year 2017 was primarily attributable to increases of $1.0 million in salaries and wages, $0.8 million in professional and subcontractor fees, and $0.3 million in travel related cost, partially offset by a decrease in clinical study cost of $0.4 million.

Sales and Marketing

Sales and marketing expenses for the year ended December 31, 2018 totaled approximately $4.3 million, an increase of $1.9 million over the $2.4 million recorded for the year ended December 31, 2017. The increase in fiscal year 2018 compared to fiscal year 2017 was primarily attributable to increases of $0.2 million in salaries and wages, $0.7 million in marketing and training product units, $0.1 million in tradeshow and promotional items, $0.6 million in subcontractor costs, $0.1 million in recruitment services, $0.1 million in travel costs and $0.1 million in other costs.

General and Administrative

General and administrative expenses for the year ended December 31, 2018 totaled approximately $8.5 million, an increase of $2.2 million over the $6.3 million recorded for the year ended December 31, 2017. The increase in fiscal year 2018 compared to fiscal year 2017 was primarily attributable to increases of $0.3 million in legal and professional fees, $0.2 million in stock-based compensation, $0.6 million in salaries and wages, $0.5 million in public relations and investor communications fees, $0.3 million in office expenses and $0.3 million in insurance expense.

Other Expenses

Other expenses were $3.3 million and $0.2 million for the years ended December 31, 2018 and 2017, respectively. The $3.1 million increase was primarily attributable to an increase of $3.2 million in warrant expense, partially offset by a $0.1 million increase in finance income.

Liquidity and Capital Resources

Since inception, we have experienced negative cash flows from operations. We have financed our operations primarily through sales of equity-related securities. At December 31, 2018, our accumulated deficit since inception was approximately $61.4 million.

At December 31, 2018, we had total current assets of approximately $22.1 million and current liabilities of approximately $2.4 million resulting in working capital of $19.7 million. Net cash used in operating activities for the year ended December 31, 2018 was approximately $14.9 million, which includes a net loss of approximately $22.3 million, offset by non-cash expenses of approximately $6.8 million principally related to warrant expense of $3.2 million, stock-based compensation expense of $2.5 million, loss on change in estimated fair value of contingent royalty obligation of $0.3 million, write-down of workstations related to evaluation agreements of $0.4 million, and depreciation and amortization of approximately $0.2 million and approximately $0.5 million of cash provided from a change in net working capital items principally related to the increase in accounts payable and accrued expenses of $0.7 million, increase in other current and non-current liabilities of $0.1 million, and decrease in prepaid expense and other current assets of $0.1 million, partially offset by the increase in inventory of $0.4 million.

Cash used in investing activities for year ended December 31, 2018 totaled approximately $3.5 million for the purchase of available-for-sale securities of approximately $5.0 million, the purchase of held-to-maturity securities of approximately $4.9 million, and the purchase of fixed assets of approximately $0.5 million, offset by the proceeds from the sale of available-for-sale securities of approximately $2.0 million, the proceeds from the maturity of held-to-maturity securities of $4.8 million, and the proceeds from shareholder loan of approximately $0.1 million.

Cash provided by financing activities for the year ended December 31, 2018 totaled approximately $29.5 million which included proceeds from public offerings of $31.0 million and proceeds from the exercise of overallotment options of $2.3 million, offset by deferred financing fees of $3.8 million. In February and March of 2018, we sold 3,556,000 shares of our Common Stock in our IPO, inclusive of 56,000 shares issued pursuant to the partial exercise of the underwriters option to purchase additional shares, which resulted in proceeds to us totaling approximately $17.8 million. In December 2018, we sold 5,750,000 shares of our Common Stock in our Follow On Offering, inclusive of 750,000 shares issued pursuant to the full exercise of the underwriters option to purchase additional shares, which resulted in gross proceeds to us totaling approximately $15.5 million.

At December 31, 2018, we had cash and cash equivalents, and short-term investments of approximately $21.1 million. Based on our current business plan, we believe our cash and cash equivalents, and short-term investments balance as of December 31, 2018 will be sufficient to meet our anticipated cash requirements through the fourth quarter of 2019.

We will need to raise significant additional capital to continue to fund operations. We may seek to sell common or preferred equity, convertible debt securities or seek other debt financing. In addition, we may seek to raise cash through collaborative agreements or from government grants. The sale of equity and convertible debt securities may result in dilution to our stockholders and those securities may have rights senior to those of our common shares. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third-party funding arrangement could require us to relinquish valuable rights.

Our independent registered public accounting firm included an explanatory paragraph about the existence of substantial doubt concerning our ability to continue as a going concern in its report on our financial statements as of and for the year ended December 31, 2018. Note 2 to our financial statements includes management's discussion on the continuation of our activities and our ability to fulfill our obligations are dependent upon our ability to raise additional financing and/or increase sales volume that will generate sufficient operating profit and cash flows to fund operations.

The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our product development, clinical and commercial activities. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate expenses.

Contractual Obligations and Commitments

Operating Leases

On January 1, 2015, we entered into a five year lease for a facility with 7,836 square feet of space in Tirat Carmel, Israel. Annual rent is $82 thousand per year.

On April 13, 2017, we entered into a lease for a facility in Fort Lauderdale, Florida, which we began occupying in October 2017. On December 20, 2017, we entered into a lease amendment upon remeasurement of the lease space. The facility currently consists of 4,554 square feet, which will increase to 6,496 square feet by the second year of the lease. The term will run for seven years and two months from September 2017. Annual base rent was amended to $159 thousand per year, subject to annual increases of 2.75%.

Other Commitments

For further information, refer to Note 7 of the Notes to the Consolidated Financial Statements included in Pages F-1 through F-28 of this Annual Report of Form 10-K

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See pages F-1 through F-28 following the signature page of this Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. As a result of the material weakness in our internal control over financial reporting described below, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of December 31, 2018.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the framework in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

In connection with the review of our third quarter 2018 financial statements and the audit of our annual consolidated financial statements, we identified a material weakness in our internal control over financial reporting related to the accounting for non-routine complex transactions. Management did not appropriately identify the proper accounting treatment related to contingent payments and stock awards owed to a non-employee. A material weakness is defined as a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected and corrected on a timely basis. The material weakness did not result in any identified misstatements to the financial statements, and there were no changes to previously released financial results. In light of the material weakness, we performed additional analyses and other post-closing procedures to ensure our consolidated financial statements are prepared in accordance with U.S. GAAP. Accordingly, our CEO and CFO have certified that, based on their knowledge, the consolidated financial statements, and other financial information included in this Form 10-K, fairly present in all material respects our financial condition, results of operations and cash flows as of, and for, the periods presented in this Form 10-K.

Because of this material weakness, management concluded that we did not maintain effective internal control over financial reporting as of December 31, 2018.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

This Annual Report does not include an attestation report of our independent registered public accounting firm because we are an "emerging growth company," and may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act.

Remediation Efforts to Address Material Weakness

We began remediation efforts in the fourth quarter of 2018 for our accounting of non-routine complex transactions control by engaging a new third-party firm with technical accounting expertise to review non-routine complex transactions on a prospective basis. We, in consultation with our Audit Committee, continue to evaluate our internal and external technical accounting resources to ensure they are appropriate for us and our needs. We have further evaluated our remediation activities to date, and in addition to utilizing multiple third-party specialists, we have implemented a remediation test plan with our third-party internal audit firm. Additionally, there is a renewed emphasis on our process going forward for initial identification of potential contracts and transactions that may be non-routine and complex during a reporting period, and then conducting the necessary procedures with the full internal accounting team and external consultants to review and research the proper guidance and approach toward the accounting, and documenting as such in a white paper or memo as needed.

We believe these measures, and others that may be implemented, will remediate the material weakness in internal control over financial reporting described above.

The material weakness will not be considered formally remediated until the control has operated effectively for a sufficient period of time and management has concluded, through testing, that the control is operating effectively. We expect this to occur prior to the end of fiscal 2019.

Changes in Internal Control over Financial Reporting

Other than the changes intended to remediate the material weakness noted above, there was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following sets forth certain information with respect to our officers and directors.

Name	Age	Position(s)
Timothy P. Moran	47	Chief Executive Officer and Director
Mark Pomeranz	57	President, Chief Operating Officer and Director
Andrew Taylor	48	Chief Financial Officer
David Hochman	43	Chairman of the Board
Darren Sherman	47	Director
Gary Jacobs	61	Director
Samuel Nussbaum	70	Director
Shervin Korangy	44	Director
Gary J. Pruden	57	Director

Management

Timothy P. Moran, Chief Executive Officer and Director

Mr. Moran has served as Chief Executive Officer since October 1, 2018. Prior to joining us, from 2015 to September 2018, Mr. Moran served as President of the Americas, ConvaTec Group Plc (LON: CTEC) ("ConvaTec"), an international medical products and technologies company, offering products and services in the areas of wound and skin care, ostomy care, continence and critical care and infusion devices. Prior to his employment at ConvaTec, Mr. Moran held roles in sales, marketing and general management over the course of eighteen years at Covidien plc ("Covidien"), an Irish-headquartered global health care products company and manufacturer of medical devices and supplies. While at Covidien, until 2015, Mr. Moran served simultaneously as VP and General Manager of both the SharpSafety and Monitoring & Operating Room divisions. Following the 2015 acquisition of Covidien by Medtronic (NYSE:MDT), Mr. Moran was named the Global Vice President and General Manager of the Patient Care and Safety Division. Mr. Moran also served on the CEO Advisory Council for Advanced Medical Technology Association (AdvaMed), a medical device trade association. Mr. Moran earned a B.A. in Organizational Communication at The State University of New York at Geneseo. Mr. Moran was selected as a director because of his broad commercial experience and leadership in the medical technology sector.

Mark Pomeranz, President, Chief Operating Officer and Director

Mr. Pomeranz has served as Chief Operating Officer since September 24, 2018. Prior to his tenure as our Chief Operating Officer, Mr. Pomeranz served as our Chief Executive Officer from December 2016 through September 2018, and as the Chief Executive Officer of Motus GI Medical Technologies Ltd., our wholly owned subsidiary, from 2014 through September 2018. Prior to joining Motus GI Medical Technologies Ltd., from 2008 to 2014, Mr. Pomeranz was the founding CEO of Svelte Medical Systems, a start-up company that is currently commercializing a unique drug eluting stent platform in the EU. From 2007 to 2008 Mr. Pomeranz was the Vice President of Research and Development at Prescient Medical, Inc. From 1998 to 2007, Mr. Pomeranz served as Vice President at Cordis, a Johnson & Johnson Company, where his responsibilities included developing new technologies, exploring new market opportunities and leading major restructuring efforts to create cross-functional global commercialization teams. Prior to that, Mr. Pomeranz held a number of senior leadership roles, including positions at Cardiac Pathways Corporations from 1991 to 1998, and Cardiovascular Imaging Systems from 1989 to 1991, both of which were acquired by Boston Scientific Corporation. Mr. Pomeranz earned a M.Sc. in biomedical engineering from the University of Miami. Mr. Pomeranz was selected as a director due to his history as a director of Motus GI Medical Technologies Ltd. and his business and leadership experience in the medical technology sector; his broad scientific background is also seen as an asset to us.

Andrew Taylor, Chief Financial Officer

Mr. Taylor has served as our Chief Financial Officer since August 2017. Prior to joining us, Mr. Taylor served as the CFO and President of Angel Medical Systems from 2007 until 2017. Angel Medical Systems is a medical device company that develops and manufactures ischemia monitoring and alerting systems. While at Angel Medical Systems, Mr. Taylor supervised the operations of more than fifty (50) employees in the United States and Brazil, while also overseeing the financial planning and analysis activities, capital raise efforts, and implementation of capital and operating budgets. From 2005 to 2007, Mr. Taylor was a Practice Leader for AC Lordi Consulting, where he oversaw staff providing CFO and Controller consulting services. Prior to that, Mr. Taylor was the CFO of Safe3w, Inc. from 2001 to 2005 until its acquisition by iPass, Inc. (NASDAQ: IPAS), where he led all accounting and finance functions as well as the fundraising efforts, and negotiated the sale of the company. From 1999 to 2001, Mr. Taylor served as the Vice President of Finance and Administration of Abridge, Inc., where he developed and managed processes for budgeting, forecasting and cash management. Prior to that, Mr. Taylor was a Senior Finance Associate at Delta Air Lines (NYSE: DAL), from 1998 to 1999. Mr. Taylor is a CFA Program Level II Candidate and earned a B.A. in Political Science and Economics at McGill University and his MBA in Finance at Northeastern University.

Directors

Timothy P. Moran, Chief Executive Officer and Director

See description under Management.

Mark Pomeranz, President, Chief Operating Officer and Director

See description under Management.

David P. Hochman, Chairman of the Board

Mr. Hochman has served as our Chairman of the Board since 2016, and as Chairman of the Board of Motus GI Medical Technologies Ltd., our wholly owned subsidiary, since 2011. Since May 2018, he has been Chairman and Chief Executive Officer of Orchestra BioMed, Inc., a biomedical innovation company focused on developing high impact therapeutic solutions to address significant unmet needs. Since 2006, he has been Managing Partner of Orchestra Medical Ventures, LLC, an investment firm that employs a strategy to create, build and invest in medical technology companies intended to generate substantial clinical value. Mr. Hochman has also served as President of Accelerated Technologies, Inc., a medical device accelerator company managed by Orchestra Medical Ventures, LLC. Mr. Hochman has over twenty-one years of healthcare entrepreneurial, venture capital and investment banking experience. Mr. Hochman currently serves as a board member of Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP), a Phase 3 clinical-stage pharmaceutical company focused on the development and commercialization of novel therapeutics to treat inflammatory and fibrotic diseases by leveraging its industry leading pipeline of endocannabinoid system-targeting drug candidates. He was a co-founder of Caliber Therapeutics, Inc., a wholly owned subsidiary of Orchestra BioMed, Inc., and was on the Board of Caliber Therapeutics, Inc. from 2009 until 2018. He was a co-founder of BackBeat Medical, Inc., a wholly owned subsidiary of Orchestra BioMed, Inc., and served as its President and a member of its Board since inception in 2010 until 2018. He was a co-founder of FreeHold Surgical, Inc., a wholly owned subsidiary of Orchestra BioMed, Inc., and served as a member of its Board from 2011 until 2018. He also serves as a director of Adgero Biopharmaceuticals Holdings, Inc. Prior to joining Orchestra Medical Ventures LLC, Mr. Hochman was Chief Executive Officer of Spencer Trask Edison Partners, LLC, an investment partnership focused on early stage healthcare companies. He was also Managing Director of Spencer Trask Ventures, Inc. during which time he led financing transactions for over twenty early-stage companies. From 1999 to 2006 Mr. Hochman was a board advisor of Health Dialog Services Corporation, a leader in collaborative healthcare management that was acquired in 2008 by the British United Provident Association. From 2005 to 2007, he was a co-founder and board member of PROLOR Biotech, Inc., a biopharmaceutical company developing longer lasting versions of approved therapeutic proteins, which was purchased by Opko Health (NYSE: OPK) in 2013. He is also President and a Board Member of the Mollie Parnis Livingston Foundation, a family foundation. He has a B.A. degree with honors from the University of Michigan. Mr. Hochman was selected as a director due to his history as a director of Motus GI Medical Technologies Ltd., our wholly owned subsidiary, his leadership experience at other public companies, including medical technology companies, his financial experience and his expertise in governance matters.

Darren Sherman, Director

Mr. Sherman has been a director of Motus GI Medical Technologies Ltd., our wholly owned subsidiary, since 2015 and has served on our board of directors since December 2016. Since May 2018, Mr. Sherman has been President, Chief Operations Officer and a member of the Board of Orchestra BioMed, Inc., a biomedical innovation company focused on developing high impact therapeutic solutions to address major medical conditions where options for high-risk patients are limited or inadequate. Mr. Sherman has over 24 years of management and entrepreneurial experience in the medical technology industry spanning interventional cardiology, cardiac electrophysiology, sudden cardiac death, stroke, surgery, GI, and neurovascular therapies. Since 2009, Mr. Sherman has been Managing Partner of Orchestra Medical Ventures, LLC, an investment firm that employs a strategy to create, build and invest in medical technology companies intended to generate substantial clinical value. Mr. Sherman has also served as Chief Technical Officer of Accelerated Technologies, Inc. (ATI), a medical device accelerator company managed by Orchestra Medical Ventures, LLC, since 2008. Until May 2018, Mr. Sherman served as Chief Executive Officer and a director of Caliber Therapeutics, Inc., and Chief Executive Officer and a director of FreeHold Surgical, Inc. From 2009 until 2016, he served on the board of directors of Vivasure Medical Limited, a medical device company based in Galway, Ireland. Prior to joining Orchestra Medical Ventures, LLC, from February 2002 until March 2008, Mr. Sherman held various positions in executive management for Cordis Neurovascular (CNV), a Johnson & Johnson company, including Executive Director R&D and Director of Strategic Marketing for stroke products. From January 1997 until February 2002, Mr. Sherman played an integral role in the formation and development of Revivant Corp (acquired by Zoll Medical Corporation) while working at Fogarty Engineering. He was Revivant Corp's first employee and managed the design, development, and testing of the AutoPulse device from concept through market introduction. From January 1995 until January 1997, Mr. Sherman held positions in research and development for Cardiac Pathways Corp., prior to its acquisition by Boston Scientific. Prior to Cardiac Pathways Corp., he worked at Baxter Healthcare. In each of these companies, he participated in the creation, development and launch of products. Mr. Sherman has authored more than seventy-five U.S. patents and has over ninety additional published applications. He earned a BS degree in Bioengineering from the University of California, San Diego. Mr. Sherman was selected as a director due to his history as a director of Motus GI Medical Technologies Ltd., our wholly owned subsidiary, and his leadership experience at other companies, including medical technology companies.

Gary Jacobs, Director

Mr. Jacobs has been a director of Motus GI Medical Technologies Ltd., our wholly owned subsidiary, since 2011 and has served on our board of directors since December 2016. Mr. Jacobs is the Founder and Managing Director at Jacobs Investment Company LLC, and served as Chief Executive Officer of DermTech, Inc. He has served as Chairman of DermTech International since 2006, NGT New Generation Technologies Ltd., Galilee Tech Management Ltd., Remedor Biomed Ltd., Sebana Medical Ltd. and ParaSonic Ltd. He serves as a Director of Bio2 Technologies, Inc. Mr. Jacobs served as a software engineer and senior education specialist of QUALCOMM, Inc. and as a software programmer at Linkabit Incorporated. He owns and operates a professional minor league baseball team, the Lake Elsinore Storm, affiliated with the San Diego Padres. In addition, Mr. Jacobs serves as Chair of the Dean's Advisory Council for Social Sciences at the University of California, San Diego and as Chairman of the Board of Trustees of High Tech High in San Diego. He serves as Chairman of the Jewish Community Center Association Continental Board. Mr. Jacobs received his B.A. in Management Science from the University of California, San Diego in 1979. Mr. Jacobs was selected as a director due to his history as a director of Motus GI Medical Technologies Ltd., our wholly owned subsidiary, his extensive experience serving on the board of directors of other companies, including medical technology companies, and his financial experience.

Samuel R. Nussbaum, M.D., Director

Dr. Nussbaum has served on our board of directors since December 2016. During 2016 Dr. Nussbaum began serving as a Strategic Consultant for EBG Advisors, the consulting arm for Epstein Becker and Green, where he advises life science companies, health care systems and provider organizations. Dr. Nussbaum also serves as a Senior Advisor to Sandbox Industries, a venture fund, and Ontario Teachers Pension Fund. He is a member of the Board of Directors of Coherus Biosciences (NASDAQ:CHRS), a leading biosimilar company that develops and commercializes high-quality therapeutics for major regulated markets, and PhyMed Healthcare Group, a physician led and owned leader of anesthesia and pain management services. From 2000 until 2016, Dr. Nussbaum served as Executive Vice President, Clinical Health Policy, and Chief Medical Officer of Anthem, Inc. (NYSE: ANTM), where he was responsible for annual health care expenditures through business units focused on care management, health improvement, and provider network contracting. Prior to joining Anthem, Dr. Nussbaum served as executive vice president, Medical Affairs and System Integration of BJC Health Care, where he led integrated clinical services and community health, served as President of its medical group and chairman of its commercial (HealthPartners of the Midwest) and Medicaid (CarePartners) health plans. He currently serves as Chair of the Strategic Advisory Panel for the Innovation and Value Initiative (IVI), a nonprofit dedicated to advancing the science and improving the practice of value assessment in healthcare, and serves on the Board of Directors of The Network for Excellence in Health Innovation (NEHI), a national nonprofit, nonpartisan organization focused on advancing innovations that improve health, enhance the quality of health care, and achieve greater value for the money spent. Dr. Nussbaum has also served on the Board of Directors of National Quality Forum, America's Health Insurance Plans (AHIP), Regenstrief Institute, National Committee for Quality Health Care, the OASIS Institute, VHA Foundation, BioCrossroads (an Indiana-based public-private collaboration that advances and invests in the life sciences), America's Agenda, Barnes-Jewish West County Hospital, and the United Way of Greater St. Louis. Dr. Nussbaum is a Professor of Clinical Medicine at Washington University School of Medicine, as an adjunct professor at the Olin School of Business, Washington University and as Senior Fellow, University of Southern California Schaeffer Center for Health Policy and Economics. Dr. Nussbaum earned his BA from New York University and his MD from Mount Sinai School of Medicine. He trained in internal medicine at Stanford University and Massachusetts General Hospital and in endocrinology at Harvard Medical School and Massachusetts General Hospital. Dr. Nussbaum was selected as a director because of his medical and business experience in the healthcare and life sciences industries.

Shervin J. Korangy, Director

Mr. Korangy has served on our board of directors since March 2017. Mr. Korangy also serves as the Chief Financial Officer and Head of Strategy of Beaver-Visitec International ("BVI"), a leading global developer, manufacturer and marketer of specialized surgical devices for the ophthalmic marketplace. From 2012 to 2017, Mr. Korangy served in various country General Management roles for Novartis Group AG (NYSE: NVS), a global healthcare company, where he worked with medical device, pharmaceutical and consumer health product segments. Prior to that, while part of Novartis Group AG from 2010 to 2012, Mr. Korangy was the Global Head of Corporate Finance, where he was responsible for global M&A, strategy, integrations, BD&L and portfolio planning. He served on the Novartis Finance Leadership Team and the Global Deal Committee. From 1996 to 2010, Mr. Korangy worked in the Private Equity and Restructuring Advisory divisions of the Blackstone Group (NYSE: BX), where he most recently was a Managing Director. Mr. Korangy is a current member of the Board of Directors (and Chairman of the audit committee) of The Hain Celestial Group (NASDAQ: HAIN), a leading organic and natural products company, and a senior advisor to Sight Sciences LLC, a medical device growth stage business. Mr. Korangy is a former member of the Board of Directors of Pelican Rouge, a consumer coffee manufacturer and vending business, Ultra Music, an electronic and dance music record label, Graham Packaging, a manufacturer and distributer of custom plastic containers for consumer product companies, Pinnacle Foods (NYSE: PF), a consumer packaged foods manufacturer and distributer and Bayview Financial, an asset manager and loan servicer. Mr. Korangy received his B.S. degree in economics at the Wharton School of the University of Pennsylvania. Mr. Korangy was selected as a director due to his management experience with medical device, pharmaceutical and consumer health products, and his financial and accounting experience.

Gary J. Pruden, Director

Mr. Pruden has served on our board of directors since December 2017. Prior to joining us, from 1985 until 2017, Mr. Pruden held a number of senior commercial leadership positions across both the medical devices and pharmaceutical sectors of Johnson & Johnson (NYSE: JNJ). In April 2004, he became President of the Johnson & Johnson subsidiary, Janssen-Ortho Inc. in Canada. In January 2006, Mr. Pruden was appointed Worldwide President of Ethicon, Inc., a Johnson & Johnson subsidiary, and in 2009 became the Company Group Chairman of Ethicon, Inc. In 2012, he was named Worldwide Chairman of Johnson & Johnson's Global Surgery Group and in 2015 he became Worldwide Chairman in the Medical Devices division. In April 2016, Mr. Pruden became a member of the Executive Committee at Johnson & Johnson where his official title was Executive Vice President, Worldwide Chairman, Medical Devices. Mr. Pruden also served in several capacities with the Advanced Medical Technology Association (AdvaMed), a medical device trade association, where he participated in negotiations with the Federal Drug Administration. While at AdvaMed Mr. Pruden served as a member of the Board of Directors, as Chair of the AdvaMed Regulatory Committee, and as a member of the AdvaMed Executive Committee. Mr. Pruden received his B.S. degree in finance at Rider University, where he later served on the Board of Trustees from 2011 until 2015. Mr. Pruden was selected as a director due to his management and regulatory experience with medical device and pharmaceutical products and his financial experience.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our employees, officers and directors. A current copy of our code is posted on the Corporate Governance section of our website, which is located at www.motusgi.com. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waivers of such provisions applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and our directors, on our website identified above or in filings with the SEC.

Committees of the Board of Directors

Our board of directors has established an Audit Committee, a Compensation Committee, and a Nominating and Corporate Governance Committee. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each of these committees operates under a charter that has been approved by our board of directors, which are available on our website.

Audit Committee. Our Audit Committee consists of Mr. Korangy, Mr. Pruden and Mr. Sherman, with Mr. Korangy serving as the Chairman of the Audit Committee. Our board of directors has determined that the three directors currently serving on our Audit Committee are independent within the meaning of the NASDAQ Marketplace Rules and Rule 10A-3 under the Exchange Act. In addition, our board of directors has determined that Mr. Korangy qualifies as an audit committee financial expert within the meaning of SEC regulations and The NASDAQ Marketplace Rules.

The Audit Committee oversees and monitors our financial reporting process and internal control system, reviews and evaluates the audit performed by our registered independent public accountants and reports to the board of directors any substantive issues found during the audit. The Audit Committee is directly responsible for the appointment, compensation and oversight of the work of our registered independent public accountants. The Audit Committee reviews and approves all transactions with affiliated parties.

Compensation Committee. Our Compensation Committee consists of Mr. Hochman, Mr. Jacobs, Mr. Pruden and Dr. Nussbaum, with Mr. Hochman serving as the Chairman of the Compensation Committee. Our board of directors has determined that the four directors currently serving on our Compensation Committee are independent under the listing standards, are "non-employee directors" as defined in rule 16b-3 promulgated under the Exchange Act and are "outside directors" as that term is defined in Section 162(m) of the Internal Revenue Code of 1986, as amended.

The Compensation Committee provides advice and makes recommendations to the board of directors in the areas of employee salaries, benefit programs and director compensation. The Compensation Committee also reviews and approves corporate goals and objectives relevant to the compensation of our President, Chief Executive Officer, and other officers and makes recommendations in that regard to the board of directors as a whole.

Nominating and Corporate Governance Committee. Our Nominating and Corporate Governance Committee consists of Mr. Sherman, Mr. Jacobs and Dr. Nussbaum, with Mr. Sherman serving as the Chairman of the Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee nominates individuals to be elected to the board of directors by our stockholders. The Nominating and Corporate Governance Committee considers recommendations from stockholders if submitted in a timely manner in accordance with the procedures set forth in our bylaws and will apply the same criteria to all persons being considered. All members of the Nominating and Corporate Governance Committee are independent directors as defined under the NASDAQ listing standards.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act, requires our directors and executive, officers, and persons who are beneficial owners of more than 10% of a registered class of our equity securities, to file reports of ownership and changes in ownership with the SEC. These persons are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us, and written representations that no other reports were required during the fiscal year ended December 31, 2018, all reports required to be filed under Section 16(a) were filed on a timely basis, except that Mr. Hochman had one late Form 4 reporting a single acquisition transaction, as a result of a technical issue with the EDGAR filing agent.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table shows the compensation awarded to or earned by our principal executive officer during the fiscal year ended December 31, 2018, our two other most highly compensated executive officers who were serving as executive officers as of December 31, 2018, and up to two additional individuals for whom disclosure would have been provided but for the fact that the individual was not serving as an executive officer as of December 31, 2018. The persons listed in the following table are referred to herein as the "named executive officers".

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($) (1)	All Other Compensation ($)	Total ($)
Timothy P. Moran (2)	2018	118,750	57,000	810,150	1,175,341	247,949	2,409,190
Chief Executive Officer	2017	—	—	—	—	—	—
Mark Pomeranz (3)	2018	359,479	110,688	—	—	31,793	501,960
President and Chief Operating Officer	2017	350,000	87,500	639	1,122,788	30,712	1,591,639
Andrew Taylor (4)	2018	295,000	29,750	—	—	31,794	356,544
Chief Financial Officer	2017	110,625	27,000	—	601,050	9,492	748,167

(1) Amounts reflect the grant date fair value of option awards granted in 2018 and 2017 and, to the extent applicable, the incremental fair value of stock options repriced in September 2017, in accordance with Accounting Standards Codification Topic 718. For information regarding assumptions underlying the valuation of equity awards, see Note 9 to our Consolidated Financial Statements and the discussion under "Part II—Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operation" included in this report. These amounts do not correspond to the actual value that may be received by the named executive officers if the stock options are exercised.

(2) Timothy P. Moran began serving as our Chief Executive Officer on October 1, 2018.

(3) Mark Pomeranz began serving as our President and Chief Operating Officer on September 24, 2018. Mark Pomeranz served as our Chief Executive Officer from December 2016 through September 23, 2018.

(4) Andrew Taylor began serving as our Chief Financial Officer on August 16, 2017.

Narrative Disclosure to Summary Compensation Table

Employment Agreements with Our Named Executive Officers

We entered into an employment agreement with Mr. Moran, which became effective on October 1, 2018, on an at-will basis, which contains non-disclosure and invention assignment provisions. Under the terms of Mr. Moran's employment agreement, he holds the position of Chief Executive Officer and receives a base salary of $475,000 annually (the "Base Salary"). In addition, Mr. Moran is eligible to receive an annual bonus payment (the "Performance Bonus") in an amount equal to up to sixty percent (60%) of his then-Base Salary (the "Bonus Target") if the Board determines that he has met the target objectives communicated to him. For the first twelve months of his employment (the period from October 1, 2018 through October 1, 2019), the payout range for the Performance Bonus is between fifty percent (50%) and two hundred percent (200%) of the Bonus Target if the Board determines the objectives have been achieved. Thereafter, subsequent payout parameters will be determined by the Board based upon parameters set by the Board and Mr. Moran for an overall executive bonus program using market data and analysis input from a third-party expert compensation firm.

In connection with his employment agreement, Mr. Moran was granted (i) an option, granted on November 8, 2018 to purchase 495,000 shares (the "Initial Option Grant") of our Common Stock pursuant to the our 2016 Equity Incentive Plan (the "Plan"), at an exercise price equal to $3.78 per share and (ii) a restricted stock unit award, granted on February 13, 2019, for 165,000 shares of Common Stock pursuant to the Plan (the "Initial Restricted Stock Unit Award"). The Initial Option Grant vests in substantially equal quarterly installments over three years commencing from October 1, 2018, subject to Mr. Moran's continued employment by us. The Initial Restricted Stock Unit Award vests in substantially equal quarterly installments over four years commencing from October 1, 2018, subject to Mr. Moran's continued employment by us. The stock option grant agreement and restricted stock unit award agreements include terms and conditions set forth in our standard forms of such agreements under the Plan. In addition, pursuant to the terms of his employment agreement, Mr. Moran is eligible to receive, from time to time, equity awards under the Plan, or any other equity incentive plan we may adopt in the future, and the terms and conditions of such awards, if any, will be determined by the Board or Compensation Committee, in their discretion. Mr. Moran is also eligible to participate in any executive benefit plan or program we adopt. Further, Mr. Moran is eligible to receive employment buy-out payments (the "Employment Buy-Out Payments") in the amount of $400,000 each on March 1, 2019, November 1, 2019, March 1, 2020 and November 1, 2020, provided he remains actively employed by us, or pursuant to certain termination conditions described below, on each such date.

In the event of death, termination due to disability, termination by us for cause or by Mr. Moran without good reason, Mr. Moran will be entitled to: (i) the amount of his earned, but unpaid salary, prior to the effective date of termination; (ii) reimbursement for any expenses incurred through the effective date of termination; and (iii) any vested amount or benefit as of the effective date of termination. In addition, in the event of death or termination due to disability Mr. Moran will be entitled to the Employment Buy-Out Payments in accordance with the schedule described above. In the event of termination by us without cause or by Mr. Moran for good reason, Mr. Moran will be entitled to receive: (i) the amount of his earned, but unpaid salary, prior to the effective date of termination; (ii) reimbursement for any expenses incurred through the effective date of termination; (iii) any vested amount or benefit as of the effective date of termination; (iv) other than in the event of a termination within twelve months of a change in control, payment as severance twelve months of his Base Salary, or if Mr. Moran is terminated within twelve months of a change in control, payment as severance eighteen months of his Base Salary; (v) other than in the event of a termination within twelve months of a change in control, payment of our portion of the cost of COBRA coverage for twelve months, or if Mr. Moran is terminated within twelve months of a change in control, payment of our portion of the cost of COBRA coverage for eighteen months; (vi) any unpaid portion of the Employment Buy-Out Payments in accordance with the schedule described above; (vii) any earned but unpaid Performance Bonus that relates to the calendar year prior to the calendar year in which termination occurs; and (viii) other than in the event of a termination within twelve months of a change in control, accelerated vesting of any options that otherwise would have vested within twelve months of the termination date, or if Mr. Moran is terminated within twelve months of a change in control, accelerated vesting of all outstanding options.

On September 24, 2018, we entered into an amended and restated employment agreement with Mark Pomeranz, pursuant to which Mr. Pomeranz transitioned from his previous role as President and Chief Executive Officer, into the role of President and Chief Operating Officer as of October 1, 2018.

The amended and restated employment agreement with Mr. Pomeranz became effective on September 24, 2018, provides for employment on an at-will basis, and contains non-disclosure and invention assignment provisions. Under the terms of the amended and restated employment agreement, Mr. Pomeranz holds the position of President and Chief Operating Officer, and receives a base salary of $385,000 annually (the "Pomeranz Base Salary"). In addition, Mr. Pomeranz is eligible to receive (i) for the calendar year ending December 31, 2018, a bonus payment in an amount equal to up to thirty one and one quarter percent (31.25%) (the "2018 Bonus Target") of his then base salary (the "2018 Bonus") if the Board determines that he has met the target objectives communicated to him, with a payout range for the 2018 Bonus of between fifty percent (50%) and two hundred percent (200%) of the 2018 Bonus Target, and (ii) effective January 1, 2019 and thereafter an annual bonus payment (the "Pomeranz Performance Bonus") in an amount equal to up to fifty percent (50%) of the Pomeranz Base Salary if the Board determines that he has met the target objectives communicated to him. Payout parameters for the Pomeranz Performance Bonus will be determined by the Board based upon parameters set by the Board and CEO for an overall executive bonus program using market data and analysis input from a third-party expert compensation firm. In May 2017, pursuant to his original employment agreement, Mr. Pomeranz received a grant of options to purchase up to 511,113 shares of our Common Stock pursuant to our Equity Incentive Plan with an exercise price of $5.00 per share, of which fifty-three percent (53%) were fully vested when issued, forty percent (40%) vest in a series of twelve (12) successive equal quarterly installments upon the completion of each successive calendar quarter of active service over the three (3) year period measured from the date of grant, as was determined by the Compensation Committee of the board of directors, and seven percent (7%) will not become fully vested until December 22, 2019. This option was repriced to $4.50 per share in September 2017. Pursuant to the terms of the amended and restated employment agreement, Mr. Pomeranz is also eligible to receive, from time to time, equity awards under our existing equity incentive plan, or any other equity incentive plan we may adopt in the future, and the terms and conditions of such awards, if any, will be determined by the Board or Compensation Committee, in their discretion. Mr. Pomeranz is also eligible to participate in any executive benefit plan or program we adopt.

In the event of termination for cause, or if Mr. Pomeranz terminates voluntarily, Mr. Pomeranz is entitled to: (i) his unpaid salary through and including the date of termination; (ii) any vested amount or benefit; and, (iii) reimbursement of business expenses. In the event of death, termination due to disability, termination without cause, or if Mr. Pomeranz terminates for good reason, Mr. Pomeranz will be entitled to: (i) his unpaid salary through and including the date of termination; (ii) any vested amount or benefit; (iii) reimbursement of business expenses; (iv) payment as severance twelve months of his base salary; (v) payment of the Company's portion of the cost of COBRA coverage for twelve months; (vi) any earned but unpaid 2018 Bonus or Pomeranz Performance Bonus that relates to the calendar year prior to the calendar year in which termination occurs; and (vii) other than in the event of a termination within twelve months of a change in control, 25% of any unvested options will vest upon termination, or if Mr. Pomeranz is terminated within twelve months of a change in control, accelerated vesting of all outstanding options.

On March 26, 2019, we entered into an amended and restated employment agreement with Andrew Taylor, our Chief Financial Officer.

The amended and restated employment agreement with Mr. Taylor became effective on March 26, 2019, provides for employment on an at-will basis, and contains non-disclosure and invention assignment provisions. Under the terms of the amended and restated employment agreement, Mr. Taylor holds the position of Chief Financial Officer, and receives a base salary of $310,000 annually (the "Taylor Base Salary"). In addition, Mr. Taylor is eligible to receive an annual bonus payment (the "Taylor Performance Bonus") in an amount equal to up to thirty-five percent (35%) of the Taylor Base Salary if the Board determines that he has met the target objectives communicated to him. Payout parameters for the Taylor Performance Bonus will be determined by the Board based upon parameters set by the Board and CEO for an overall executive bonus program using market data and analysis input from a third-party expert compensation firm. In September 2017, pursuant to his original employment agreement, Mr. Taylor received a grant of options to purchase up to 240,000 shares of our Common Stock pursuant to our Equity Incentive Plan with an exercise price of $4.50 per share, which vests in a series of twelve (12) successive equal quarterly installments upon the completion of each successive calendar quarter of active service over the three (3) year period measured from the date of grant, as determined by the Compensation Committee of the board of directors. Pursuant to the terms of the amended and restated employment agreement, Mr. Taylor is also eligible to receive, from time to time, equity awards under our existing equity incentive plan, or any other equity incentive plan we may adopt in the future, and the terms and conditions of such awards, if any, will be determined by the Board or Compensation Committee, in their discretion. Mr. Taylor is also eligible to participate in any executive benefit plan or program we adopt.

In the event of termination for cause, or if Mr. Taylor terminates voluntarily, Mr. Taylor is entitled to: (i) his unpaid salary through and including the date of termination; (ii) any vested amount or benefit; and, (iii) reimbursement of business expenses. In the event of death, termination due to disability, termination without cause, or if Mr. Taylor terminates for good reason, Mr. Taylor will be entitled to: (i) his unpaid salary through and including the date of termination; (ii) any vested amount or benefit; (iii) reimbursement of business expenses; (iv) payment as severance nine months of his base salary; (v) payment of the Company's portion of the cost of COBRA coverage for twelve months; (vi) any earned but unpaid Taylor Performance Bonus that relates to the calendar year prior to the calendar year in which termination occurs; and (vii) other than in the event of a termination within twelve months of a change in control, 25% of any unvested options will vest upon termination, or if Mr. Taylor is terminated within twelve months of a change in control, accelerated vesting of all outstanding equity awards.

The employment agreements with Israeli employees of Motus GI Medical Technologies Ltd., our wholly owned subsidiary, contain standard provisions for a company in our industry regarding non-competition, confidentiality of information and assignment of inventions. The enforceability of covenants not to compete in Israel is subject to limitations. For example, Israeli courts have recently required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or its intellectual property.

Outstanding Equity Awards at Fiscal Year-End Table – 2018

The following table summarizes, for each of the named executive officers, the number of shares of our Common Stock underlying outstanding stock options held as of December 31, 2018.

	Number of Securities Underlying Unexercised Options			
Name	Exercisable	Unexercisable	Option Exercise Price ($)	Option Expiration Date
Timothy P. Moran (CEO)	—	495,000 (1)	3.78 (1)	November 8, 2028
Mark Pomeranz (COO)	67,238(2)	— (2)	2.38 (2)	April 2, 2024
	373,112 (3)	138,001 (3)	4.50 (3)	May 3, 2027
Andrew Taylor (CFO)	100,000 (4)	140,000 (4)	4.50 (4)	September 29, 2027

(1) Represents options to purchase shares of our Common Stock granted on November 8, 2018 with an exercise price of $3.78 per share. The shares underlying the option vest in a series of twelve (12) successive equal quarterly installments commencing on October 1, 2018 and continuing on the first day of each third month thereafter.

(2) Represents options to purchase shares of our Common Stock granted on April 2, 2014, under the Motus G.I. Medical Technologies LTD Employee Share Option Plan that were outstanding as of the Share Exchange Transaction, which were assumed by the 2016 Equity Incentive Plan (the "2016 Plan") and continue in effect in accordance with their terms, on an adjusted basis to reflect the Share Exchange Transaction. 61% of the option was vested as of December 31, 2017, with the remaining 39% of the option vesting in full in November 2018.
(3) Represents options to purchase shares of our Common Stock granted on May 4, 2017, with an exercise price of $5.00 per share. Fifty-three percent (53%) of the option vested immediately upon grant, forty percent (40%) of the option vests in a series of twelve (12) successive equal quarterly installments commencing on May 4, 2017 and continuing on the first day of each third month thereafter, and the remaining seven percent (7%) of the option vests on December 22, 2019. This option was repriced to $4.50 per share in September 2017.
(4) Represents options to purchase shares of our Common Stock granted on September 29, 2017, with an exercise price of $4.50 per share. The shares underlying the option vest in a series of twelve (12) successive equal quarterly installments commencing on December 1, 2017 and continuing on the first day of each third month thereafter.

2016 Equity Incentive Plan

General

On December 14, 2016, our board of directors adopted our 2016 Equity Incentive Plan (the "2016 Plan") having substantially the terms described herein.

The general purpose of the 2016 Plan is to provide a means whereby eligible employees, officers, non-employee directors and other individual service providers develop a sense of proprietorship and personal involvement in our development and financial success, and to encourage them to devote their best efforts to our business, thereby advancing our interests and the interests of our stockholders. By means of the 2016 Plan, we seek to retain the services of such eligible persons and to provide incentives for such persons to exert maximum efforts for our success and the success of our subsidiaries.

Description of the 2016 Equity Incentive Plan

The following is a summary description of the principal terms of the 2016 Plan and is qualified in its entirety by the full text of the 2016 Plan.

***Administration*.** The 2016 Plan is administered by the Compensation Committee of our board of directors. The Compensation Committee is authorized to grant options to purchase shares of our Common Stock, stock appreciation rights, restricted stock, stock units, performance shares, performance units, incentive bonus awards, other cash-based awards and other stock-based awards. Stock options granted under the Motus G.I. Medical Technologies LTD Employee Share Option Plan that were outstanding as of the Share Exchange Transaction were assumed by the 2016 Plan and continue in effect in accordance with their terms, subject to appropriate adjustments to reflect the Share Exchange Transaction (the "Assumed Options"). The Compensation Committee also has authority to determine the terms and conditions of each award, prescribe, amend and rescind rules and regulations relating to the 2016 Plan, and amend the terms of awards in any manner not inconsistent with the 2016 Plan (provided that no amendment may adversely affect the rights of a participant without his or her consent), including authority to reduce or reprice the exercise price of outstanding options or stock appreciation rights. The Compensation Committee is permitted to delegate to officers and employees authority to grant options and other awards to employees (other than themselves), subject to applicable law and restrictions in the 2016 Plan. No award will be granted under the 2016 Plan on or after the ten year anniversary of the adoption of the 2016 Plan by our board of directors, but awards granted prior to the ten year anniversary may extend beyond that date.

***Eligibility*.** Persons who are eligible to receive awards under the 2016 Plan include any person who is an employee, officer, director, consultant, advisor or other individual service provider of the Company or any subsidiary, or any person who is determined by the Compensation Committee to be a prospective employee, officer, director, consultant, advisor or other individual service provider of the Company or any subsidiary.

Shares Subject to the 2016 Plan. As of January 1, 2019, the aggregate number of shares of our Common Stock that are available for issuance in connection with options and awards granted under the 2016 Plan and Assumed Options is 3,927,659. Up to 2,011,656 of the shares available for issuance under the 2016 Plan may be granted with respect to Incentive Stock Options. If any award granted under the 2016 Plan payable in shares of our Common Stock is forfeited, cancelled, returned for failure to satisfy vesting requirements, is otherwise forfeited, otherwise terminates without payment being made, or if shares of our Common Stock are surrendered in full or partial payment of the exercise price or withheld to cover withholding taxes on options or other awards, the number of shares of our Common Stock as to which such option or award was forfeited, or which were surrendered or withheld, will be available for future grants under the 2016 Plan.

In addition, the 2016 Plan contains an "evergreen" provision allowing for an annual increase, on January 1 of each year during the term of the 2016 Plan, in the number of shares of our Common Stock available for issuance under the 2016 Plan. The annual increase in the number of shares shall be equal to six percent (6%) of the total number of shares of our Common Stock outstanding on December 31st of the preceding calendar year; provided, however, that our board of directors may act prior to the first day of any calendar year to provide that there shall be no increase such calendar year, or that the increase shall be a lesser number of shares of our Common Stock than would otherwise occur.

Terms and Conditions of Options. Options granted under the 2016 Plan may be either "incentive stock options" that are intended to meet the requirements of Section 422 of the Code or "nonqualified stock options" that do not meet the requirements of Section 422 of the Code. The Compensation Committee will determine the exercise price of options granted under the 2016 Plan. The exercise price of stock options may not be less than the fair market value per share of our Common Stock on the date of grant (or 110% of fair market value in the case of incentive stock options granted to a ten-percent stockholder). The maximum number of shares of our Common Stock with respect to which any one participant may be granted stock options (or stock appreciation rights) under the 2016 Plan during any calendar year is 1,500,000 shares.

If on the date of grant our Common Stock is listed on a stock exchange or national market system, the fair market value will generally be the closing sale price on the date of grant. If our Common Stock is not traded on a stock exchange or national market system on the date of grant, the fair market value will generally be the average of the closing bid and asked prices for our Common Stock on the date of grant. If no such prices are available, the fair market value shall be determined in good faith by the Compensation Committee based on the reasonable application of a reasonable valuation method.

No option will be exercisable for more than ten years from the date of grant (five years in the case of an incentive stock option granted to a ten-percent stockholder). Options granted under the 2016 Plan will be exercisable at such time or times as the Compensation Committee prescribes at the time of grant. No employee may receive incentive stock options that first become exercisable in any calendar year in an amount exceeding $100,000. The Compensation Committee has authority, in its discretion, to permit a holder of a nonqualified stock option to exercise the option before it has otherwise become exercisable, in which case the shares of our Common Stock issued to the recipient will be restricted stock subject to vesting requirements analogous to those that applied to the option before exercise.

Generally, the exercise price of an option is payable (a) in cash or by certified bank check, (b) through delivery of shares of our Common Stock having a fair market value equal to the purchase price, or (c) such other method as approved by the Compensation Committee and set forth in an award agreement. The Compensation Committee is also authorized to establish a cashless exercise program and to permit the exercise price to be satisfied by reducing from the shares otherwise issuable upon exercise a number of shares having a fair market value equal to the exercise price.

No option will be transferrable other than by will or by the laws of descent and distribution, and during a recipient's lifetime an option will be exercisable only by the recipient. However, the Compensation Committee is authorized to permit the holder of nonqualified stock options, share-settled stock appreciation rights, restricted stock, performance shares or other share-settled stock based awards to transfer the option, right or other award to immediate family members, to a trust for estate planning purposes, or by gift to charitable institutions. The Compensation Committee has the authority to determine the extent to which a holder of a stock option may exercise the option following termination of service with us.

Restricted Stock and Stock Units. The Compensation Committee is authorized to award restricted Common Stock and/or stock units under the 2016 Plan. Restricted stock awards consist of shares of stock that are transferred to a participant subject to restrictions that may result in forfeiture if specified conditions are not satisfied. Stock units confer the right to receive shares of our Common Stock, cash, or a combination of shares and cash, at a future date upon or following the attainment of such conditions as may be specified by the Compensation Committee. The Compensation Committee is authorized to determine the restrictions and conditions applicable to each award of restricted stock or stock units, which may include performance-based conditions. The 2016 Plan provides that dividends with respect to restricted stock may be paid to the holder of the shares as and when dividends are paid to stockholders or at the time that the restricted stock vests, as determined by the Compensation Committee. Dividend equivalent amounts under the 2016 Plan may also be paid with respect to stock units, and are subject to the same restrictions on transferability as the stock units with respect to which they were paid. Unless the Compensation Committee determines otherwise, holders of restricted stock have the right to vote the shares.

Other Awards. The 2016 Plan also permits the grant of performance share and performance unit awards, incentive bonus awards payable in cash or shares of our Common Stock, as well as other stock based and cash based awards.

Section 162(m). Section 162(m) of the Code, as amended by the 2017 Tax Cuts and Jobs Act (the "2017 Act"), generally limits the deductibility of compensation paid by a publicly-held company to a "covered employee" for a taxable year to $1 million. Under the 2017 Act, the performance-based pay exception to Section 162(m) was eliminated, but a transition rule may allow the exception to continue to apply to certain performance-based compensation payable under written binding contracts that were in effect on November 2, 2017.

Effect of Certain Corporate Transactions. The Compensation Committee has the authority to provide, at the time of the grant of an award, for the effect of a change in control (as defined in the 2016 Plan) on any award, including (i) accelerating or extending the time periods for exercising, vesting in, or realizing gain from any award, (ii) eliminating or modifying the performance or other conditions of an award, (iii) providing for the cash settlement of an award for an equivalent cash value, as determined by the Compensation Committee, or (iv) such other modification or adjustment to an award as the Compensation Committee deems appropriate to maintain and protect the rights and interests of participants following a change in control. The Compensation Committee has the authority, in its discretion and without the need for the consent of any recipient of an award, to also take one or more of the following actions contingent upon the occurrence of a change in control: (a) cause any or all outstanding options and stock appreciation rights to become immediately exercisable, in whole or in part; (b) cause any other awards to become non-forfeitable, in whole or in part; (c) cancel any option or stock appreciation right in exchange for a substitute option; (d) cancel any award of restricted stock, stock units, performance shares or performance units in exchange for a similar award of the capital stock of any successor corporation; (e) redeem any restricted stock for cash and/or other substitute consideration with a value equal to the fair market value of an unrestricted share of our Common Stock on the date of the change in control; (f) cancel any option or stock appreciation right in exchange for cash and/or other substitute consideration based on the value of our Common Stock on the date of the change in control, and cancel any option or stock appreciation right without any payment if its exercise price exceeds the value of our Common Stock on the date of the change in control; or (g) make such other modifications, adjustments or amendments to outstanding awards as the Compensation Committee deems necessary or appropriate.

Israeli Aspects of the 2016 Plan

The 2016 Israeli Sub-Plan (the "Sub-Plan") provides for the grant of awards pursuant to the Israeli Income Tax Ordinance (New Version), 1960, as amended (the "Israeli Tax Ordinance"): awards granted pursuant to (i) Section 102 of the Israeli Tax Ordinance ("Section 102 Awards") and (ii) Section 3(i) of the Israeli Tax Ordinance ("Section 3(i) Awards"). The 2016 Plan and the Sub-Plan provide, subject to applicable law, that Section 102 Awards may be granted only to Israeli employees, officers and directors (excluding Controlling Shareholders as defined by the Israeli Tax Ordinance) and Section 3(i) Awards (which do not provide for similar tax benefits) may be granted to Israeli non-employees including consultants, service providers and Controlling Shareholders (as defined by the Israeli Tax Ordinance), in each case, of our company or any subsidiary. The 2016 Plan and the Sub-Plan were approved by the Israeli Tax Authority (the "ITA") in January 2017 pursuant to applicable law.

Section 102 of the Israeli Tax Ordinance includes two alternatives for tax treatment involving the issuance of options or shares to a trustee for the benefit of the grantees, which are referred to as the capital gains track and the ordinary income track, and also includes an additional alternative for the issuance of options or shares issued directly to the grantee. Under the Sub-Plan, each Section 102 Award designates that such award be granted under the capital gains track or the ordinary income track. We cannot select both tracks simultaneously for Section 102 Awards and the election of the type of track shall apply to all Section 102 Awards awarded under the Sub-Plan (unless the election is changed pursuant to the provisions of the Israeli Tax Ordinance).

In order to comply with the terms of the "capital gains track", all options granted under a specific plan and subject to the provisions of Section 102 of the Israeli Tax Ordinance, as well as the shares issued upon exercise of such options and other shares received subsequently following any realization of rights with respect to such options, such as share dividends and share splits, must be registered in the name of a trustee selected by the board of directors and held in trust for the benefit of the relevant employee, director or officer for a period of two years from the date of grant and deposit with such trustee. However, under this track, the "employing company" (within the meaning of Section 102(a) of the Israeli Tax Ordinance) is not allowed to deduct an expense with respect to the issuance of the options or shares.

Director Compensation

The following table sets forth information concerning the compensation paid to certain of our non-employee directors during 2018.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($) (1)	Total ($)
David Hochman (2)	$ 68,000.00	—	$ 68,000.00
Darren Sherman (3)	$ 32,000.00	—	$ 32,000.00
Gary Jacobs (4)	$ 26,750.00	—	$ 26,750.00
Samuel Nussbaum (5)	$ 26,000.00	—	$ 26,000.00
Shervin Korangy (6)	$ 36,000.00	—	$ 36,000.00
Gary Pruden (7)	$ 26,000.00	$ 139,650.00	$ 165,650.00

(1) Amounts reflect the aggregate grant date fair value of each stock option granted in 2018 in accordance with the Accounting Standards Codification Topic 718. For information regarding assumptions underlying the valuation of equity awards, see Note 9 to our Consolidated Financial Statements and the discussion under "Part II—Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operation" included in this report. These amounts do not correspond to the actual value that may be received by the directors if the stock options are exercised.

(2) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2018 held by Mr. Hochman was 175,000.

(3) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2018 held by Mr. Sherman was 100,000.

(4) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2018 held by Mr. Jacobs was 92,500.

(5) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2018 held by Dr. Nussbaum was 50,000.

(6) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2018 held by Mr. Korangy was 65,000.

(7) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2018 held by Mr. Pruden was 50,000.

Non-Employee Director Compensation

Our board of directors approved a director compensation policy for our directors, effective February 2019. This policy provides for the following cash compensation:

- each director is entitled to receive a quarterly fee from us of $6,500;
- the chairman of the Board will receive a quarterly fee from us of $9,000;
- the chair of the Audit Committee will receive a quarterly fee from us of $2,500;
- each chair of any other board of director committee will receive a quarterly fee from us of $1,500;
- each non-employee director sitting on more than two Board committees will receive an additional quarterly fee of $750;
- each non-chairperson member of the audit committee, the compensation committee and the nominating and corporate governance committee will receive annual fees from us of $7,500, $5,000 and $5,000, respectively.;

Each non-employee director is also eligible to receive an annual option grant in an amount to be determined annually by our Compensation Committee in consultation with an independent compensation consultant, to purchase shares of our Common Stock under our existing equity incentive plan, or any other equity incentive plan we may adopt in the future, which shall vest in two equal annual installments, beginning on the first anniversary of the date of grant, and ending on the second anniversary of the date of grant.

All fees under the director compensation policy will be paid on a quarterly basis in arrears and no per meeting fees will be paid. We will also reimburse non-employee directors for reasonable expenses incurred in connection with attending board of director and committee meetings.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information with respect to our compensation plans under which equity compensation was authorized as of December 31, 2018.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column a) (c)(2)
Equity compensation plans approved by security holders(1)	2,520,101	$ 4.32	99,417
Equity compensation plans not approved by security holders	—	$ —	—
Total	2,520,101	$ 4.32	99,417

(1) The amounts shown in this row include securities under the Motus GI Holdings, Inc. 2016 Equity Incentive Plan and 2016 Israeli Sub-Plan to the Motus GI Holdings, Inc. 2016 Equity Incentive Plan (the "2016 Plan").

(2) In accordance with the "evergreen" provision in our 2016 Plan, an additional 1,286,409 shares were automatically made available for issuance on the first day of 2019, which represents 6% of the number of shares outstanding on December 31, 2018; these shares are excluded from this calculation.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information regarding the beneficial ownership of our Common Stock as of the date of this report by:

- each of our stockholders who is known by us to beneficially own 5% or more of our Common Stock;
- each of our named executive officers;
- each of our directors; and
- all of our directors and current officers as a group.

Beneficial ownership is determined based on the rules and regulations of the SEC. A person has beneficial ownership of shares if such individual has the power to vote and/or dispose of shares. This power may be sole or shared and direct or indirect. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of our Common Stock that are subject to options or warrants held by that person and exercisable as of, or within 60 days of, March 1, 2019 are counted as outstanding. These shares, however, are not counted as outstanding for the purposes of computing the percentage ownership of any other person(s). Except as otherwise noted in the footnotes to the table, we believe that each person or entity named in the table has sole voting and investment power with respect to all shares of the Company's Common Stock shown as beneficially owned by that person or entity (or shares such power with his or her spouse). Unless indicated below, the address of each individual listed below is c/o Motus GI Holdings, Inc., 1301 East Broward Boulevard, 3rd Floor, Ft. Lauderdale, FL 33301.

The percentage of the Common Stock beneficially owned by each person or entity named in the following table is based on 21,440,564 shares of Common Stock issued and outstanding as of March 1, 2019 plus any shares issuable upon exercise of options or warrants that are exercisable on or within 60 days after March 1, 2019 held by such person or entity.

Beneficial ownership representing less than 1% is denoted with an asterisk (*).

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Officers and Directors		
Timothy P. Moran (1)	131,141	*
Mark Pomeranz (2)	481,428	2.20 %
David Hochman (3)(5)(6)(7)(8)(9)	2,011,361	9.17 %
Darren Sherman (4)(5)(6)(7)(8)(9)	1,864,861	8.52 %
Gary Jacobs (10)(11)	942,598	4.36 %
Samuel Nussbaum (12)	35,000	*
Shervin Korangy (13)	52,500	*
Andrew Taylor (14)	130,369	*
Gary Pruden (15)	75,000	*
Directors and Officers as a Group (9 persons)	3,918,697	17.15 %
5% Stockholders		
ABV, LLC (16)(17)	1,607,163	7.36 %
Orchestra MOTUS Co-Investment Partners, LLC (7)	1,345,101	6.22 %
Orchestra BioMed, Inc. (8)	2,000,000	9.33 %
Perceptive Life Sciences Master Fund Ltd. (18)	3,456,596	15.94 %
Larry N. Feinberg (19)	2,775,000	12.94 %

* Less than 1%

1. Includes 84,912 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of March 1, 2019. Does not include 439,032 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 1, 2019. Includes 21,229 shares of our Common Stock pursuant to restricted stock unit awards which have vested as of March 1, 2019, or which will be vested within sixty days of March 1, 2019. Does not include 153,419 shares of our Common Stock issuable upon the vesting of restricted stock units that will not vest within sixty days of March 1, 2019.

2. Includes 468,107 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of March 1, 2019. Does not include 238,885 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 1, 2019. Includes 2,680 shares of our Common Stock pursuant to restricted stock unit awards which have vested as of March 1, 2019, or which will be vested within sixty days of March 1, 2019. Does not include 40,220 shares of our Common Stock issuable upon the vesting of restricted stock units that will not vest within sixty days of March 1, 2019.

3. Includes (i) 87,500 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of March 1, 2019, (ii) 300 shares of our Common Stock issuable upon exercise of warrants that are exercisable within sixty days of March 1, 2019, and (iii) 100,000 shares of Common Stock held by a family trust of which Mr. Hochman is a co-trustee and sole beneficiary. Does not include 127,500 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 1, 2019.

4. Includes (i) 50,000 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of March 1, 2019, and (ii) 300 shares of our Common Stock issuable upon exercise of warrants that are exercisable within sixty days of March 1, 2019. Does not include 75,000 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 1, 2019.

5. Includes 109,792 shares of our Common Stock held by Orchestra Medical Ventures II, L.P., and 215,818 shares of our Common Stock issuable upon exercise of warrants that are exercisable within sixty days of March 1, 2019, held by Orchestra Medical Ventures II, L.P. Orchestra Medical Ventures II GP, LLC serves as general partner to Orchestra Medical Ventures II, L.P. The managing members of Orchestra Medical Ventures II GP, LLC, David Hochman and Darren Sherman, exercise sole dispositive and voting power over the shares owned by Orchestra Medical Ventures II, L.P. The principal address for Orchestra Medical Ventures II, L.P. is 150 Union Square Drive, New Hope, PA 18938.

6. Includes 83,352 shares of our Common Stock held by Orchestra Medical Ventures II Reserve, L.P. Orchestra Medical Ventures II GP, LLC serves as general partner to Orchestra Medical Ventures II Reserve, L.P. The managing members of Orchestra Medical Ventures II GP, LLC, David Hochman and Darren Sherman, exercise sole dispositive and voting power over the shares owned by Orchestra Medical Ventures II Reserve, L.P. The principal address for Orchestra Medical Ventures II Reserve, L.P. is 150 Union Square Drive, New Hope, PA 18938.

7. Based on the information provided in the Schedule 13D/A filed with the SEC on February 15, 2019 by Orchestra Motus Co-Investment Partners, LLC. Includes 185,133 shares of our Common Stock issuable upon exercise of warrants that are exercisable within sixty days of March 1, 2019, held by Orchestra MOTUS Co-Investment Partners, LLC. Orchestra Medical Ventures, LLC, serves as managing member to Orchestra Motus Co-Investment Partners, LLC. The managing partners of Orchestra Medical Ventures, LLC, David Hochman and Darren Sherman, exercise sole dispositive and voting power over the shares owned by Orchestra MOTUS Co-Investment Partners, LLC. The principal address for Orchestra MOTUS Co-Investment Partners, LLC is 150 Union Square Drive, New Hope, PA 18938.

8. Based on the information provided in the Schedule 13D filed with the SEC on February 15, 2019 by Orchestra BioMed, Inc. The principal address for Orchestra BioMed, Inc. is 150 Union Square Drive, New Hope, PA 18938.

9. Includes 51,498 shares of Common Stock held by Accelerated Technologies, Inc. David Hochman and Darren Sherman share dispositive and voting power over the shares owned by Accelerated Technologies, Inc.

10. Includes 46,250 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of March 1, 2019. Does not include 71,250 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 1, 2019.

11. Includes 745,956 shares of our Common Stock held by Jacobs Investment Company LLC, and 141,292 shares of our Common Stock issuable upon exercise of warrants that are exercisable within sixty days of March 1, 2019 held by Jacobs Investment Company LLC. The managing member of Jacobs Investment Company LLC, Gary Jacobs, exercises sole dispositive and voting power over the shares owned by Jacobs Investment Company LLC.

12. Includes 25,000 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of March 1, 2019. Does not include 50,000 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 1, 2019.

13. Includes 32,500 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of March 1, 2019. Does not include 57,500 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 1, 2019.

14. Includes 125,895 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of March 1, 2019. Does not include 184,858 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 1, 2019. Includes 1,474 shares of our Common Stock pursuant to restricted stock unit awards which have vested as of March 1, 2019, or which will be vested within sixty days of March 1, 2019. Does not include 22,110 shares of our Common Stock issuable upon the vesting of restricted stock units that will not vest within sixty days of March 1, 2019.

15. Includes 25,000 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of March 1, 2019. Does not include 50,000 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 1, 2019.

16. Based on the information provided in the Schedule 13G filed with the SEC on February 13, 2019 by ABV, LLC. Includes 591,481 shares of our Common Stock held by Ascent Biomedical Ventures II, L.P. and 315,883 shares of our Common Stock issuable upon exercise of warrants that are exercisable within sixty days of March 1, 2019, held by Ascent Biomedical Ventures II, L.P. ABV, LLC serves as general partner to Ascent Biomedical Ventures II, L.P. The managing members of ABV, LLC, Geoffrey W. Smith and Steve Hochberg, exercise sole dispositive and voting power over the shares owned by Ascent Biomedical Ventures II, L.P. The principal address for the entities affiliated with ABV, LLC is 60 East 42nd Street, New York, NY 10165.

17. Based on the information provided in the Schedule 13G filed with the SEC on February 13, 2019 by ABV, LLC. Includes 611,241 shares of our Common Stock held by Ascent Biomedical Ventures Synecor, L.P. and 88,558 shares of our Common Stock issuable upon exercise of warrants that are exercisable within sixty days of March 1, 2019, held by Ascent Biomedical Ventures Synecor, L.P. ABV, LLC serves as general partner to Ascent Biomedical Ventures Synecor, L.P. The managing members of ABV, LLC, Geoffrey W. Smith and Steve Hochberg, exercise sole dispositive and voting power over the shares owned by Ascent Biomedical Ventures Synecor, L.P. The principal address for the entities affiliated with ABV, LLC is 60 East 42nd Street, New York, NY 10165.

18. Based on the information provided in the Schedule 13G/A filed with the SEC on February 14, 2019 by Mr. Joseph Edelman with respect to himself, Perceptive Life Sciences Master Fund Ltd. and Perceptive Advisors LLC (Mr. Edelman, together with Perceptive Life Sciences Master Fund Ltd. and Perceptive Advisors LLC, the "Perceptive Reporting Persons"). Includes 246,055 shares of our Common Stock issuable upon exercise of warrants that are exercisable within sixty days of March 1, 2019, held by Perceptive Life Sciences Master Fund Ltd. Perceptive Life Sciences Master Fund Ltd., Perceptive Advisors LLC and Mr. Edelman have shared voting and dispositive power with respect to the shares of our Common Stock held by Perceptive Life Sciences Master Fund Ltd. Perceptive Advisors LLC serves as the investment manager to Perceptive Life Sciences Master Fund Ltd. and may be deemed to beneficially own the securities directly held by Perceptive Life Sciences Master Fund Ltd. Mr. Edelman is the managing member of Perceptive Advisors LLC and may be deemed to beneficially own the securities directly held by Perceptive Life Sciences Master Fund Ltd. The principal address for the Perceptive Reporting Persons is 51 Astor Place, 10th Floor New York, NY 10003.

19. Based on the information provided in the Schedule 13G filed with the SEC on December 26, 2018 by Larry N. Feinberg with respect to himself, Oracle Associates, LLC ("Oracle Associates"), Oracle Partners, L.P. ("Oracle Partners"), Oracle Investment Management, Inc. ("Investment Manager"), Oracle Ten Fund Master, LP ("Ten Fund") and Oracle Institutional Partners, L.P. ("Institutional Partners") (Mr. Feinberg, together with Oracle Associates, Oracle Partners, Investment Manager, Ten Fund and Institutional Partners, the "Oracle Reporting Persons"). The Oracle Reporting Persons reported that each of Mr. Feinberg, Oracle Associates, and Investment Manager have shared voting and dispositive power with respect to 2,775,000 shares of our Common Stock; Oracle Partners has shared voting and dispositive power with respect to 2,077,000 shares of our Common Stock; Institutional Partners has shared voting and dispositive power with respect to 286,000 shares of our Common Stock; and Ten Fund has shared voting and dispositive power with respect to 412,000 shares of our Common Stock. Oracle Associates is the general partner of each of Oracle Partners, Ten Fund and Institutional Partners. Investment Manager is the investment manager to each of Oracle Partners, Ten Fund and Institutional Partners. Mr. Feinberg is the managing member of Oracle Associates and the sole stockholder, director and president of Investment Manager. The principal address for the Oracle Reporting Persons is Oracle Investment Management, Inc. 262 Harbor Drive, 3rd Floor, Stamford, Connecticut 06902.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDECE

Other than compensation arrangements for our named executive officers and directors, we describe below each transaction or series of similar transactions, since January 1, 2018, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed the lesser of (i) $120,000 or (ii) 1% of the average total assets of the Company at year end for the last two completed fiscal years; and

- any of our directors, executive officers, promoters or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and directors are described in Part III—Item 11—Executive Compensation."

Ten Percent Warrants - Related Party Participation

Upon the completion of our IPO in February 2018, we issued the Ten Percent Warrants to certain of our former Series A Convertible Preferred Stock holders, pursuant to an amendment to the Registration Rights Agreement and an amendment to the Certificate of Designation, to purchase an aggregate of 1,095,682 shares of our Common Stock, including (i) Ten Percent Warrants to purchase 300 shares of our Common Stock to David Hochman, the Chairman of our Board, (ii) Ten Percent Warrants to purchase 300 shares of our Common Stock to Darren Sherman, one of our directors, (iii) Ten Percent Warrants to purchase an aggregate of 220,274 shares of our Common Stock to Ascent Biomedical Ventures II, L.P. and Ascent Biomedical Ventures Synecor, L.P., beneficial owners of more than five percent of our Common Stock, (iv) Ten Percent Warrants to purchase 106,980 shares of our Common Stock to Orchestra Medical Ventures II, L.P., a former beneficial owner of more than five percent of our Common Stock, (v) Ten Percent Warrants to purchase 115,997 shares of our Common Stock to Orchestra MOTUS Co-Investment Partners, LLC, a beneficial owner of more than five percent of our Common Stock, (vi) Ten Percent Warrants to purchase 72,386 shares of our Common Stock to Jacobs Investment Company LLC, an investment firm in which Gary Jacobs, one of our Directors, serves as Founder and Managing Director, (vii) Ten Percent Warrants to purchase 180,055 shares of our Common Stock to Perceptive Life Sciences Master Fund Ltd., a beneficial owner of more than five percent of our Common Stock, (viii) Ten Percent Warrants to purchase an aggregate of 57,035 shares of our Common Stock to E. Jeffrey Peierls, including the Peierls Trusts and the Peierls Entities, a former beneficial owner of more than five percent of our Common Stock.

Royalty Payment Rights Certificates - Related Party Participation

Simultaneously with the closing of our IPO in February 2018, all 1,581,128 previously outstanding shares of our Series A Convertible Preferred Stock were converted, on a one-to-one basis, into an aggregate of 1,581,128 shares of our Common Stock. In connection with the conversion of the Series A Convertible Preferred Stock we issued Royalty Payment Rights Certificates (the "Royalty Payment Rights Certificates") to each former holder of our Series A Convertible Preferred Stock, including certain of our directors and executive officers, and certain of our existing stockholders, including stockholders affiliated with certain of our directors including (i) a Royalty Payment Rights Certificate for 0.05% of the aggregate royalty amount payable to the holders of the Royalty Payment Rights Certificates to David Hochman, the Chairman of our Board, (ii) a Royalty Payment Rights Certificate for 0.05% of the aggregate royalty amount payable to the holders of the Royalty Payment Rights Certificates to Darren Sherman, one of our directors, (iii) Royalty Payment Rights Certificate for an aggregate of 10.79% of the aggregate royalty amount payable to the holders of the Royalty Payment Rights Certificates to Ascent Biomedical Ventures II, L.P. and Ascent Biomedical Ventures Synecor, L.P., beneficial owners of more than five percent of our Common Stock, (iv) a Royalty Payment Rights Certificate for 6.31% of the aggregate royalty amount payable to the holders of the Royalty Payment Rights Certificates to Orchestra Medical Ventures II, L.P., a former beneficial owner of more than five percent of our Common Stock, (v) a Royalty Payment Rights Certificate for 4.11% of the aggregate royalty amount payable to the holders of the Royalty Payment Rights Certificates to Orchestra MOTUS Co-Investment Partners, LLC, a beneficial owner of more than five percent of our Common Stock, (vi) a Royalty Payment Rights Certificate for 4.00% of the aggregate royalty amount payable to the holders of the Royalty Payment Rights Certificates to Jacobs Investment Company LLC, an investment firm in which Gary Jacobs, one of our Directors, serves as Founder and Managing Director, and (vii) a Royalty Payment Rights Certificate for 16.22% of the aggregate royalty amount payable to the holders of the Royalty Payment Rights Certificates to Perceptive Life Sciences Master Fund Ltd., a beneficial owner of more than five percent of our Common Stock. Pursuant to the terms of the Royalty Payment Rights Certificates, if and when we generate sales of the Pure-Vu System, or if we receive any proceeds from the licensing of the Pure-Vu System, then we will pay to the holders of the Royalty Payment Rights Certificates (the "Holders") the allocation of such royalty payment rights as listed on such Holders Royalty Payment Rights Certificate, a royalty (the "Royalty Amount") equal to, in the aggregate, in royalty payments in any calendar year for all products:

The Company Commercializes Product Directly	The Rights to Commercialize the Product is Sublicensed by the Company to a third-party
3% of Net Sales*	5% of any Licensing Proceeds**

* Notwithstanding the foregoing, with respect to Net Sales based Royalty Amounts, (a) no Net Sales based Royalty Amount shall begin to accrue or become payable until we have first generated, in the aggregate, since inception, Net Sales equal to $20 million (the "Initial Net Sales Milestone"), and royalties shall only be computed on, and due with respect to, Net Sales generated in excess of the Initial Net Sales Milestone, and (b) the total Net Sales based Royalty Amount due and payable in any calendar year shall be subject to a cap per calendar year of $30 million. "Net Sales" is defined in the Royalty Payment Rights Certificates.

** Notwithstanding the foregoing, with respect to Licensing Proceeds based Royalty Amounts, (a) no Licensing Proceeds based Royalty Amount shall begin to accrue or become payable until we have first generated, in the aggregate, since inception, Licensing Proceeds equal to $3.5 million (the "Initial Licensing Proceeds Milestone"), and royalties shall only be computed on, and due with respect to, Licensing Proceeds in excess of the Initial Licensing Proceeds Milestone and (b) the total Licensing Proceeds based Royalty Amount due and payable in any calendar year shall be subject to a cap per calendar year of $30 million. "Licensing Proceeds" is defined in the Royalty Payment Rights Certificates.

The royalty will be payable up to the later of (i) the latest expiration date of our patents issued as of December 22, 2016, or (ii) the latest expiration date of any pending patents as of December 22, 2016 that have since been issued or may be issued in the future (which is currently November 2034). Following the expiration of all such patents, the Holders of the Royalty Payment Rights Certificates will no longer be entitled to any further royalties for any period following the latest to occur of such patent expiration.

Participation in Initial Public Offering

In addition to the shares issued pursuant to the directed share program described below, all of our directors and executive officers, and certain of our existing stockholders who held greater than 5% of our Common Stock, including stockholders affiliated with certain of our directors, purchased an aggregate of 1,435,000 shares of our Common Stock in our IPO, completed February 2018, at the public offering price of $5.00 per share, including (i) Perceptive Life Sciences Master Fund Ltd., a greater than 5% shareholder, which purchased 1,010,000 shares, (ii) Orchestra Medical Ventures II, L.P., a former greater than 5% shareholder, which purchased 40,000 shares, (iii) Gary Pruden, one of our directors, who purchased 50,000 shares, (iv) David Hochman, the chairman of our board, who purchased 75,000 shares, (v) Shervin Korangy, one of our directors, who purchased 20,000 shares, (vi) Mark Pomeranz, our President and Chief Operating Officer, who purchased 8,000 shares, (vii) Samuel Nussbaum, one of our directors, who purchased 10,000 shares, (viii) Darren Sherman, one of our directors, who purchased 5,000 shares and (ix) Andrew Taylor, our Chief Financial Officer, who purchased 2,000 shares.

Directed Share Program

At our request, the underwriters sold 175,000 shares of our Common Stock, or five percent (5%) of the shares offered in our IPO, completed February 2018, at the public offering price of $5.00 per share, to our employees and other persons associated with us, including Gary Jacobs, one of our Directors, who purchased 5,000 shares of our Common Stock at the IPO price. The directed share program was arranged through the representative of the underwriters in the IPO.

Sales and Marketing Services Arrangement with FreeHold Surgical, Inc.

In August, 2017, we began paying a monthly fee to FreeHold Surgical, Inc., or FreeHold, an entity in which David Hochman, the Chairman of our Board, serves as a Director, and Darren Sherman, one of our Directors, serves as a Director and President. Pursuant to the fee arrangement, we paid FreeHold a monthly amount of approximately $25,000 as all-in compensation for sales and marketing services performed for us, on a part time basis, by two FreeHold sales representatives (the "FreeHold Services"), through June 2018. Effective July 2018, pursuant to an amendment to the fee arrangement, we paid FreeHold a monthly amount of approximately $8,333 as all-in compensation for the FreeHold Services. Effective as of November 30, 2018, we terminated the fee arrangement for the FreeHold Services. As of November 30, 2018 our payment obligations to FreeHold pursuant to the fee arrangement have terminated and all FreeHold Services obligations by FreeHold have ceased.

Participation in Follow On Offering

Certain of our directors and executive officers, and certain of our stockholders who hold greater than 5% of our Common Stock, including stockholders affiliated with certain of our directors, purchased an aggregate of 3,218,500 shares of our Common Stock in our Follow On Offering, completed December 2018, at the public offering price of $2.70 per share, including (i) the Oracle Reporting Persons, greater than 5% holders of our Common Stock, which purchased an aggregate 2,775,000 shares, (ii) Perceptive Life Sciences Master Fund Ltd., a greater than 5% shareholder, which purchased 400,000 shares, (iii) David Hochman, the chairman of our board, who purchased 20,000 shares, (iv) Timothy P. Moran, our chief executive officer, who purchased 10,000 shares, (v) Jacobs Investment Company LLC, an investment firm in which Gary Jacobs, one of our Directors, serves as Founder and Managing Director, which purchased 10,000 shares, (vi) Mark Pomeranz, our President and Chief Operating Officer, who purchased 2,500 shares, and (vii) Andrew Taylor, our Chief Financial Officer, who purchased 1,000 shares.

Indemnification Agreements

We have entered into indemnification agreements with all of our directors and named executive officers. These agreements require us to indemnify these individuals to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to us, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified. We also intend to enter into indemnification agreements with our future directors and executive officers.

Policies and Procedures for Related Party Transactions

Our board of directors has adopted a policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our Common Stock, any members of the immediate family of any of the foregoing persons and any firms, corporations or other entities in which any of the foregoing persons is employed or is a partner or principal or in a similar position or in which such person has a 5% or greater beneficial ownership interest (collectively "related parties"), are not permitted to enter into a transaction with us without the prior consent of our board of directors acting through the Audit Committee or, in certain circumstances, the chairman of the Audit Committee. Any request for us to enter into a transaction with a related party, in which the amount involved exceeds $100,000 and such related party would have a direct or indirect interest must first be presented to our Audit Committee, or in certain circumstances the chairman of our Audit Committee, for review, consideration and approval. In approving or rejecting any such proposal, our Audit Committee, or the chairman of our Audit Committee, is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances, the extent of the benefits to us, the availability of other sources of comparable products or services and the extent of the related party's interest in the transaction.

Director Independence

Our board of directors undertook a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that Mr. Hochman, Mr. Sherman, Mr. Jacobs, Dr. Nussbaum, Mr. Korangy and Mr. Pruden do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the Rules of the Nasdaq Market and the SEC.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Principal Accountant Fees and Services

As disclosed in our Form 8-K filed on April 2, 2018, we dismissed Brightman Almagor Zohar & Co., member of Deloitte Touche Tohmatsu Limited as our independent accountant on March 27, 2018, and engaged EisnerAmper LLP to serve as our new independent accountant.

The following table summarizes the fees paid for professional services rendered by EisnerAmper LLP, our independent registered public accounting firm, for each of the last two fiscal years:

Fee Category	2018	2017
Audit Fees	$ 182,345	$ —
Audit-Related Fees	$ —	$ —
Tax Fees	$ 22,000	$ 46,950
All Other Fees	$ —	$ —
Total Fees	$ 204,345	$ 46,950

Audit Fees

Represents fees, including out of pocket expenses, for professional services provided in connection with the audit of our annual audited financial statements, the review of our quarterly financial statements and for consents and comfort letters provided in connection with the offerings of our Common Stock.

Tax Fees

Tax fees were principally for services related to tax preparation and filing, as well as tax consulting services associated with tax preparation and filings and intercompany transfer pricing activities.

Procedures for Approval of Fees

The Audit Committee is responsible for appointing, setting compensation and overseeing the work of the independent auditors. The Audit Committee has established a policy regarding pre-approval of all auditing services and the terms thereof and non-audit services (other than non-audit services prohibited under Section 10A(g) of the Exchange Act or the applicable rules of the SEC or the Public Company Accounting Oversight Board) to be provided to us by the independent auditor. However, the pre-approval requirement may be waived with respect to the provision of non-audit services for us if the "de minimus" provisions of Section 10A(i)(1)(B) of the Exchange Act are satisfied.

The Audit Committee has considered whether the provision of Audit-Related Fees, Tax Fees, and all other fees as described above is compatible with maintaining EisnerAmper LLP's independence and has determined that such services for fiscal year 2018 were compatible. All such services were approved by the Audit Committee pursuant to Rule 2-01 of Regulation S-X under the Exchange Act to the extent that rule was applicable.

The Audit Committee is responsible for reviewing and discussing the audited financial statements with management, discussing with the independent registered public accountants the matters required in Auditing Standards No. 16, receiving written disclosures from the independent registered public accountants required by the applicable requirements of the Public Company Accounting Oversight Board regarding the independent registered public accountants' communications with the Audit Committee concerning independence and discussing with the independent registered public accountants their independence, and recommending to the Board of Directors that the audited financial statements be included in our annual report on Form 10-K.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) List of Documents filed as part of this Report

(1) Consolidated Financial Statements

The financial statements and related notes, together with the report of EisnerAmper LLP appear at pages F-1 through F-28 following the Exhibit List as required by "Part II—Item 8—Financial Statements and Supplementary Data" of this Form 10-K.

(2) Financial Statement Schedules.

Schedules are omitted because they are either not required, not applicable, or the information is otherwise included.

(3) Exhibits

The Company has filed with this report or incorporated by reference herein certain exhibits as specified below pursuant to Rule 12b-32 under the Exchange Act.

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
2.1 +	Share Exchange Agreement, dated December 1, 2016	S-1	333-222441	2.1	1/5/2018	
3.1	Certificate of Incorporation	S-1	333-222441	3.1	1/5/2018	
3.2	Certificate of Amendment to the Certificate of Incorporation	S-1	333-222441	3.2	1/5/2018	
3.3	Bylaws	S-1	333-222441	3.3	1/5/2018	
3.4	Certificate of Designations of Series A Convertible Preferred Stock	S-1	333-222441	3.4	1/5/2018	
3.5	Certificate of Amendment of Certificate of Designations of Series A Convertible Preferred Stock	10-Q	001-38389	3.1	5/14/2018	
4.1	Form of Common Stock Certificate	S-1	333-222441	4.1	1/5/2018	
4.2	Form of Series A Convertible Preferred Stock Certificate	S-1	333-222441	4.2	1/5/2018	
4.3	Form of Exchange Warrant	S-1	333-222441	4.3	1/5/2018	
4.4	Form of Placement Agent Warrant	S-1	333-222441	4.4	1/5/2018	
4.5	Form of Registration Rights Agreement	S-1	333-222441	4.5	1/5/2018	

4.6	Form of May 2017 Consultant Warrant	S-1	333-222441	4.6	1/5/2018
4.7	Form of Placement Agent Royalty Payment Rights Certificate	S-1	333-222441	4.7	1/5/2018
4.8	Form of Amendment to Registration Rights Agreement	S-1	333-222441	4.8	1/5/2018
4.9	Form of Ten Percent Warrant	S-1	333-222441	4.9	1/5/2018
4.10	Form of Royalty Payment Rights Certificate	S-1/A	333-222441	4.10	1/31/2018
4.11	Form of June 2018 Consultant Warrant	10-Q	001-38389	4.1	8/13/2018
4.12	Form of May 2017 Additional Consultant Warrant	10-Q	001-38389	4.2	8/13/2018
4.13	Form of July 2018 Consultant Warrant	10-Q	001-38389	4.3	8/13/2018
4.14	Form of November 2018 Consultant Warrant	10-Q	001-38389	4.4	11/14/2018
10.1	Placement Agency Agreement, dated December 1, 2016, between the Company and Placement Agent	S-1	333-222441	10.1	1/5/2018
10.2	Form of Subscription Agreement	S-1	333-222441	10.2	1/5/2018
10.3	Form of Voting Agreement, dated December 1, 2016, by and among the Company and the stockholders named therein	S-1	333-222441	10.3	1/5/2018
10.4 †	2016 Equity Incentive Plan and 2016 Israel Sub-Plan	S-1	333-222441	10.4	1/5/2018
10.5 †	Form of Incentive Stock Option Agreement	S-1	333-222441	10.5	1/5/2018
10.6 †	Form of Non-Qualified Stock Option Agreement	S-1	333-222441	10.6	1/5/2018
10.7 †	Form of Restricted Stock Agreement	S-1	333-222441	10.7	1/5/2018
10.8 †	Form of Assumed Options to Israeli Employees and Directors Agreement	S-1	333-222441	10.8	1/5/2018
10.9	Form of Assumed Options to Israeli Non-Employees and Controlling Shareholders Agreement	S-1	333-222441	10.9	1/5/2018
10.10 †	Form of Israeli Option Grant to Israeli Employees and Directors Agreement	S-1	333-222441	10.10	1/5/2018

10.11	Form of Israeli Option Grant to Israeli Non-Employees and Controlling Shareholders Agreement	S-1	333-222441	10.11	1/5/2018	
10.12 †	Employment Agreement, dated December 22, 2016, between the Company and Mark Pomeranz	S-1	333-222441	10.12	1/5/2018	
10.13	Lease, dated April 13, 2017, between Company and Victoriana Building, LLC	S-1	333-222441	10.13	1/5/2018	
10.14	Form of Subscription Agreement for Convertible Notes Offering	S-1	333-222441	10.14	1/5/2018	
10.15	Finders Agreement, dated October 14, 2016, between the Company and Aegis Capital Corporation	S-1	333-222441	10.15	1/5/2018	
10.16	Finders Agreement, dated December 22, 2016, between the Company and Aegis Capital Corporation	S-1	333-222441	10.16	1/5/2018	
10.17 †	Form of Indemnification Agreement	S-1	333-222441	10.17	1/5/2018	
10.18 †	Employment Agreement, dated August 16, 2017, between the Company and Andrew Taylor	S-1	333-222441	10.18	1/5/2018	
10.19 #	Supply Agreement, dated September 1, 2017, between Motus GI Technologies Ltd. and Polyzen, Inc.	S-1/A	333-222441	10.19	2/7/2018	
10.20 †	Amended and Restated Employment Agreement, effective September 24, 2018, between the Company and Mark Pomeranz	8-K	001-38389	10.2	9/25/2018	
10.21 †	Employment Agreement, effective October 1, 2018, between the Company and Timothy P. Moran	8-K	001-38389	10.1	9/25/2018	
10.22	Form of Restricted Stock Unit Award Agreement					X
10.23 †	Amended and Restated Employment Agreement, effective March 26, 2019, between the Company and Andrew Taylor					X
21.1	List of Subsidiaries of the Company	S-1	333-222441	21.1	1/5/2018	
23.1	Consent of EisnerAmper LLP					X
23.2	Consent of Brightman Almagor Zohar & Co.					X
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a)					X

31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a)	X
32.1 **	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350	X
101.INS	XBRL INSTANCE DOCUMENT	X
101.SCH	XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT	X
101.CAL	XBRL TAXONOMY EXTENSION CALCULATION LINKBASE	X
101.DEF	XBRL TAXONOMY EXTENSION DEFINITION LINKBASE	X
101.LAB	XBRL TAXONOMY EXTENSION LABELS LINKBASE	X
101.PRE	XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE	X

+ As permitted by Item 601(b)(2) of Regulation S-K, certain schedules to this agreement have not been filed herewith. The company will furnish supplementally a copy of any omitted schedule to the SEC upon request.

† Indicates management contract or compensatory plan.

Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been submitted separately to the SEC.

** The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf on the date set forth below by the undersigned thereunto duly authorized.

MOTUS GI HOLDINGS, INC.

Date: March 26, 2019

By: */s/ Timothy P. Moran*
Timothy P. Moran
Chief Executive Officer
(Principal Executive Officer)

Date: March 26, 2019

By: */s/ Andrew Taylor*
Andrew Taylor
Chief Financial Officer
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Timothy P. Moran Timothy P. Moran	President, Chief Executive Officer and Director (Principal Executive Officer)	March 26, 2019
/s/ Andrew Taylor Andrew Taylor	Chief Financial Officer (Principal Financial and Accounting Officer)	March 26, 2019
/s/ David Hochman David Hochman	Chairman of the Board	March 26, 2019
/s/ Mark Pomeranz Mark Pomeranz	President, Chief Operating Officer, and Director	March 26, 2019
/s/ Darren Sherman Darren Sherman	Director	March 26, 2019
/s/ Gary Jacobs Gary Jacobs	Director	March 26, 2019
/s/ Samuel Nussbaum Samuel Nussbaum	Director	March 26, 2019
/s/ Shervin Korangy Shervin Korangy	Director	March 26, 2019
/s/ Gary Pruden Gary Pruden	Director	March 26, 2019

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CONSOLIDATED FINANCIAL STATEMENTS

Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Motus GI Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Motus GI Holdings, Inc. and Subsidiaries (the "Company") as of December 31, 2018, and the related consolidated statements of comprehensive loss, changes in shareholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2018, and the consolidated results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has generated minimal revenues, experienced negative cash flows from operating activities and has incurred substantial operating losses from its activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Change in Accounting Principle

As discussed in Note 3 to the consolidated financial statements, the Company has changed its method of accounting for revenue recognition in 2018 due to the adoption of ASU 2014-09, Revenue from Contracts with Customers.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2018.

EISNERAMPER LLP
Philadelphia, PA
March 26, 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
To the Board of Directors and Stockholders of
MOTUS GI HOLDINGS, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Motus GI Holdings, Inc. and its subsidiaries (the "Company") as of December 31, 2017 and the related consolidated statement of comprehensive loss, stockholders' equity and cash flows for year ended December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and the results of its operations and its cash flows for the period then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company's minimal revenues and substantial operating losses raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 2 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Brightman Almagor Zohar & Co.
Brightman Almagor Zohar & Co.
Certified Public Accountants
Member of Deloitte Touche Tohmatsu Limited

Tel Aviv, Israel
March 28, 2018

We began serving as the Company's auditor in 2009. In 2018, we became the predecessor auditor.

Motus GI Holdings, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets		
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
Total current assets	22,051	8,286
Fixed assets, net	846	783
Other non-current assets	57	99
Total assets	$ 22,954	$ 9,168
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 2,140	$ 1,733
Other current liabilities	253	250
Total current liabilities	2,393	1,983
Contingent royalty obligation	1,953	1,662
Other non-current liabilities	91	—
Total liabilities	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	(61,378)	(39,121)
Total shareholders' equity	18,517	5,523
Total liabilities and shareholders' equity	$ 22,954	$ 9,168

The accompanying notes are an integral part of these consolidated financial statements.

Motus GI Holdings, Inc.
Consolidated Statements of Comprehensive Loss
(In thousands, except share and per share amounts)

	Years Ended December 31,	
	2018	**2017**
Revenue	$ 36	$ —
Cost of revenue	54	—
Gross loss	(18)	—
Operating expenses:		
Research and development	6,048	4,262
Sales and marketing	4,312	2,415
General and administrative	8,547	6,287
Total operating expenses	18,907	12,964
Operating loss	(18,925)	(12,964)
Warrant expense	(3,156)	—
Loss on change in estimated fair value of contingent royalty obligation	(291)	(252)
Finance income (expense), net	103	(6)
Other income	38	—
Foreign currency (loss) gain	(26)	22
Loss before income taxes	(22,257)	(13,200)
Income tax expense	—	—
Net loss	$ (22,257)	$ (13,200)
Basic and diluted loss per common share	$ (1.47)	$ (1.28)
Weighted average number of common shares outstanding, basic and diluted	15,137,144	10,332,554

Motus GI Holdings, Inc.
Consolidated Statement of Changes in Shareholders' Equity
(In thousands, except share and per share amounts)

	Preferred Stock		Preferred Series A Stock		Common Stock		Additional paid-in	Accumulated	Total shareholders'
	Shares	Amount	Shares	Amount	Shares	Amount	capital	deficit	equity
Balance at January 1, 2017	—	$ —	1,214,845	$ —	9,294,463	$ 1	$ 35,949	$ (25,921)	$ 10,029
Issuance of shares	—	—	366,283	—	1,098,849	—	6,474	—	6,474
Share based compensation	—	—	—	—	99,167	—	2,220	—	2,220
Exercise of options	—	—	—	—	754	—	—	—	—
Net loss	—	—	—	—	—	—	—	(13,200)	(13,200)
Balance at December 31 , 2017	—	—	1,581,128	—	10,493,233	1	44,643	(39,121)	5,523
Issuance of common shares upon initial public offering, net of offering costs of $2,546	—	—	—	—	3,500,000	—	14,955	—	14,955
Conversion of preferred shares to commons shares in connection with initial public offering	—	—	(1,581,128)	—	1,581,128	—	—	—	—
Issuance of common shares upon public offering, net of offering costs of $1,346	—	—	—	—	5,000,000	1	12,153	—	12,154
Issuance of common shares upon exercise of overallotments, net of offering costs of $164	—	—	—	—	806,000	—	2,141	—	2,141
Issuance of common shares upon exercise of options	—	—	—	—	14,396	—	48	—	48
Issuance of common shares upon cashless exercise of options	—	—	—	—	391	—	—	—	—
Share based compensation	—	—	—	—	45,000	—	2,797	—	2,797
Warrant expense	—	—	—	—	—	—	3,156	—	3,156
Net loss	—	—	—	—	—	—	—	(22,257)	(22,257)
Balance at December 31, 2018	—	$ —	—	$ —	21,440,148	$ 2	$ 79,893	$ (61,378)	$ 18,517

Motus GI Holdings, Inc.
Consolidated Statements of Cash Flows
(In thousands, except share and per share amounts)

	For the year ended December 31,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (22,257)	$ (13,200)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	152	65
Loss on change in estimated fair value of contingent royalty obligation	291	252
Share based compensation	2,475	2,220
Amortization of bond premium	33	—
Warrant expense	3,156	—
Inventory write-down	364	72
Write-down of workstations related to evaluation agreements	332	—
Changes in operating assets and liabilities:		
Accounts receivable	(5)	—
Inventory	(381)	3
Prepaid expenses and other current assets	69	(476)
Accounts payable and accrued expenses	744	210
Other current and non-current liabilities	94	456
Net cash used in operating activities	(14,933)	(10,398)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of fixed assets	(547)	(707)
Repayment from long-term deposits	—	(44)
Repayment of shareholder loan receivable	126	—
Purchase of available-for-sale securities	(5,043)	—
Proceeds from sale of available-for-sale securities	2,000	—
Purchase of held-to-maturity securities	(4,863)	—
Proceeds from sale of held-to-maturity securities	4,830	—
Net cash used in investing activities	(3,497)	(751)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from public offerings	31,000	—
Proceeds from exercise of over-allotment options	2,305	—
Proceeds from exercise of options	48	—
Proceeds from issuance of shares, net of financing costs of $851	—	6,474
Financing fees	(3,812)	(37)
Net cash provided by financing activities	29,541	6,437
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	11,111	(4,712)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	6,939	11,651
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 18,050	$ 6,939
SUPPLEMENTAL CASH FLOW INFORMATION:		
CASH PAID FOR:		
Interest	$ —	$ —
Income taxes	$ —	$ —
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING ACTIVITIES:		
Reclassification of deferred financing costs from current assets to common stock	$ 602	$ —
Cashless exercise of options	$ 2	$ —
Financing fees included in accounts payable and accrued expenses	$ 207	$ 565

Note 1 – Description of Business

Motus GI Holdings, Inc. (the "Company") was incorporated in Delaware, U.S.A. in September 2016. The Company and its subsidiaries, Motus, Ltd. and Motus, Inc., are collectively referred to as "Motus GI" or the "Company".

The Company has developed the Pure-Vu System (the "Pure-Vu System"), a medical device that has received 510(k) clearance from the U.S. Food and Drug Administration (the "FDA") and CE mark approval in the European Economic Area. The Pure-Vu System is 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 by irrigating the colon and evacuating the irrigation fluid (water), feces and other bodily fluids and matter. To date, as part of the limited market development launch, the Company has focused on collecting additional clinical and health economic data, as exemplified by the initiated Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement Study (the "REDUCE Study"), along with garnering valuable experience in key hospitals on the use of the Pure-Vu System to support a planned full launch in the United States inpatient colonoscopy market in 2019. The Company does not expect to generate significant revenue from product sales unless and until the Company expands its commercialization efforts.

Note 2 – Going Concern

To date, the Company has generated minimal revenues, experienced negative cash flows from operating activities and has incurred substantial operating losses from its activities. Management expects the Company to continue to generate substantial operating losses and to continue to fund its operations primarily through utilization of its current financial resources, future product sales, and through additional raises of capital.

The Company has financed its operations primarily through sales of equity-related securities. At December 31, 2018, the Company had an accumulated deficit of approximately $61.4 million, total current assets of approximately $22.1 million and total current liabilities of approximately $2.4 million resulting in working capital of approximately $19.7 million. At December 31, 2018, the Company had cash and cash equivalents, and short-term investments of approximately $21.1 million. Based on the Company's current business plan, it believes their cash, cash equivalents, and short-term investments balance as of December 31, 2018 will be sufficient to meet its anticipated cash requirements through the fourth quarter of 2019. However, there is no assurance that the current business plan will be achievable.

Such conditions raise substantial doubts about the Company's ability to continue as a going concern. Management's plan includes revenue generation through the sale of products and raising funds from outside investors. However, there is no assurance that such sale of products will occur or that outside funding will be available to the Company, will be obtained on favorable terms or will provide the Company with sufficient capital to meet its objectives. These financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount and classification of liabilities that may be required should the Company be unable to continue as a going concern.

Note 3 – Significant Accounting Policies

A summary of the significant accounting policies applied in the preparation of the accompanying consolidated financial statements follows:

Basis of presentation and principles of consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and include the accounts of the Company and its wholly owned subsidiaries, Motus Ltd., an Israel corporation, which has operations in Tirat Carmel, Israel, and Motus Inc., a Delaware corporation, which has operations in the U.S. All inter-company accounts and transactions have been eliminated in consolidation.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current period presentation. The Company reclassified short-term deposits to prepaid expenses and other current assets, other current liabilities to accounts payable and accrued expenses, revenue and cost of revenue to research and development expense, and finance income (expense), net to loss on change in estimated fair value of contingent royalty obligation and foreign currency (loss) gain.

Use of estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Functional currency and foreign currency translation

The functional currency of the Company, inclusive of foreign subsidiaries, is the U.S dollar ("dollar") since the dollar is the currency of the primary economic environment in which the Company has operated and expects to continue to operate in the foreseeable future. Transactions and balances denominated in dollars are presented at their original amounts. Transactions and balances denominated in foreign currencies have been re-measured to dollars in accordance with the provisions of ASC 830-10, "Foreign Currency Translation". All transaction gains and losses from re-measurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the statement of comprehensive loss as foreign currency (loss) gain, as appropriate.

Cash and cash equivalents

The Company considers all highly liquid investment securities with an original maturity of three months or less to be cash equivalents. Due to the short-term maturity of such investments, the carrying amounts are a reasonable estimate of fair value. Cash and cash equivalents include cash on-hand and highly-rated U.S. government backed money market fund investments.

Short-term investments

The Company invests all excess cash primarily in debt securities.

Investment securities that management has the positive intent and ability to hold to maturity are classified as held-to-maturity securities and are carried at amortized cost. Purchase premiums and discounts are recognized in finance income (expense), net over the term of the security. Investment securities not classified as held-to-maturity securities are classified as available-for-sale securities and recorded at fair value, with unrealized gains and losses reported in net loss. Gains and losses on the sale of available-for-sale securities are recorded on the trade date.

Management evaluates whether available-for-sale securities and held-to-maturity securities are other-than-temporarily impaired (OTTI) on a quarterly basis. Debt securities with unrealized losses are considered OTTI if the Company intends to sell the security or if it is more likely than not that the Company will be required to sell such security prior to any anticipated recovery. If management determines that a security is OTTI under these circumstances, the impairment recognized in earnings is measured as the entire difference between the amortized cost and the then-current fair value. During the years ended December 31, 2018 and 2017, no investment OTTI losses were realized.

The Company's investment policy is focused on the preservation of capital, liquidity and return. From time to time, the Company may sell certain securities, but the objectives are generally not to generate profits on short-term differences in price.

Revenue Recognition

The FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. The Company adopted this ASU effective January 1, 2018 on a full retrospective basis. Adoption of this standard did not result in significant changes to accounting policies, business processes, systems or controls, or have a material impact on the financial position, results of operations and cash flows or related disclosures. As such, prior period financial statements were not recast.

The Pure-Vu System – The Company developed a medical device system (a "Workstation") and a single use disposable sleeve (a "Disposable") designed to improve a colonoscopy procedure. The Company places its Workstations in a healthcare professional's office at no charge. The Disposables are used in conjunction with the Workstation. The Company typically enters into agreements for an evaluation period that have terms of two and three months and can be extended for successive periods by written agreement by both the Company and the customer. The Company initially provides the customer with a free demonstration pack of Disposables so that the customer can evaluate both the Workstation and Disposables. After the evaluation period, the Company charges a fee for the Disposables shipped once the free demonstration pack was used. The Company recognizes revenue for the fees charged over the term of the arrangement, which equated to usage.

(In thousands, except share and per share amounts)

For the purposes of U.S. GAAP only, this type of arrangement is treated as a short term operating lease, and thus is outside the scope of ASC 606 and is accounted for in accordance with ASC 840, Leases. While this arrangement is not an operating lease contractually, this arrangement is viewed as an operating lease for accounting purposes since in this arrangement the Company provides the customer the rights to use the Workstation and Disposables, which are interdependent, and the customer controls physical access to the Workstation while controlling the utility and output during the term of the arrangement.

During the year ended December 31, 2018, the Company recognized revenue of $36 from the sale of Disposables which equates to the usage period of the Disposables over the term of the agreement.

The Company recorded no revenue during the year ended December 31, 2017.

Accounts receivable and allowance for doubtful accounts

Accounts receivable are recorded and carried at the original invoiced amount less an allowance for any potential uncollectible amounts. The Company makes estimates for the allowance for doubtful accounts based upon its assessment of various factors, including historical experience, the age of the accounts receivable balances, credit quality of our customers, current economic conditions, and other factors that may affect customers' ability to pay. As of December 31, 2018 and 2017, the allowance for doubtful accounts was $0.

Inventory

Inventories are stated at lower of cost or net realizable value using the weighted average cost method and are evaluated at least annually for impairment. Inventories at December 31, 2018 and 2017 consisted of finished goods. Write-downs for potentially obsolete or excess inventory are made based on management's analysis of inventory levels, historical obsolescence and future sales forecasts. For the years ended December 31, 2018 and 2017, an inventory write-down charge of $364 and $72 was recorded, respectively, based on managements' determination to use the inventory for clinical trials, training and demonstration purposes.

Deferred financing fees

Initial public offering ("IPO") fees and expenses reflect costs directly attributable to the Company's IPO process, which closed on February 16, 2018. The Company accounted for such costs in accordance with ASC 340-10, *Other Assets and Deferred Costs.* ASC 340 states that costs directly attributable to a successfully completed offering of equity securities may be deferred and charged against the gross proceeds of the offering as a reduction of additional paid-in capital. As of December 31, 2017, the Company recorded deferred financing fees in the amount of $602 in relation to its IPO. During the year ended December 31, 2018, the entire amount of deferred financing fees was recorded as additional paid in capital.

Fixed assets, net

Fixed assets are stated at cost less accumulated depreciation. Depreciation is calculated based on the straight-line method, at annual rates reflecting the estimated useful lives of the related assets, as follows:

Office equipment	5-15 years
Computers and software	3-5 years
Machinery	5-10 years
Lab and medical equipment	5-7 years
Leasehold improvements	Shorter of lease term or useful life

(In thousands, except share and per share amounts)

Fixed assets, summarized by major category, consist of the following for the years ended:

	December 31,	
	2018	2017
Office equipment	$ 144	$ 134
Computers and software	284	192
Machinery	329	328
Lab and medical equipment	391	279
Leasehold improvements	105	105
Total	1,253	1,038
Less: accumulated depreciation and amortization	(407)	(255)
Fixed assets, net	$ 846	$ 783

For the years ended December 31, 2018 and 2017, the Company recorded a write down charge related to workstations used for evaluations (see Revenue Recognition above) of $332 and $0, respectively.

Stock-based compensation

The Company applies ASC 718-10, "Share-Based Payment," which requires the measurement and recognition of compensation expenses for all share-based payment awards made to employees and directors including employee stock options under the Company's stock plans based on estimated fair values.

ASC 718-10 requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The fair value of the award is recognized as an expense on a straight-line basis over the requisite service periods in the Company's statement of comprehensive loss. The Company recognizes share-based award forfeitures as they occur rather than estimate by applying a forfeiture rate.

The Company accounts for stock-based compensation awards to non-employees in accordance with FASB ASC 505-50, "Equity-Based Payments to Non-Employees" ("FASB ASC 505-50"). Under FASB ASC 505-50, the Company determines the fair value of the warrants or stock-based compensation awards granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable.

All issuances of stock options or other equity instruments to non-employees as consideration for goods or services received by the Company are accounted for based on the fair value of the equity instruments issued. Non-employee equity based payments are recorded as an expense over the service period, as if the Company had paid cash for the services. At the end of each financial reporting period, prior to vesting or prior to the completion of the services, the fair value of the equity based payments will be re-measured and the non-cash expense recognized during the period will be adjusted accordingly. Since the fair value of equity based payments granted to non-employees is subject to change in the future, the amount of the future expense will include fair value re-measurements until the equity based payments are fully vested or the service completed.

The Company recognizes compensation expense for the fair value of non-employee awards based on the straight-line method over the requisite service period of each award.

The Company estimates the fair value of stock options granted as equity awards using a Black-Scholes options pricing model. The option-pricing model requires a number of assumptions, of which the most significant are share price, expected volatility and the expected option term (the time from the grant date until the options are exercised or expire). Expected volatility is estimated based on volatility of similar companies in the technology sector. The Company has historically not paid dividends and has no foreseeable plans to issue dividends. The risk-free interest rate is based on the yield from governmental zero-coupon bonds with an equivalent term. The expected option term is calculated for options granted to employees and directors using the "simplified" method. Grants to non-employees are based on the contractual term. Changes in the determination of each of the inputs can affect the fair value of the options granted and the results of operations of the Company.

Basic and diluted net loss per share

Basic loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the year. Diluted loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the year, plus the number of common shares that would have been outstanding if all potentially dilutive ordinary shares had been issued, using the treasury stock method, in accordance with ASC 260-10 "Earnings per Share". Potentially dilutive common shares were excluded from the calculation of diluted loss per share for all periods presented due to their anti-dilutive effect due to losses in each period.

Research and development expenses, net

Research and development expenses are charged to the consolidated statement of comprehensive loss as incurred. Grants received for funding of approved research and development projects are recognized at the time the Company is entitled to such grants, on the basis of the costs incurred expenses.

Patent costs

Costs incurred in connection with acquiring patent rights and the protection of proprietary technologies are charged to expense as incurred.

Liabilities due to termination of employment agreements

Under Israeli employment laws, employees of Motus Ltd. are included under Article 14 of the Severance Compensation Act, 1963 ("Article 14") for a portion of their salaries. According to Article 14, these employees are entitled to monthly deposits made by Motus Ltd. on their behalf with insurance companies.

Payments in accordance with Article 14 release Motus Ltd. from any future severance payments (under the Israeli Severance Compensation Act, 1963) with respect of those employees. The aforementioned deposits are not recorded as an asset in the Company's balance sheet, and there is no liability recorded as the Company does not have a future obligation to make any additional payments.

Income taxes

The Company provides for income taxes using the asset and liability approach. Deferred tax assets and liabilities are recorded based on the differences between the financial statement and tax bases of assets and liabilities and the tax rates in effect when these differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. As of December 31, 2018 and 2017, the Company had a full valuation allowance against deferred tax assets.

The Company is subject to the provisions of ASC 740-10-25, Income Taxes (ASC 740). ASC 740 prescribes a more likely-than-not threshold for the financial statement recognition of uncertain tax positions. ASC 740 clarifies the accounting for income taxes by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. On a quarterly basis, the Company undergoes a process to evaluate whether income tax accruals are in accordance with ASC 740 guidance on uncertain tax positions. There are currently no open Federal or State audits. The Company has not recorded any liability for uncertain tax positions at December 31, 2018 or December 31, 2017.

The Tax Cuts and Jobs Act (the "Tax Act"), enacted on December 22, 2017, among other things, permanently lowered the statutory federal corporate tax rate from 35% to 21%, effective for tax years including or beginning January 1, 2018. Under the guidance of ASC 740, "Income Taxes" ("ASC 740"), the Company reduced its gross deferred tax assets and corresponding valuation allowance by approximately $0.4 million on the date of enactment based on the reduction in the overall future tax benefit expected to be realized at the lower tax rate implemented by the new legislation. Although in the normal course of business the Company is required to make estimates and assumptions for certain tax items which cannot be fully determined at period end, the Company did not identify items for which the income tax effects of the Tax Act have not been completed as of December 31, 2017 and, therefore, considers its accounting for the tax effects of the Tax Act on its deferred tax assets and liabilities to be complete as of December 31, 2017.

(In thousands, except share and per share amounts)

For the years ended December 31, 2018 and 2017, the Company recorded zero income tax expense. No tax benefit has been recorded in relation to the pre-tax loss for the years ended December 31, 2018 and 2017, due to a full valuation allowance to offset any deferred tax asset related to net operating loss carry forwards attributable to the losses.

Fair value of financial instruments

The Company accounts for financial instruments in accordance with ASC 820, "Fair Value Measurements and Disclosures" ("ASC 820"). ASC 820 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy under ASC 820 are described below:

Level 1 – Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2 – Quoted prices in non-active markets or in active markets for similar assets or liabilities, observable inputs other than quoted prices, and inputs that are not directly observable but are corroborated by observable market data;

Level 3 – Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

There were no changes in the fair value hierarchy leveling during the years ended December 31, 2018 and 2017.

The following table summarizes the fair value of our financial assets and liabilities that were accounted for at fair value on a recurring basis, by level within the fair value hierarchy, as of December 31, 2018 and 2017:

	December 31, 2018			
	Level 1	Level 2	Level 3	Fair Value
Assets				
Short-term investments	$ 3,043	$ —	$ —	$ 3,043
Liabilities				
Contingent royalty obligation	$ —	$ —	$ 1,953	$ 1,953

	December 31, 2017			
	Level 1	Level 2	Level 3	Fair Value
Liabilities				
Contingent royalty obligation	$ —	$ —	$ 1,662	$ 1,662

(In thousands, except share and per share amounts)

Financial instruments with carrying values approximating fair value include cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses, and certain other current liabilities, due to their short-term nature.

Contingent Royalty Obligation

In estimating the fair value of the Company's contingent royalty obligation (see Note 7), the Company used the discounted cash flow method as of December 31, 2018 and 2017. Based on the fair value hierarchy, the Company classified contingent royalty obligation within Level 3 because valuation inputs are based on projected revenues discounted to a present value.

The following table sets forth a summary of changes in the estimated fair value of the Company's Level 3 contingent royalty obligation for the years ended December 31, 2018 and 2017:

	Fair Value Measurements of Contingent Royalty Obligation (Level 3)
Balance at January 1, 2017	$ 1,410
Change in estimated fair value of contingent royalty obligation	252
Balance at December 31, 2017	1,662
Change in estimated fair value of contingent royalty obligation	291
Balance at December 31, 2018	$ 1,953

The contingent royalty obligation is re-measured at each balance sheet date using the following assumptions as of December 31, 2018 and 2017: 1) Discount rate of 20%, and 2) rate of royalty payment of 3%.

In accordance with ASC-820-10-50-2(g), the Company performed a sensitivity analysis of the liability, which was classified as a Level 3 financial instrument. The Company recalculated the fair value of the liability by applying a +/- 2% change to the input variable in the discounted cash flow model; the discount rate. A 2% decrease in the discount rate would increase the liability by approximately $210 and a 2% increase in the discount rate would decrease the liability by approximately $185.

Recent accounting standards

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. Originally, entities were required to adopt ASU 2016-02 using a modified retrospective approach at the beginning of the earliest comparative period presented in the financial statements and the recognition of a cumulative-effect adjustment to the opening balance of retained earnings. The FASB subsequently issued Accounting Standards Update No. 2018-10 and Accounting Standards Update No. 2018-11 in July 2018, which provide clarifications and improvements to ASU 2016-02 (collectively, the "new lease standard"). Accounting Standards Update No. 2018-11 also provides the optional transition method which allows companies to apply the new lease standard at the adoption date instead of at the earliest comparative period presented and continue to apply the provisions of the previous lease standard in its annual disclosures for the comparative periods. The new lease standard requires lessees to present a right-of-use asset and a corresponding lease liability on the balance sheet. Lessor accounting is substantially unchanged compared to the current accounting guidance. Additional footnote disclosures related to leases will also be required.

On January 1, 2019, the Company adopted the new lease standard using the optional transition method. The comparative financial information will not be restated and will continue to be reported under the previous lease standard in effect during those periods. In addition, the new lease standard provides a number of optional practical expedients in transition. The Company elected the package of practical expedients. As such, the Company will not reassess whether expired or existing contracts are or contain a lease; will not need to reassess the lease classifications or reassess the initial direct costs associated with expired or existing leases. The Company did not elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable to the Company.

The new lease standard also provides practical expedients for an entity's ongoing accounting. The Company elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, the Company will not recognize ROU assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. The Company elected the practical expedient to not separate lease and non-lease components for certain classes of assets (office buildings).

On January 1, 2019, the Company expects to recognize right of use assets and lease liabilities in the range of approximately $800-$1,100 and no adjustment to the accumulated deficit. The Company does not expect the adoption of the new lease standard to impact its consolidated statement of comprehensive loss or its consolidated statement of cash flows.

In June 2016, the FASB issued ASU 2016-13 "Financial Instruments – Credit Losses" to improve information on credit losses for financial assets and net investment in leases that are not accounted for at fair value through net income. The ASU replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses. The ASU is effective for the Company in the first quarter of 2020, with early adoption permitted. The Company is currently evaluating the effect the adoption of this ASU will have on its consolidated financial statements.

(In thousands, except share and per share amounts)

In November 2016, the FASB issued ASU No. 2016-18 "Statement of Cash Flows (Topic 230): Restricted Cash" which requires that restricted cash and restricted cash equivalents be included as components of total cash and cash equivalents as presented on the statement of cash flows. This amendment is effective for periods beginning after December 15, 2017 for public entities. The Company adopted the guidance in the first quarter of 2018 on a retrospective basis. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, "Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting," which clarifies when a change to terms or conditions of a share-based payment award must be accounted for as a modification. The new guidance requires modification accounting if the vesting condition, fair value or the award classification is not the same both before and after a change to the terms and conditions of the award. The new guidance was adopted by the Company on January 1, 2018, on a prospective basis. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, "Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting", which simplifies the accounting for nonemployee share-based payment transactions. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The Company will adopt ASU 2018-07 effective January 1, 2019, and the adoption of this ASU will not have a material effect on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, "Changes to Disclosure Requirements for Fair Value Measurements", which will improve the effectiveness of disclosure requirements for recurring and nonrecurring fair value measurements. The standard removes, modifies, and adds certain disclosure requirements, and is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company will be evaluating the impact this standard will have on the Company's consolidated financial statements.

Note 4 – Short-term Investments

Short term investments as of December 31, 2018 consist of available-for-sale securities which are carried at fair value. Interest and dividends on short-term investments are included in finance income, net. The Company did not have any short-term investments at December 31, 2017.

The following table summarizes, by major security type, the Company's short-term investments as of December 31, 2018:

	Amortized Cost	Carrying Value
Mutual fund, available for sale	$ 3,043	$ 3,043
Total	$ 3,043	$ 3,043

Note 5 – Prepaid Expenses and Other Current Assets

During the year ended December 31, 2018, the Company entered into non-employee agreements with service providers where it issued fully vested and non-forfeitable warrants and common stock for future services to be rendered. As of December 31, 2018, the Company recorded, in the aggregate, a prepaid expense totaling $344 for the value of the vested warrants.

The Company contracts with vendors to produce components and inventory for the Company's clinical studies, training, and future sales. As of December 31, 2018 and 2017, the Company recorded advanced payments as prepaid expenses totaling $353 and $408, respectively, with two of these suppliers which was recorded as vendor deposits against future purchases.

(In thousands, except share and per share amounts)

Note 6 – Other Current and Non-Current Liabilities

As of December 31, 2018 and 2017, other current and non-current liabilities consisted of the following:

Other Current Liabilities:	December 31,	
	2018	2017
Employment buy-out payments	$ 240	$ —
Royalty on coated products	13	—
Deferred financing fees	—	250
Total	$ 253	$ 250

Other Non-Current Liabilities:	December 31,	
	2018	2017
Royalty on coated products	38	—
Deferred rent	53	—
Total	$ 91	$ —

Note 7 – Commitments and Contingencies

Royalty on Coated Products

On January 30, 2018, the Company entered into a license and supply agreement with a third party whereby it was granted a worldwide license to sell its products coated with an agent that is the intellectual property of the third party for providing a lubricious surface to the Company's products (a "Coated Product" or "Coated Products"). The third party is entitled to a royalty in the amount of:

a. 2% of the first $25 million in annual net sales of Coated Products; and
b. 1.5% once annual net sales exceed $25 million of Coated Products.

The above two tiers reset annually on January 1st of each calendar year.

Minimum royalties shall be paid for each Coated Product sold by the Company as follows:

a. January 1, 2020 to December 31, 2020 - $5 per calendar quarter;
b. January 1, 2021 to December 31, 2021 - $10 per calendar quarter;
c. January 1, 2022 and beyond - $15 per calendar quarter.

Additionally, the Company shall make one-time milestone payments as follows:

a. $12.5 due 6 months after the first commercial sale of a Coated Product.
b. $12.5 due 12 months after the first commercial sale of a Coated Product.
c. $25 due 18 months after the first commercial sale of a Coated Product.

(In thousands, except share and per share amounts)

For the year ended December 31, 2018, the Company recorded $50 as general and administrative expense to accrue the one-time milestone payments in anticipation of the first commercial sale of a coated product in the next six months. As of December 31, 2018, the Company has recorded $13 as other current liabilities and $38 as long-term liabilities. After discussions with the vendor, previous shipments have been deemed for pilot use and not a commercial sale.

Royalties to the IIA

The Company has received grants from the Government of the State of Israel through the Israeli National Authority for Technical Innovation (the "IIA") (formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry (the "OCS")) for the financing of a portion of its research and development expenditures pursuant to the Israeli law for Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984 ("Research Law"), and the regulations previously promulgated thereunder, as well as the IIA's rules and benefit tracks which apply to companies receiving IIA funding (collectively, including the Research Law, the "IIA Regulations"). The Company has received funding from the IIA, which was received and recorded between the periods ending December 31, 2011 through 2016, in the aggregate amount of $1,332 and has a contingent obligation to the IIA in the amount of approximately $1,383 and $1,370 as of December 31, 2018 and 2017, respectively, which is generally repaid in the form of royalties ranging from 3% to 3.5% (which may be increased under certain circumstances) of revenues generated (in any fashion) from know-how developed using IIA grants, up to an aggregate of 100% (which may be increased under certain circumstances) of the U.S. dollar-linked value of the grant, plus interest at the rate of 12-month LIBOR.

Repayment of the grants is contingent upon the successful completion of the Company's R&D programs and generating sales. The Company has no obligation to repay these grants if the R&D program fails, is unsuccessful, or aborted, or if no sales are generated. The Company has recorded an immaterial expense and liability during the years ended December 31, 2018 and 2017 as sales occur.

Lease Agreements

On April 13, 2017, the Company entered into a lease for a facility in Fort Lauderdale, Florida, which the Company began occupying in October 2017. On December 20, 2017, the Company entered into an amended lease agreement upon remeasurement of the lease space. The facility currently consists of approximately 4,600 square feet, which will increase to approximately 6,500 square feet by the second year of the lease. The term runs for seven years and two months from September 2017. Annual base rent is amended to $159 per year, subject to annual increases of 2.75%, which is recognized on a straight-line basis.

On January 1, 2015, the Company entered into a five year lease agreement for its facilities in Israel through December 31, 2019. The annual lease fees are $82. The Company has an option to renew the lease agreement for three more years after the initial term period ends. The annual lease fees will increase by 4% beginning on the renewal option date.

For the years ended December 31, 2018 and 2017, the Company recorded rent expense of $526 and $211, respectively.

Certain vehicles are leased by the Company under agreements that expire at various dates through 2021.

Many of these leases provide for payment by the Company, as the lessee, of taxes, insurance premiums, costs of maintenance and other costs. At December 31, 2018, the Company had the following future minimum lease commitments:

Twelve Months Ended December 31,	Amount
2019	$ 376
2020	282
2021	207
2022	181
2023	184
Thereafter	157
Total	$ 1,387

Royalty Payment Rights on Royalty Payment Rights Certificates

The Company filed a Certificate of Designation of Preferences, Rights and Limitations (the "Certificate of Designation"), establishing the rights and preferences of the holders of the Series A Convertible Preferred Stock, including certain directors and officers of the Company (the "Royalty Payment Rights"). As set forth in the in the Certificate of Designation, the Royalty Payment Rights initially entitled the holders in aggregate, to a royalty in an amount of:

- 3% of net sales subject to a maximum in any calendar year equal to the total dollar amount of Units closed on in the Company's 2017 private placement (the "2017 Private Placement"); and
- 5% of licensing proceeds subject to a maximum in any calendar year equal to the total dollar amount of Units closed on in the 2017 Private Placement.

In addition, in connection with completion of the 2017 Private Placement, the Company issued the placement agent royalty payment rights certificates (the "Placement Agent Royalty Payment Rights Certificates") which grants the placement agent, and its designees, the right to receive, in the aggregate, 10% of the amount of payments paid to the holders of the Series A Convertible Preferred Stock, or the holders of the Royalty Payment Rights Certificates (the "Royalty Payment Rights Certificates"), upon the conversion of the Series A Convertible Preferred Stock into shares of the Company's common stock. The Placement Agent Royalty Payment Rights Certificates are on substantially similar terms as the Royalty Payment Rights of the Series A Convertible Preferred Stock.

The Royalty Payment Rights Certificate obligation and Placement Agent Royalty Payment Rights Certificate obligation (the "Contingent Royalty Obligation") was recorded as a liability at fair value as "Contingent royalty obligation" in the consolidated balance sheets at December 31, 2018 and 2017 (see Contingent Royalty Obligation below). The fair value at inception was allocated to the royalty rights and the residual value was allocated to the preferred shares and recorded as equity.

The Company amended its Certificate of Designation to modify the Royalty Payment Rights when the Company consummated its Initial Public Offering ("IPO") on February 16, 2018, at which time the Company converted the Series A Convertible Preferred Stock into shares of the Company's common stock and issued the Royalty Payment Rights Certificates. Pursuant to the terms of the Royalty Payment Rights Certificates, if and when the Company generates sales of the current and potential future versions of the Pure-Vu System, including disposables, parts, and services, or if the Company receives any proceeds from the licensing of the current and potential future versions of the Pure-Vu System, then the Company will pay to the holders of the Royalty Payment Rights Certificates a royalty (the "Royalty Amount") equal to, in the aggregate, in royalty payments in any calendar year for all products:

- 3% of Net Sales* for commercialized product directly;
- 5% of any Licensing Proceeds** for rights to commercialize the product if sublicensed by the Company to a third-party.

* Notwithstanding the foregoing, with respect to Net Sales based Royalty Amounts, (a) no Net Sales based Royalty Amount shall begin to accrue or become payable until the Company has first generated, in the aggregate, since its inception, Net Sales equal to $20,000 (the "Initial Net Sales Milestone"), and royalties shall only be computed on, and due with respect to, Net Sales generated in excess of the Initial Net Sales Milestone, and (b) the total Net Sales based Royalty Amount due and payable in any calendar year shall be subject to a royalty cap amount per calendar year of $30,000. "Net Sales" is defined in the Royalty Payment Rights Certificates. The Company has not reached the Initial Net Sales Milestone as of December 31, 2018.

** Notwithstanding the foregoing, with respect to Licensing Proceeds based Royalty Amounts, (a) no Licensing Proceeds based Royalty Amount shall begin to accrue or become payable until the Company has first generated, in the aggregate, since its inception, Licensing Proceeds equal to $3,500 (the "Initial Licensing Proceeds Milestone"), and royalties shall only be computed on, and due with respect to, Licensing Proceeds in excess of the Initial Licensing Proceeds Milestone and (b) the total Licensing Proceeds based Royalty Amount due and payable in any calendar year shall be subject to a royalty cap amount per calendar year of $30,000. "Licensing" Proceeds is defined in the Royalty Payment Rights Certificate. The Company has not reached the Initial Licensing Proceeds Milestone as of December 31, 2018.

The Royalty Amount will be payable up to the later of (i) the latest expiration date of the Company's patents issued as of December 22, 2016, or (ii) the latest expiration date of any pending patents as of December 22, 2016 that have since been issued or may be issued in the future (which is currently November 2034). Following the expiration of all such patents, the holders of the Royalty Payment Rights Certificates and the holders of the Placement Agent Royalty Payment Rights Certificates will no longer be entitled to any further royalties for any period following the latest to occur of such patent expiration.

On February 16, 2018, the date of the closing of the IPO, (1) the amendment to the Certificate of Designation became effective, (2) all outstanding shares of Series A Convertible Preferred Stock were converted into shares of the Company's common stock pursuant to a mandatory conversion, and (3) the Royalty Payment Rights Certificates were issued to the former holders of the Series A Convertible Preferred Stock.

Contingent Royalty Obligation

The Contingent Royalty Obligation was recorded as a long-term liability at fair value in the consolidated balance sheets at December 31, 2018 and 2017 in the amount of $1,953 and $1,662, respectively. For the years ended December 31, 2018 and 2017, the Company recorded a loss on change in fair value of Contingent Royalty Obligation in the amount of $291 and $236, respectively.

Employment Agreements

Employment Agreement with Mr. Moran

The Company entered into an employment agreement with Mr. Moran, which became effective on October 1, 2018. Under the terms of Mr. Moran's employment agreement, he holds the position of Chief Executive Officer and receives a base salary of $475 annually. In addition, Mr. Moran is eligible to receive an annual bonus payment in an amount equal to up to sixty percent (60%) of his then-Base Salary if the Board determines that he has met the target objectives communicated to him. For the first twelve months of his employment (the period from October 1, 2018 through October 1, 2019), the payout range for the Performance Bonus shall be between fifty percent (50%) and two hundred percent (200%) of the Bonus Target if the Board determines the objectives have been achieved. Thereafter, subsequent payout parameters will be determined by the Board based upon parameters set by the Board and Mr. Moran for an overall Company executive bonus program using market data and analysis input from a third-party expert compensation firm.

In connection with his employment agreement, Mr. Moran was granted (i) an option, granted on November 8, 2018, to purchase 495,000 shares (the "Initial Option Grant") of the Company's common stock pursuant to the Company's 2016 Equity Incentive Plan, at an exercise price of $3.78 per share (see Note 9 for recognition of stock options granted during 2018) and (ii) a restricted stock unit award granted on October 1, 2018 for 165,000 shares of common stock (the "Initial Restricted Stock Unit Award"). The Company valued the restricted stock award at its fair market value on the grant date for a total of $810 which vests in equal quarterly installments over four years, and common stock related to the restricted stock unit is issued in quarterly installments upon vesting. The Company recorded as general and administrative expense $152 in the consolidated statement of comprehensive loss for the restricted stock unit award for the year ended December 31, 2018. As agreed between Mr. Moran and the Board of Directors, the Initial Option Grant will vest in equal quarterly installments over three years commencing from October 1, 2018 and the restricted stock unit will vest in equal quarterly installments over four years commencing from October 1, 2018. Further, Mr. Moran was granted employment buy-out payments in the amount of $400 each on March 1, 2019, November 1, 2019, March 1, 2020 and November 1, 2020, which Mr. Moran will receive if actually employed by the Company on such dates. The employment buy-out payments are being accrued ratably for the amount earned from each payment date. During the year ended December 31, 2018, the Company recorded $240 related to the employment buy-out payments included in general and administrative expenses in the consolidated statement of comprehensive loss and in other current liabilities on the accompanying balance sheet as of December 31, 2018.

(In thousands, except share and per share amounts)

Amended and Restated Employment Agreement with Mr. Pomeranz

On September 24, 2018, the Company entered into an amended and restated employment agreement with Mark Pomeranz, pursuant to which Mr. Pomeranz transitioned from his previous role as President and Chief Executive Officer, into the role of President and Chief Operating Officer as of October 1, 2018. Under the terms of the amended and restated employment agreement, Mr. Pomeranz holds the position of President and Chief Operating Officer and receives a base salary of $385 annually. In addition, Mr. Pomeranz is eligible to receive (i) for the calendar year ending December 31, 2018, a bonus payment in an amount equal to up to thirty one and one quarter percent (31.25%) of his then base salary if the Board determines that he has met the target objectives communicated to him, with a payout range for the 2018 Bonus of between fifty percent (50%) and two hundred percent (200%) of the 2018 Bonus Target, and (ii) effective January 1, 2019 and thereafter an annual bonus payment in an amount equal to up to fifty percent (50%) of his base salary if the Board determines that he has met the target objectives communicated to him. Payout parameters for his bonus will be determined by the Board based upon parameters set by the Board and CEO for an overall Company executive bonus program using market data and analysis input from a third-party expert compensation firm.

Amended and Restated Employment Agreement with Mr. Taylor

On March 26, 2019, the Company entered into an amended and restated employment agreement with Andrew Taylor, the Company's Chief Financial Officer.

Under the terms of the amended and restated employment agreement, Mr. Taylor holds the position of Chief Financial Officer, and receives a base salary of $310 annually. In addition, Mr. Taylor is eligible to receive an annual bonus payment, initially for the twelve-month period ending December 31, 2019, in an amount equal to up to thirty-five percent (35%) of his base salary if the Board determines that he has met the target objectives communicated to him. Payout parameters for his bonus will be determined by the Board based upon parameters set by the Board and CEO for an overall Company executive bonus program using market data and analysis input from a third-party expert compensation firm.

Other Commitments

The Company has a severance contingency for severance payments to its CEO, COO, and CFO in the aggregate of approximately $1,319, in the event that they are terminated without cause or leave due to good cause, as outlined in their employee agreements. Management estimates that the likelihood of payment is remote; therefore, no liability was reflected in these consolidated financial statements.

Other Contractual Commitments

At December 31, 2018, the Company had the following future minimum other contractual commitments:

Year Ended December 31,	Amount
2019	$ 107
Thereafter	—
Total	$ 107

Note 8 – Related Party Transactions

Other than transactions and balances related to cash and share-based compensation to officers and directors, the Company did not have any transactions and balances with related parties and executive officers during the years ending December 31, 2018 and 2017 except for the following:

Shareholder Loan

During the year ended December 31, 2018, the Company received $126 in cash proceeds as repayment of a shareholder loan. The loan was entered into on May 15, 2017 for a principal balance of $122 at a stated interest rate of 3.4%. The loan principal and accrued interest was repaid in full as of December 31, 2018. For the years ended December 31, 2018 and 2017, the Company recorded $4 and $0 as finance income related to the shareholder loan.

Sales and Marketing Services Arrangement with FreeHold Surgical, Inc.

Beginning in the fourth quarter of 2017, the Company began to make payments to FreeHold Surgical, Inc ("FreeHold"), an entity in which one of our Directors serves as a Director and President, for services rendered beginning August 2017. In the third quarter of 2018, the agreement was amended to reduce the number of sales representatives from two to one and revise the fee arrangement from $25 to $8 for each month. Pursuant to the fee arrangement, the Company paid FreeHold a monthly amount of approximately $25 for each month through June 30, 2018 and approximately $8 for each month from July 1, 2018 for sales and marketing services performed for the Company, on a part time basis, by two Freehold sales representatives through June 2018 and one Freehold sales representative from July 2018 to September 2018 (the "FreeHold Services"). As of December 31, 2018 and 2017, the Company had $8 and $50 recorded as accounts payable to FreeHold, respectively. For the years ended December 31, 2018 and 2017, the Company recorded $192 and $80, respectively, as sales and marketing expense related to this arrangement. On October 31, 2018, the Company gave thirty-day notice to FreeHold for termination of its services agreement effective November 30, 2018.

Note 9 – Stockholder's Equity

Initial Public Offering

On February 16, 2018, the Company closed its IPO in which it sold 3,500,000 shares of the Company's common stock at a public offering price of $5.00 per share. In connection with the closing of the IPO, (1) the Company received net proceeds of approximately $15,000 after deducting underwriting discounts and commissions of $1,400 and other offering expenses of approximately $1,100, (2) the amendment to the registration rights agreement described below became effective, (3) the amendment to the Certificate of Designation described above in Note 7 became effective, (4) all outstanding shares of Series A Convertible Preferred Stock converted, on a one-to-one basis, into shares of the Company's common stock, (5) the Company issued the Royalty Payment Rights Certificates as described in Note 7, and (6) the Company issued warrants to certain of the former Series A Convertible Preferred Stock holders, pursuant to the amendment to the Registration Rights Agreement, the amendment to the Certificate of Designation, and the execution of a lock up agreement, to purchase an aggregate of 1,095,682 shares of the Company's common stock (the "Ten Percent Warrants"). The Ten Percent Warrants are currently exercisable, have a five-year term, and provide for cashless exercise. In addition, the Company granted the representative of the several underwriters in the IPO (the "Representative") a 30-day option (the "Over-Allotment Option") to purchase up to an aggregate 525,000 additional shares of the Company's common stock at an exercise price of $5.00 per share.

The Ten Percent Warrants were valued using the Black-Scholes option pricing model using the following assumptions, (i), exercise price of $5.00 (ii) expected life of 5 years, (iii) volatility of 67.08%, (iv) risk-free rate of 2.63%, and (v) dividend rate of zero. For the year ended December 31, 2018, the Company recorded $3,156 for the fair value of the Ten Percent Warrants as warrant expense in the accompanying consolidated statement of comprehensive loss.

On March 12, 2018, the Company issued an additional 56,000 shares of its common stock at a price of $5.00 per share, pursuant to the Representative's partial exercise of the Over-Allotment Option. In connection with the closing of the partial exercise of the Over-Allotment Option, the Company received net proceeds of $258 after deducting underwriting discounts and commissions of $22.

Follow On Public Offering

On December 24, 2018, the Company completed a follow on underwritten public offering of 5,750,000 shares of the Company's common stock at a public offering price of $2.70 per share (the "Follow On Offering"), inclusive of 750,000 shares issued pursuant to the full exercise of the underwriters option to purchase up to an additional 750,000 shares (the "Underwriters Option") of the Company's common stock in connection with the Follow On Offering. Net proceeds from the Follow On Offering were approximately $14,036, inclusive of $1,883 pursuant to the full exercise of the Underwriters Option, after deducting, in the aggregate, underwriting discounts and commissions $1,086 and other offering expenses of approximately $402.

Issuance of Common Stock and Warrants to Purchase Common Stock

On March 27, 2018, the Company's Board of Directors approved the issuance of 15,000 shares of the Company's common stock to a third party for services to be provided. The stock vests immediately and is subject to a lock-up through February 14, 2019. The Company recorded the fair market value of the stock as stock-based compensation in the amount of $69.

On June 6, 2018, the Company entered into a consultant agreement with a service provider which shall continue until the agreement is terminated by the Company or service provider by providing at least five business days' prior written notice. Pursuant to the agreement, the Company (a) issued a warrant on June 6, 2018 to purchase 10,000 shares of the Company's common stock, with an exercise price of $5.25 per share, at which time a measurement date was reached (b) upon the four (4) month anniversary of the execution of the agreement will issue a warrant to purchase 10,000 shares of the Company's common stock, with an exercise price of $6.25 per share, and (c) upon the eight (8) month anniversary of the execution of the agreement, provided the service provider is still engaged at that time, will issue a warrant to purchase 10,000 shares of the Company's common stock, with an exercise price of $7.25 per share (collectively, such warrants referred to as the "Consultant Warrants"). The Consultant Warrants will each have a five-year term, vest immediately, and will provide for cashless exercise. Warrants totaling 30,000 in relation to this agreement were valued using the Black-Scholes option pricing model under the following assumptions, (i) expected life of 5 years, (ii) volatility of 67.25%, 69.23%, and 70.86% (iii) risk-free rate of 2.51%, 2.81%, and 3.07%, and (iv) dividend rate of zero. The fair value of the 30,000 warrants was initially estimated to be $95 at the inception of the agreement. At December 31, 2018, the fair value was re-measured to be $79 which is expensed using the straight-line method over eight months. The Company recorded $67 as general and administrative expense in the accompanying consolidated statement of comprehensive loss in relation to the 30,000 warrants for the year ended December 31, 2018.

On July 2, 2018, the Company entered into a consultant agreement with a service provider which shall continue until February 28, 2019, unless and until sooner terminated by the Company or service provider by providing, at any time after October 2, 2018, at least five business days' prior written notice. Pursuant to the agreement, the Company (i) issued a fully-vested and nonforfeitable warrant on July 2, 2018 (at which point a measurement date was reached) to purchase 25,000 shares of the Company's common stock, with an exercise price of $7.39 per share, and expires 12 months from the date of agreement, (ii) issued a fully-vested and nonforfeitable warrant on July 2, 2018 (at which point a measurement date was reached) to purchase 25,000 shares of the Company's common stock, with an exercise price of $7.39 per share, and expires 18 months from the date of the agreement, (iii) upon the three (3) month anniversary of the date of the agreement will issue a fully-vested and nonforfeitable warrant to purchase 25,000 shares of the Company's common stock with an exercise price of $8.75 per share, and expires 18 months from the date of the agreement and (iv) upon the six (6) month anniversary of the date of the agreement, provided the service provider is still engaged at that time, will issue a fully-vested and nonforfeitable warrant to purchase 25,000 shares of common stock of the Company with an exercise price of $10.00 per share, and expires 24 months from the date of the agreement. The warrants issued under this agreement are callable by the Company and it will have the right to require the consultant to exercise all or any warrants still unexercised for a cash exercise or the Company may re-purchase the warrant at a price of $0.01 per warrant share if the Company's stock trades above a closing floor price ranging from $9.00 to $13.00 per share for ten (10) consecutive trading days. In accordance with FASB ASC 480, the call feature is a conditional obligation upon an event not certain to occur that becomes mandatorily redeemable if that event occurs, the condition is resolved, or that event becomes certain to occur. Because the conditional event is within control of the Company, the call feature is not recognized for accounting purposes until the Company exercises its rights under agreement. Warrants totaling 100,000 in relation to this agreement were valued using the Black-Scholes option pricing model under the following assumptions, (i) expected life of 1-2 years, (ii) volatility of 62.04% - 65.84%, (iii) risk-free rate of 2.34% - 2.66%, and (iv) dividend rate of zero. The aggregate fair value of the 100,000 warrants was initially estimated to be $146 and was re-measured at December 31, 2018 for $122 which will be expensed using the straight-line method over eight months. The Company recorded $95 as general and administrative expense in the accompanying consolidated statement of comprehensive loss for the year ended December 31, 2018. As of December 31, 2018, the Company has recorded a prepaid expense in the amount of $27, related to the fully vested, nonforfeitable warrants issued for which services have not been rendered.

On July 3, 2018, the Company entered into an amendment to a consulting agreement dated May 27, 2017 as a continuation of investor relation and consulting services to extend the termination of the agreement to July 2019 and issued 30,000 shares of common stock which vests immediately and a warrant to purchase 90,000 shares of common stock which vests immediately. The warrants are exercisable at $8.50 per share and expire five years from the date of issuance. The 90,000 warrants were valued using the Black-Scholes option pricing model under the following assumptions, (i) expected life of 5 years, (ii) volatility of 68.31%, (iii) risk-free rate of 2.72%, and (iv) dividend rate of zero. The fair value of the 90,000 warrants and 30,000 shares of common stock was estimated to be $594 which will be expensed using the straight-line method over thirteen months, the expected term of the agreement. The Company recorded $276 as general and administrative expense in the accompanying consolidated statement of comprehensive loss for the year ended December 31, 2018. As of December 31, 2018, the Company has recorded a prepaid expense in the amount of $317, related to the fully vested nonforfeitable shares of common stock and warrants issued for which services have not been rendered.

Consultant Award

On July 3, 2018, the Company engaged an executive search firm (the "Firm") to conduct a confidential search for a Chief Executive Officer (the "CEO") for the Company. The terms of the engagement were that upon a successful search, the Company would compensate the Firm one-third of the total first-year actual cash compensation for the position. The Company agreed to (a) make payments based on the CEO's base salary of $475, and (b) make a true-up payment (the "True-up Payment") at the end of the CEO's first year of employment based on the actual cash compensation earned within the CEO's first year of employment, exclusive of any Employment Buy-Out Payments.

The recruiter was successful in recruiting a new CEO for the Company. An employment agreement was finalized and entered into during the third quarter and effective October 1, 2018. The Company deemed the Firm's services were rendered in the third quarter of 2018 as an employment agreement was finalized in September 2018. The CEO's annual base salary is $475 and is entitled to bonus and Employment Buy-Out Payments.

Firm Compensation

The Firm's total compensation is to be paid 75% in cash and 25% in equity in the form of a warrant valued per the last round valuation. The cash component for the initial base salary measurement for $119 was payable in three (3) monthly installments with the first installment dated at the start date of the engagement. Therefore, the first installment was dated July 3, 2018; since, the Company deemed the services began in July 2018. As of December 31, 2018, the $119 cash component has been paid and was expensed as general and administrative in the accompanying consolidated statement of comprehensive loss for the year ended December 31, 2018.

On November 8, 2018, the Company issued a warrant (the "Base Warrant") to purchase 7,917 shares of the Company's common stock, with an exercise price of $5.00 per share and expires on November 8, 2021, as payment for the equity component for the initial base salary measurement. The Base Warrant is fully-vested, nonforfeitable and was valued on November 8, 2018 (at which point a measurement date was reached) using the Black-Scholes option pricing model under the following assumptions, (i) expected life of 3 years, (ii) volatility of 63.62%, (iii) risk-free rate of 3.05%, and (iv) dividend rate of zero. The aggregate fair value of the 7,917 warrants was estimated to be $11 which was recorded as general and administrative expense in the accompanying consolidated statement of comprehensive loss for the year ended December 31, 2018.

The Firm's total compensation is the aggregate of one-third of the base salary of $475 which was paid as of December 31, 2018 and one-third of any additional cash compensation earned within the CEO's first year of employment. As of December 31, 2018, the Company owes the following payments: (i) a warrant (the "Contingent Warrant") for 25% of one-third of any additional cash compensation earned by the CEO during his first year of employment, and (ii) a cash payment for 75% of one-third of any additional cash compensation earned by the CEO during his first year of employment. For items (i) and (ii), a True-up Payment will be determined after the first year of employment ends and the additional cash compensation is known.

Contingent Warrant

The Contingent Warrant will be issued with an exercise price subject to adjustment and with a three-year term, to purchase shares of the Company's common stock. As of December 31, 2018, the Contingent Warrant has not been issued but will be fully vested upon issuance.

Consultant Expense

The Company valued the entire agreement and recorded $251 as general and administrative expense for the year ended December 31, 2018 as follows: (i) $158 earned for one-third of $475 paid 75% in cash and 25% by issuing the Base Warrant, and (ii) $93 for the estimated cash portion of the True-up Payment that will also be paid 75% in cash and 25% by issuing a variable number of warrants. As of December 31, 2018, the Company has recorded in the aggregate $93 in accounts payable and accrued expenses in relation to this agreement.

(In thousands, except share and per share amounts)

Employment Buy-Out Payments

The Firm agreed not to include any Employment Buy-Out Payments stipulated in the agreement as a calculation in the Firm's fee as these Employment Buy Out Payments were deemed to be earned at the CEO's previous place of employment. The Employment Buy-Out Payments represent any cash and equity bonuses earned that the CEO forfeited upon departing his previous place of employment, thus the Employment Buy-Out Payments will not be considered in the True-up Payment.

Warrants

A summary of the Company's warrants to purchase common stock activity is as follows:

	Shares Underlying Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at January 1, 2017	907,237	$ 5.00	2.92	$ —
Granted	433,632	5.21		
Outstanding at December 31, 2017	1,340,869	5.07	4.03	—
Granted	1,288,599	5.42		
Outstanding at December 31, 2018	2,629,468	$ 5.24	3.58	$ —

At December 31, 2018, outstanding warrants to purchase 2,629,468 shares of common stock were exercisable with a weighted-average exercise price per share of $5.24.

Stock Options

Exercise of Options

On February 21, 2018, a consultant exercised 896 options on a cashless basis which resulted in the issuance of 391 shares of the Company's common stock.

On July 5, 2018, the Company issued 773 shares of its common stock upon the exercise of 773 employee options at an exercise price of $4.50 per share. In connection with the exercise, the Company received $3 in proceeds.

On July 31, 2018, the Company issued 1,792 shares of its common stock upon the exercise of 1,792 employee options at an exercise price of $2.52 per share. In connection with the exercise, the Company received $5 in proceeds.

On August 23, 2018, the Company issued 3,943 shares of its common stock upon the exercise of 3,943 employee options at an exercise price of $2.38 per share. In connection with the exercise, the Company received $9 in proceeds.

On August 23, 2018, the Company issued 2,389 shares of its common stock upon the exercise of 2,389 employee options at an exercise price of $2.52 per share. In connection with the exercise, the Company received $6 in proceeds.

On September 14, 2018, the Company issued 5,000 shares of its common stock upon the exercise of 5,000 employee options at an exercise price of $4.50 per share. In connection with the exercise, the Company received $23 in proceeds.

(In thousands, except share and per share amounts)

On September 14, 2018, the Company issued 499 shares of its common stock upon the exercise of 499 employee options at an exercise price of $5.00 per share. In connection with the exercise, the Company received $2 in proceeds.

2016 Equity Incentive Plan

In December 2016, the Company adopted the Motus GI Holdings, Inc. 2016 Equity Incentive Plan (the "2016 Plan"). Pursuant to the 2016 Plan, the Company's board of directors may grant options to purchase shares of the Company's common stock, stock appreciation rights, restricted stock, stock units, performance shares, performance units, incentive bonus awards, other cash-based awards and other stock-based awards to employees, officers, directors, consultants and advisors. Pursuant to the terms of an annual evergreen provision in the 2016 Plan, the number of shares of common stock available for issuance under the 2016 Plan shall increase annually by six percent (6%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year; provided, however, that the board of directors may act prior to the first day of any calendar year to provide that there shall be no increase such calendar year, or that the increase shall be a lesser number of shares of our common stock than would otherwise occur. On January 1, 2018, pursuant to an annual evergreen provision, the number of shares of common stock reserved for future grants was increased by 629,594 shares. As of December 31, 2018, there was a total of 2,641,250 shares of common stock reserved for issuance under the 2016 Plan and there were 99,417 shares of common stock available for future grant under the 2016 Plan. In accordance with the terms of the 2016 Plan, effective as of January 1, 2019, the number of shares of common stock available for issuance under the 2016 Plan increased by 1,286,409 shares, which was six (6%) of the outstanding shares of common stock on December 31, 2018. As of January 1, 2019, the 2016 Plan had a total reserve of 3,927,659 shares and there were 1,381,473 shares available for future issuance.

A summary of the Company's stock option activity is as follows:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at January 1, 2017	125,730	$ 2.43	7.87	$ 204
Granted	2,020,769	4.51		
Exercised	(1,438)	2.38		
Forfeited/cancelled	(341,967)			
Outstanding at December 31, 2017	1,803,094	4.41	8.86	421
Granted	812,000	4.16		
Exercised	(15,292)	3.31		6
Forfeited/cancelled	(79,701)			
Outstanding at December 31, 2018	2,520,101	$ 4.32	8.72	$ —

The options granted during the year ended December 31, 2018 were valued using the Black-Scholes option pricing model using the following weighted average assumptions: (i) expected life of 5.8 years, (ii) volatility of 68.72%, (iii) risk free interest rate of 3.01% and (iv) dividend yield of zero. The weighted average grant date fair value during 2018 was $2.59.

The options granted during the year ended December 31, 2017 were valued using the Black-Scholes option pricing model using the following weighted average assumptions: (i) expected life of 5.8 years, (ii) volatility of 60%, (iii) risk free interest rate of 1.92% to 2.36% and (iv) dividend yield of zero.

At December 31, 2018, unamortized stock compensation for stock options was $2,898, with a weighted-average recognition period of 1.16 years.

At December 31, 2018, outstanding options to purchase 1,113,792 shares of common stock were exercisable with a weighted-average exercise price per share of $4.36.

For the year ended December 31, 2018, the Company recorded $1,832 for stock based compensation expense related to stock options.

For the year ended December 31, 2017, the Company recorded $1,744 for stock based compensation expense related to stock options.

Stock Based Compensation

The following table sets forth total non-cash stock-based compensation for the issuance of common stock, options to purchase common stock, warrants to purchase common stock, and restricted stock unit award by operating statement classification for the years ended December 31, 2018 and 2017:

	December 31,	
	2018	2017
Research and development	$ 170	$ 182
Sales and marketing	158	139
General and administrative	2,147	1,899
Total [1], [2]	2,475	2,220

(1) As of December 31, 2018 and 2017, the Company recorded a prepaid expense in the amount of $344 and $0, respectively, for the value of vested warrants for future services to be rendered.

(2) As of December 31, 2018 and 2017, the Company recorded a warrant liability in the amount of $22 and $0, respectively, for the value of warrants to be issued for services provided.

(In thousands, except share and per share amounts)

Note 10 – Income Taxes

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company's deferred tax assets relate primarily to its net operating loss carryforwards and other balance sheet basis differences. In accordance with ASC 740, "Income Taxes," the Company recorded a valuation allowance to fully offset the gross deferred tax asset, because it is not more likely than not that the Company will realize future benefits associated with these deferred tax assets at December 31, 2018 and 2017.

At December 31, 2018 and 2017, the Company had deferred tax assets of $12.1 million and $7.9 million, respectively, against which a full valuation allowance of $12.1 million and $7.9 million, respectively, had been recorded. The change in the valuation allowance for the year ended December 31, 2018 was an increase of $4.2 million. The increase in the valuation allowance for the year ended December 31, 2018 was mainly attributable to increases in net operating losses, non-deductible share based compensation, and accrued liabilities, which resulted in an increase in the deferred tax assets with a corresponding valuation allowance. Significant components of the Company's deferred tax assets at December 31, 2018 and 2017 were as follows:

	December 31,	
	2018	**2017**
Deferred tax assets:		
Net operating loss carryforwards – Federal and state.	$ 1,413	291
Net operating loss carryforwards – Israel	8,453	6,295
Share based compensation	735	—
Accrued liabilities	1,543	1,269
Gross deferred tax assets	12,144	7,855
Valuation allowance	(12,144)	(7,855)
Gross deferred tax assets after valuation allowance	$ —	$ —

(In thousands, except share and per share amounts)

A reconciliation of the federal statutory tax rate and the effective tax rates for the years ended December 31, 2018 and 2017 is as follows:

	For the Year Ended December 31,	
	2018	**2017**
U.S. federal statutory tax rate	21.0%	34.0%
State income taxes, net of federal benefit	1.1	1.1
U.S. vs. foreign tax rate differential	0.9	(8.8)
Impact of tax law change	—	(3.0)
Non-deductible expenses	(3.7)	(0.1)
Change in valuation allowance	(19.3)	(23.2)
Effective tax rate	—%	—%

The Company had approximately $48.2 million and $29.5 million of gross net operating loss ("NOL") carryforwards (federal, state and Israel) as of December 31, 2018 and 2017, respectively. Sections 382 and 383 of the Internal Revenue Code, and similar state regulations, contain provisions that may limit the NOL carryforwards available to be used to offset income in any given year upon the occurrence of certain events, including changes in the ownership interests of significant stockholders. In the event of a cumulative change in ownership in excess of 50% over a three-year period, the amount of the NOL carryforwards that the Company may utilize in any one year may be limited.

A reconciliation of the Company's NOLs for the years ended December 31, 2018 and 2017 is as follows:

	December 31,	
	2018	**2017**
U.S. Federal NOL's	$ 5,720	$ 1,074
U.S. State NOL's	5,720	1,074
Israel NOL's	36,751	27,371
Total NOL's	$ 48,191	$ 29,519

The Company's federal and state NOL's of $1.1 million and $5.7 million, respectively, begin to expire after 2036 through 2037. The Company's federal NOL of $4.6 million, generated in 2018, and the Israel NOL of $36.8 million do not expire.

The Tax Cuts and Jobs Act (the "Act") was enacted in December 2017. Among other things, the Act reduced the U.S. federal corporate tax rate from 35 percent to 21 percent, eliminated the alternative minimum tax ("AMT") for corporations, and provided that AMT credit carryforwards are refundable over a period of time beginning with the Company's 2018 tax year through 2021. The reduction of the corporate tax rate resulted in a write-down of the Company's gross deferred tax assets of approximately $0.4 million, and a corresponding write-down of the valuation allowance as of December 31, 2017.

Note 11 – Segment Information

The Company's Chief Executive Officer ("CEO") has been identified as the chief operating decision maker. The CEO evaluates the performance of the Company and allocates resources based on the information provided by the Company's internal management system at a consolidated level. The Company has determined that it has only one operating segment.

Revenues from external customers are attributed to geographic areas based on location of the contracting customers.

	2018	2017
Revenue in Israel	$ —	$ —
Revenue in United States	36	—
Total	$ 36	$ —

Long lived assets (property and equipment) attributed to geographic areas are as follows:

	2018	2017
Property and equipment in Israel	$ 662	$ 586
Property and equipment in United States	184	197
Total	$ 846	$ 783

Note 12 – Subsequent Events

The Company has analyzed its operations subsequent to December 31, 2018 and noted the following subsequent events:

On January 1, 2019, the number of shares of common stock available for issuance under the 2016 Plan increased by 1,286,409 shares (see Note 9).

On January 2, 2019, the Company issued a warrant to purchase 25,000 shares of the Company's common stock with an exercise price of $10.00 per share and an exercise period of 24 months in connection with an agreement entered into on July 2, 2018 (see Note 9).

On January 31, 2019, the Company issued 416 shares of its common stock upon the exercise of 416 employee options at an exercise price of $3.78 per share. In connection with the exercise, the Company received $2 in proceeds.

On February 6, 2019, the Company issued a warrant to purchase 10,000 shares of the Company's common stock with an exercise price of $7.25 per share and an exercise period of five years in connection with an agreement entered into on June 6, 2018 (see Note 9).

On February 13, 2019, the Company's Compensation Committee approved the issuance of a 165,000 restricted stock unit award in accordance with the CEO's employment agreement which vests over a four-year period on a quarterly basis beginning October 1, 2018. On March 5, 2019, the Company issued 10,313 shares of its common stock related to the vested portion of the restricted stock unit award (see Note 7).

On February 13, 2019, the Company's Compensation Committee approved the issuance of 76,112 restricted stock unit awards, in the aggregate, to executives which vests over a four-year period on a quarterly basis beginning on the February 13, 2019.

On February 13, 2019, the Company's Compensation Committee approved the issuance of 672,144 options to employees which vest over a three-year period on a quarterly basis to purchase shares of the Company's common stock at $4.32, the closing share price of the Company's common stock on the Nasdaq Capital Market on February 13, 2019.

On February 13, 2019, the Company's Compensation Committee approved the issuance of 165,000 options to members of the Board of Directors which vest over a two-year period on an annual basis to purchase shares of the Company's common stock at $4.32, the closing share price of the Company's common stock on the Nasdaq Capital Market on February 13, 2019.

On March 20, 2019 the Company's Board of Directors approved the issuance of warrants to two consultants which vests immediately to purchase 80,000 shares, in the aggregate, of the Company's common stock at an exercise price of $5 per share.

On March 26, 2019, the Company entered into an amended and restated employment agreement with Andrew Taylor, the Company's Chief Financial Officer (see Note 7).

Exhibit 10.22

RESTRICTED STOCK UNIT AWARD AGREEMENT

MOTUS GI HOLDINGS, INC.

This Restricted Stock Unit Award Agreement (the "Agreement" or "Award Agreement"), dated as of the "Award Date" set forth in the attached Exhibit A, is entered into between Motus GI Holdings, Inc., a Delaware corporation (the "Company"), and the individual named in Exhibit A hereto (the "Awardee").

WHEREAS, the Company desires to provide the Awardee an incentive to participate in the success and growth of the Company through the opportunity to earn a proprietary interest in the Company; and

WHEREAS, to give effect to the foregoing intention, the Company desires to award the Awardee Restricted Stock Units pursuant to the Motus GI Holdings, Inc. 2016 Equity Incentive Plan (the "Plan");

NOW, THEREFORE, the following provisions apply to this Award:

1. Award. The Company hereby awards the Awardee the number of Restricted Stock Units (each an "RSU" and collectively the "RSUs") set forth in Exhibit A. Such RSUs shall be subject to the terms and conditions set forth in this Agreement and the provisions of the Plan, the terms of which are incorporated herein by reference. Capitalized terms used but not otherwise defined herein shall have the meanings as set forth in the Plan.

2. Vesting. Except as otherwise provided in this Agreement, the RSUs shall vest in accordance with the vesting schedule set forth in Exhibit A, provided that the Awardee remains in Continuous Service through the applicable vesting date.

For each RSU that becomes vested in accordance with this Agreement, the Company shall issue and deliver to Awardee one share of the Company's common stock, par value $.0001 per share (the "Common Stock"). Such shares shall be issued and delivered within 150 days following the vesting date of each such RSU, but in no event later than March 15 of the year following the year in which such vesting date occurs. Except as provided above, in the event that the Awardee ceases to be in Continuous Service, any RSUs that have not vested as of the date of such cessation of service shall be forfeited.

3. Dividend Equivalent Units. If and to the extent that the Company pays a cash dividend with respect to the Common Stock, Awardee shall be credited with an additional number of RSUs ("Dividend Equivalent Units"), including a fractional Dividend Equivalent Unit if applicable, equal to (i) the amount of such dividends as would have been paid with respect to Awardee's outstanding RSUs on the record date of such dividend (the " record date") had each such outstanding RSU been an outstanding share of Common Stock on such record date, divided by (ii) the closing price of a share of Common Stock on such record date. Dividend Equivalent Units shall be subject to the same vesting terms and conditions as the RSUs to which they relate.

4 . No Rights as Stockholder. The Awardee shall not be entitled to any of the rights of a stockholder with respect to any share of Common Stock that may be acquired following vesting of an RSU unless and until such share of Common Stock is issued and delivered to the Awardee. Without limitation of the foregoing, the Awardee shall not have the right to vote any share of Common Stock to which an RSU relates and shall not be entitled to receive any dividend attributable to such share of Common Stock for any period priot to the issuance and delivery of such share to Awardee (but Awardee shall have dividend equivalent rights as provided in Section 3 above).

5 . Transfer Restrictions. Neither this Agreement nor the RSUs may be sold, assigned, pledged or otherwise transferred or encumbered without the prior written consent of the Committee.

6 . Government Regulations. Notwithstanding anything contained herein to the contrary, the Company's obligation hereunder to issue or deliver certificates evidencing shares of Common Stock shall be subject to the terms of all applicable laws, rules and regulations and to such approvals by any governmental agencies or national securities exchanges as may be required.

7 . Withholding Taxes. The Awardee shall pay to the Company, or make provision satisfactory to the Company for payment of, the minimum statutory amount required to satisfy all federal, state and local income tax withholding requirements and the Awardee's share of applicable employment withholding taxes in connection with the issuance and deliverance of shares of Common Stock following vesting of RSUs, in any manner permitted by the Plan. No shares of Common Stock shall be issued with respect to RSUs unless and until satisfactory arrangements acceptable to the Company have been made by the Awardee with respect to the payment of any income and other taxes which the Company determines must be withheld or collected with respect to the RSUs.

8 . Investment Purpose. Any and all shares of Common Stock acquired by the Awardee under this Agreement will be acquired for investment for the Awardee's own account and not with a view to, for resale in connection with, or with an intent of participating directly or indirectly in, any distribution of such shares of Common Stock within the meaning of the Securities Act of 1933, as amended (the "Securities Act"). The Awardee shall not sell, transfer or otherwise dispose of such shares unless they are either (1) registered under the Securties Act and all applicable state securities laws, or (2) exempt from such registration in the opinion of Company counsel.

9 . Securities Law Restrictions. Regardless of whether the offering and sale of shares of Common Stock issuable to Awardee pursuant to this Agreement and the Plan have been registered under the Securities Act, or have been registered or qualified under the securities laws of any state, the Company at its discretion may impose restrictions upon the sale, pledge or other transfer of such shares of Common Stock (including the placement of appropriate legends on stock certificates or the imposition of stop-transfer instructions) if, in the judgment of the Company, such restrictions are necessary in order to achieve compliance with the Securities Act or the securities laws of any state or any other law.

10. Lock-Up Agreement. The Awardee, in the event that any shares of Common Stock which become deliverable to Awardee with respect to RSUs at a time during which any directors or officers of the Company have agreed with one or more underwriters not to sell securities of the Company, shall enter into an agreement, in form and substance satisfactory to the Company, pursuant to which the Awardee shall agree to restrictions on transferability of the shares of such Common Stock comparable to the restrictions agreed upon by such directors or officers of the Company.

11. Awardee Obligations. The Awardee should review this Agreement with his or her own tax advisors to understand the federal, state, local and foreign tax consequences of the transactions contemplated by this Agreement. The Awardee will rely solely on such advisors and not on any statements or representations of the Company or any of its agents, if any, made to the Awardee. The Awardee (and not the Company) shall be responsible for the Awardee's own tax liability arising as a result of the transactions contemplated by this Agreement.

12. No Guarantee of Continued Service. The Awardee acknowledges and agrees that (i) nothing in this Agreement or the Plan confers on the Awardee any right to continue an employment, service or consulting relationship with the Company, nor shall it affect in any way the Awardee's right or the Company's right to terminate the Awardee's employment, service, or consulting relationship at any time, with or without cause, subject to any employment or service agreement that may have been entered into by the Commpany and the Awardee; and (ii) the Company would not have granted this Award to the Awardee but for these acknowledgements and agreements.

13. Notices. Notices or communications to be made hereunder shall be in writing and shall be delivered in person, by registered mail, by confirmed facsimile or by a reputable overnight courier service to the Company at its principal office or to the Awardee at his or her address contained in the records of the Company. Alternatively, notices and other communications may be provided in the form and manner of such electronic means as the Company may permit.

14. Entire Agreement; Governing Law. The Plan is incorporated herein by reference. The Plan and this Award Agreement constitute the entire Agreement with respect to the subject matter hereof and supersede in their entirety all prior undertakings and agreements of the Company and the Awardee with respect to the subject matter hereof, and except as provided in the Plan or in this Agreement, may not be modified adversely to the Awardee's interest except by means of a writing signed by the Company and the Awardee. In the event of any conflict between this Award Agreement and the Plan, the Plan shall be controlling. This Award Agreement shall be construed under the laws of the State of Delaware, without regard to conflict of laws principles.

15. Opportunity for Review. Awardee and the Company agree that this Award is granted under and governed by the terms and conditions of the Plan and this Award Agreement. The Awardee has reviewed the Plan and this Award Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to accepting this Award Agreement and fully understands all provisions of the Plan and this Award Agreement. The Awardee hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Committee upon any questions relating to the Plan and this Award Agreement. The Awardee further agrees to notify the Company upon any change in Awardee's residence address.

16. Binding Effect. This Agreement shall be binding upon and inure to the benefit of the Company and the Awardee and their respective permitted successors, assigns, heirs, beneficiaries and representatives.

17. Section 409A Compliance. To the extent that this Agreement and the award of RSUs hereunder are or become subject to the provisions of Section 409A of the Code, the Company and the Awardee agree that this Agreement may be amended or modified by the Company, in its sole discretion and without the Awardee's consent, as appropriate to maintain compliance with the provisions of Section 409A of the Code.

18. Recoupment. In the event the Company restates its financial statements due to material noncompliance with any financial reporting requirements under applicable securities laws, any payments made or shares issued pursuant to this Agreement for or in respect of the year that is restated, or the prior three years, may be recovered to the extent the payments made or shares issued exceed the amount that would have been paid or issued based on the restatement. In addition and without limitation of the foregoing, any amounts paid hereunder shall be subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company or as is otherwise required by applicable law or stock exchange listing conditions.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date set forth in Exhibit A.

MOTUS GI HOLDINGS, INC.

By: _____
Name:
Title:

AWARDEE

_____
Name:

EXHIBIT A

MOTUS GI HOLDINGS, INC.

RESTRICTED STOCK UNIT AWARD AGREEMENT

(a). **Awardee's Name**: **_____**

(b). **Award Date**: **_____**

(c). **Number of Restricted Stock Units Granted**: **_____**

(d). **Vesting Schedule**:

_____ (Initials)
Awardee

_____ (Initials)
Company Signatory

Exhibit 10.23

FIRST AMENDED EMPLOYMENT AGREEMENT

This First Amended Employment Agreement ("Agreement"), dated March 26, 2019 (the "Effective Date") is entered into between Motus GI Holdings, Inc., a Delaware corporation, having its corporate headquarters at 1301 East Broward Blvd, Fort Lauderdale, Florida ("Company"), and Andrew Taylor, an individual residing at 816 Winter Road, Rydal, PA 19046 ("Executive") (Company and Executive, each a "Party" and together, the "Parties").

WHEREAS, the Parties previously entered into an employment agreement dated as of August 16, 2017 (the "Initial Employment Agreement"); and

WHEREAS, the Parties have mutually agreed to modify and amend the terms and conditions of employment as set forth in this Agreement; and

WHEREAS, the Initial Employment Agreement is no longer in effect and has been superseded and replaced by this Agreement.

NOW, THEREFORE, in consideration of the mutual agreements set forth herein, Company and Executive hereby agree as follows:

ARTICLE I
EMPLOYMENT; POSITION, DUTIES AND RESPONSIBILITIES

1.01 Employment and Acceptance. Company agrees to, and does hereby, employ Executive, and Executive agrees to, and does hereby accept, such employment, upon the terms and subject to the conditions set forth in this Agreement.

1.02 Position, Duties and Responsibilities. During the Term (as defined in Section 2.01 below), Executive shall serve as Chief Financial Officer of the Company as well as in such other positions or capacities as may be reasonably requested by the Chief Executive Officer ("CEO") and/or the Board of Directors of Company (the "Board") and shall have such duties and responsibilities as are customary for, and are consistent with, such position(s) as may, from time to time, be assigned to him. Executive's employment by Company shall be full-time and exclusive to Company and Executive shall (a) report to the CEO, (b) comply with Company's policies and procedures in place from time to time, and (c) serve Company faithfully and to the best of Executive's ability. During the Term, and except for paid time off in accordance with the terms of Section 3.01(E) below or absences due to illness or incapacity, Executive shall devote all of Executive's business time, attention, skill and efforts exclusively to the business and affairs of Company (including its affiliates) and the promotion of its interests. Notwithstanding anything contained herein to the contrary, Executive may do the following, provided that such activities do not inhibit or prohibit the performance of Executive's duties hereunder or inhibit or conflict with the business of Company and/or its affiliates: (i) engage in charitable, educational, religious, civic and similar types of activities and manage Executive's personal investments, (ii) continue to serve on the board of directors of Angel Medical Systems, Inc., and (iii) with the prior written consent of the Board which shall not be unreasonably withheld, serve on the board of directors, managers, advisors (or their equivalent) of outside business enterprises. The Parties acknowledge that the Executive currently resides in Pennsylvania; while the Executive will not be required to relocate his home residence, Executive acknowledges that he shall be required to travel as reasonably necessary to perform Executive's duties hereunder, including international travel.

ARTICLE II
TERM

2.01 Term of Employment. The terms of this Agreement shall commence as of the Effective Date and shall continue on an at-will basis. The period during which Executive is employed pursuant to this Agreement shall be referred to as the "Term."

ARTICLE III
COMPENSATION AND BENEFITS; EXPENSES

3.01 Compensation and Benefits. For all services rendered by Executive in any capacity during the Term (including, without limitation, serving as an officer, director or member of any committee of Company or any affiliate or division thereof), Executive shall be compensated as follows (subject, in each case, to the provisions of Article IV below):

(A) Base Salary. During the Term, Company shall pay to Executive a base salary at the initial rate of $310,000 (less applicable withholdings and deductions) on an annualized basis (the "Base Salary"). As used in this Agreement, the term "Base Salary" shall refer to Base Salary as may be adjusted upward from time to time by the Board. Base Salary shall be payable in accordance with the customary payroll practices of Company.

(B) Performance Bonus. The Executive shall be eligible to receive an annual bonus payment in an amount equal to up to thirty-five percent (35%) of the Executive's then-Base Salary ("Bonus Target") if the Board determines that the Executive has met the target objectives communicated to him. Payout parameters will be determined by the Board based upon parameters set by the Board and the Chief Executive Officer of the Company for an overall Company executive bonus program using market data and analysis input from a third-party expert compensation firm. Any bonus earned by the Executive shall be paid to Executive no later than March 15th of the calendar year following the calendar year to which the bonus relates.

(C) Equity Compensation.

a. During the Term, Executive shall be eligible to receive from time to time such additional equity grants or awards, if any, pursuant to the terms of the Company's 2016 Equity Incentive Plan (the "Plan") (or any successor plan as may be in place from time to time) as may be approved by the Board or the Compensation Committee in its discretion. Such grants or awards will be subject to the terms and conditions of the Plan (or any successor plan) and such other terms and conditions as the Board or the Compensation Committee in its discretion may establish.

b. The Parties acknowledge, pursuant to the Initial Employment Agreement, the Executive received a grant of options (the "Option Grant") to purchase up to 240,000 shares of Common Stock pursuant to the Plan with an exercise price of $4.50 per share, which vests in a series of twelve (12) successive equal quarterly installments upon the completion of each successive calendar quarter of active service over the three (3) year period measured from the date of grant, as was determined by the Compensation Committee of the Board of Directors. Pursuant to the Initial Employment Agreement, Executive's Option Grant contained the following additional terms:

(1) Upon a "change-in-control" of the Company, all outstanding unvested shares pursuant to the Option Grant shall become fully vested and exercisable for the remainder of their full term. "Change in Control" shall mean the consummation of any one of the following events: (i) a sale, lease, transfer or other disposition of all or substantially all of the assets of the Company; (ii) a consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization, in which the stockholders of the Company immediately prior to such consolidation, merger or reorganization, own less than fifty percent (50%) of the Company's outstanding voting power of the surviving entity following the consolidation, merger or reorganization; or (iii) any transaction (or series of related transactions involving a person or entity, or a group of affiliate persons or entities) in which in excess of fifty percent (50%) of the Company's then outstanding voting power is transferred, excluding any consolidation or merger, effected exclusively to change the domicile of the Company and excluding any such change of voting power resulting from a bona fide equity financial event or public offering of the stock of the Company.

(2) If the Executive is terminated without Cause (as defined in the Initial Employment Agreement), the Option Grant shall vest with respect to the additional number of shares that would have become vested under its terms through the last day of the calendar quarter during which such termination date occurs.

(3) Terms otherwise in accordance with the Company's stock option plan as in effect as of December 22, 2016.

(D) Benefits. During the Term, Executive shall be entitled to participate in all Executive benefit plans and programs (excluding severance plans, if any) generally made available by Company to Executives of Company, to the extent permissible under the general terms and provisions of such plans or programs and in accordance with the provisions thereof. Company may amend, modify or rescind any employee benefit plan or program and/or change employee contribution amounts to benefit costs without notice in its discretion. Executive's eligibility for severance shall be governed by the terms of this Agreement.

(E) Paid Time Off (PTO). During the Term, Executive shall be entitled to paid time off in accordance with Company's policy in place from time to time; *provided, however,* that Executive shall be eligible to accrue no less than twenty (20) days per calendar year. The Executive shall be permitted to carry over PTO into the following calendar year; provided however that any unused, accrued PTO shall expire two years following the applicable year in which PTO was earned. The Executive shall be required to obtain the Board's approval if he wishes to take more than two weeks of PTO consecutively.

3.02 Expenses. Executive shall be entitled to receive reimbursement from Company for reasonable out-of-pocket expenses incurred by Executive during the Term in connection with the performance of Executive's duties and obligations under this Agreement, according to Company's expense account and reimbursement policies in place from time to time and provided that Executive shall submit reasonable documentation with respect to such expenses; *provided, however*, in no event shall a reimbursement be made later than December 31 of the year following the year in which the expense was incurred.

ARTICLE IV
TERMINATION

4.01 Events of Termination. This Agreement and Executive's employment hereunder shall terminate upon the occurrence of any one or more of the following events:

(A) Death. In the event of Executive's death, this Agreement and Executive's employment hereunder shall automatically terminate on the date of death.

(B) Disability. To the extent permitted by law, in the event of Executive's physical or mental disability that prevents Executive from performing the essential functions of Executive's duties under this Agreement (with or without reasonable accommodation) for a period of at least ninety (90) consecutive days in any twelve (12)-month period or one hundred twenty (120) non-consecutive days in any twelve (12)-month period, Company may terminate this Agreement and Executive's employment hereunder upon giving written notice of termination to Executive.

(C) Termination by Company for Cause. Company may, at its option, terminate this Agreement and Executive's employment hereunder for Cause (as defined below) upon giving notice of termination to Executive. As used in this Agreement, "Cause" shall mean the termination of the Executive's employment because of:

(1) gross negligence or willful misconduct in the performance of the Executive's duties hereunder, or if the Executive otherwise materially breaches this Agreement;

(2) the Executive's failure to obey a lawful and appropriate directive that is from the CEO or the Board, which failure is not cured within 15 days written notice of the alleged failure to perform;

(3) a material violation of the restrictive covenants described in Article V below or of any written employee conduct policy of the Company against workplace harassment or discrimination);

(4) conviction of a felony or other serious crime; or

(5) any other act or omission that results in material harm to the business, reputation of the Company.

(D) Without Cause by Company. Company may, at its option, at any time terminate this Agreement and Executive's employment hereunder for no reason or for any reason whatsoever (other than for Cause or as a result of Executive's death or Disability) by giving written notice of termination to Executive.

(E) Termination by Executive. Executive may terminate this Agreement and Executive's employment hereunder with or without Good Reason (as defined below) by: (i) in the case of a resignation without Good Reason, giving thirty (30) days prior written notice of termination to Company; or (ii) in the case of a resignation for Good Reason, giving written notice of resignation within thirty (30) days after the expiration of the Good Reason Cure Period; *provided, however*, in each case, Company reserves the right, upon written notice to Executive, to accept Executive's notice of resignation and to accelerate such notice and make Executive's resignation effective immediately, or on such other date prior to Executive's intended last day of work as Executive deems appropriate. The Company's election to accelerate Executive's notice of resignation shall not be deemed a termination by Company. For purposes of this Agreement, "Good Reason" means the occurrence of any of the following circumstances without Executive's prior express written consent: (i) a material adverse change in the nature of Executive's title, duties or responsibilities with the Company that represents a material demotion from his title, duties or responsibilities as in effect immediately prior to such change; (ii) a material breach of this Agreement by the Company; (iii) a failure by the Company to make any payments to Executive when due, unless the payment is not material and is being contested by the Company, in good faith; (iv) the Company's performance of any illegal or civilly actionable act that materially damages Executive's reputation or is considered harassment under applicable law; (v) any material reduction of the Executive's then current annual Base Salary except to the extent that the annual Base Salary of all other similarly situated employees of the Company or its successor is similarly reduced; (vi) any requirement that the Executive relocate to a work site that is more than fifty miles from his home; or (vii) a liquidation, bankruptcy or receivership of the Company. Notwithstanding the foregoing, no Good Reason shall be deemed to exist with respect to the Company's acts described in clause (i) above, unless Executive shall have given written notice to the company specifying the Good Reason with reasonable particularity within (ninety) 90 days after the date Executive first knew or should reasonably have known of the occurrence of any such event and, within fifteen (15) days after such notice, the Company shall not have cured or eliminated the problem or thing giving rise to such Good Reason; *provided*, *however*, that a repeated breach after notice and cure of any provision of clause (i) above involving the same or substantially similar actions or conduct, shall be grounds for termination for Good Reason without any additional notice from Executive. If Executive fails to provide the notice and Good Reason Cure Period prior to Executive's resignation, or resigns more than ninety (90) days after the initial existence of the condition, Executive's resignation will not be deemed to be for "Good Reason" and any claim of such circumstances as "Good Reason" shall be deemed irrevocably waived by Executive.

(F) Mutual Agreement. This Agreement and Executive's employment hereunder may be terminated at any time by the mutual agreement of Company and Executive.

4.02 Company's Obligations upon Termination.

(A) Termination by Company for Cause; Termination by Executive without Good Reason; Mutual Agreement. In the event of a termination of this Agreement and Executive's employment hereunder pursuant to Sections 4.01(C), 4.01(E) (other than a termination for Good Reason), or 4.01(F) above, then this Agreement and Executive's employment with Company shall terminate and Company's sole obligation to Executive (or Executive's estate, heirs, executors, administrators, representatives and assigns) under this Agreement or otherwise shall be to: (i) pay to Executive (or, if applicable, Executive's estate) any Base Salary earned, but not yet paid, prior to the effective date of such termination, payable in accordance with Company's standard payroll practices; (ii) reimburse Executive (or, if applicable, Executive's estate) for any expenses incurred by Executive through the effective date of such termination in accordance with Section 3.02 above; and (iii) pay and/or provide any amounts or benefits that are vested amounts or vested benefits or that Executive is otherwise entitled to receive under any plan, program, policy or practice (with the exception of those, if any, relating to severance) on the date of termination, in accordance with such plan, program, policy, or practice (including payment for unused, accrued vacation) (clauses (i), (ii) and (iii) of this sentence are collectively referred to herein as the "Accrued Obligations").

(B) Termination by Company without Cause; Termination by Executive for Good Reason; Death or Disability

(1) Subject to Section 4.02(B) below, in the event of a termination of this Agreement and Executive's employment hereunder by Company pursuant to Section 4.01A, 4.01B, 4.01(D) or a termination of this Agreement and Executive's employment hereunder by Executive for Good Reason (as defined in Section 4.01(E) above) pursuant to Section 4.01(E), then this Agreement and Executive's employment with Company shall terminate and Company's sole obligation to Executive under this Agreement or otherwise shall be to: (i) pay and/or provide, as applicable, the Accrued Obligations in accordance with the terms set forth in Section 4.02(A) above; and (ii) subject to Section 4.02(C) below, (a) an aggregate amount equal to the Executive's Base Salary for nine (9) months (the "Severance Payments"), (b) if Executive timely elects COBRA coverage, Company shall pay the Company portion of Executive's healthcare continuation payments under COBRA for a twelve (12)-month period following the date of Executive's termination of employment with Company (the "COBRA Assistance") during which time Executive shall be responsible for the Executive portion (unless Executive becomes eligible to obtain healthcare coverage from a new company before the twelve (12)-month anniversary of the termination of Executive's employment, in which case Company's obligation to contribute to Executive's health care continuation payments under COBRA shall cease), (c) pay to Executive any earned but unpaid Performance Bonus that relates to the calendar year prior to the calendar year in which the termination of Executive's employment from the Company occurs, which shall be paid in lump sum on the date when bonuses otherwise would be paid, (d) reimbursement of business expenses as set forth herein, and (e) 25% of any unvested options shall upon such termination vest. Any unvested portion of the Executive's Option Grant and unpaid performance bonus shall be forfeited without payment. If, following a termination of employment without Cause or due to permanent disability, the Executive breaches the provisions of Section 5 below, the Executive shall not be eligible, as of the date of such breach, for any additional Severance Payments, and any and all further obligations and agreements of the Company with respect to such payments shall thereupon cease. Additionally, if, following a termination of employment without Cause or due to Disability, the Executive accepts and commences alternate employment while receiving the Severance Payments, the base compensation received by Executive from such alternate employment shall be applied as an offset against future Severance Payments due the Executive. By way of example, if Executive is able to secure alternate employment at a monthly base salary rate of $20,000, the Executive's monthly Severance Payment would be reduced by $20,000 during the remaining severance period.

(2) In the event of a termination of this Agreement and Executive's employment hereunder by Company pursuant to Section 4.01(D) or a termination of this Agreement and Executive's employment hereunder by Executive for Good Reason (as defined in Section 4.01(E) above) pursuant to Section 4.01(E) during the twelve (12)-months immediately following a Change in Control (as defined below), then this Agreement and Executive's employment with Company shall terminate and Company's sole obligation to Executive under this Agreement or otherwise shall be to: (i) make the payments described in Section 4.02(B)(1)(i) and Section 4.02(B)(ii)(a)-(d) above, and (ii) subject to Section 4.02(C) below, accelerate the vesting of all unvested equity awards either existing and future awards (including the unvested portion of the Option Grant). Except for Section 3.01(C)(b)(1), as used in this Agreement, a "Change in Control" shall have the meaning of Change in Control set forth in the Company's Plan, as in effect on the date of this Agreement. In the event the unvested portion of Executive's equity awards are not assumed or substituted with substantially equivalent awards with the successor corporation in connection with a Change in Control, such unvested equity awards shall become immediately vested immediately prior to such Change in Control.

Notwithstanding anything set forth in this Section 4.02(B) to the contrary, in the event of a material breach by Executive under Article V of this Agreement or the Release and in addition to any other remedies hereunder, the Release or at law or in equity, Company's obligation to make any remaining installments of the Severance Payment shall terminate as of the date of such breach and Company shall have no further obligations under this Section 4.02(B) other than to pay/provide the Accrued Obligations (to the extent not previously paid/provided) and Executive shall be required, upon demand, to return to Company fifty percent (50%) of the Severance Payment (or installments thereof) paid by the Company pursuant to this Section 4.02(B).

(C) Release. With the exception of Accrued Obligations, all payments and benefits to Executive pursuant to this Section 4.02 shall be contingent upon Executive's execution, delivery within 21 days (or 45 days in the case of a group termination) following receipt by Executive, and non-revocation of a general release in a form satisfactory to the Company (the "Release"). The Release will be delivered to Executive within ten (10) business days following the effective date of Executive's termination and will include, without limitation, a general release from all liability of Company, its affiliates and each of their respective officers, directors, shareholders, partners, managers, agents, employees and other related parties. Notwithstanding anything to the contrary contained herein, in the event that any payment hereunder is contingent upon Executive's execution and delivery of the Release and the 21 (or 45 day) period covers more than one calendar year, the payment shall be paid in the second calendar year (on the first regular pay date of such calendar year following the date that the Release becomes effective and is no longer subject to revocation, all subject to Section 4.02(D) below), regardless of whether the Executive executes and delivers the Release in the first or the second calendar year encompassed in such 21 (or 45) day period.

(D) Specified Employee. If the Executive is a "specified employee" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code") at the time of the Executive's termination of employment, amounts or benefits (including the Severance Payments) that are deferred compensation subject to Section 409A of the Code, as determined in the reasonable discretion of the Company, that would otherwise be payable or provided during the six (6)-month period immediately following the termination of employment will instead be paid or provided, with interest on any delayed payment at the short-term applicable federal rate under Section 1274(d) of the Code (with monthly compounding and at the rate published for the month prior to the month in which the Executive's termination of employment occurs), on the first business day after the date that is six months following the Executive's termination of employment.

(E) Removal from any Positions and Boards. If the Executive's employment is terminated for any reason under this Agreement, he shall be deemed (without further action, deed or notice) to resign (i) if a member, from the Board or board of directors (or similar governing body) of any Affiliate of the Company or any other board to which he has been appointed or nominated by or on behalf of the Company and (ii) from all other positions with the Company or any subsidiary or other Affiliate of the Company, including, but not limited to, as an officer of the Company and any of its subsidiaries or other Affiliates.

ARTICLE V
CONFIDENTIALITY, NONCOMPETITION, NONSOLICITATION AND OTHER COVENANTS

5.01 Confidentiality. Executive shall be provided with access to Confidential Information relating to the Company, its business, potential business or that of its clients and customers. "Confidential Information" includes all trade secrets, know-how, show-how, theories, technical, operating, financial, and other business information, whether or not reduced to writing or other medium and whether or not marked or labeled confidential, proprietary or the like, specifically including, but not limited to, information regarding source codes, software programs, computer systems, concepts, creations, costs, plans, materials, enhancements, research, specifications, works of authorship, techniques, documentation, models and systems, sales and pricing techniques, designs, inventions, discoveries, products, improvements, modifications, methodology, processes, concepts, records, files, memoranda, reports, plans, proposals, price lists, product development and project procedures. Confidential Information does not include general skills, experience or information that is generally available to the public, other than information which has become generally available as a result of Executive's direct or indirect act or omission. With respect to Confidential Information of the Company and its clients and customers:

(A) Executive will use Confidential Information only in the performance of Executive's duties for Company. Executive will not use Confidential Information at any time (during or after Executive's employment with Company) for Executive's personal benefit, for the benefit of any other individual or entity, or in any manner adverse to the interests of Company and its clients and customers except to the extent permitted by applicable law, including to enable Executive to exercise any protected legal right he may have;

(B) Executive will not disclose Confidential Information at any time (during or after Executive's employment with Company) except to authorized Company personnel, unless Company consents in advance in writing or unless the Confidential Information indisputably becomes of public knowledge or enters the public domain (other than through Executive's direct or indirect act or omission) or as authorized by a court or regulatory agency.

(C) Executive will safeguard the Confidential Information by all reasonable steps and abide by all policies and procedures of Company in effect from time to time regarding storage, copying, destroying, and handling of documents; and

(D) Executive will return or destroy all materials, models, software, prototypes and the like containing and/or relating to Confidential Information, together with all other property of Company and its clients and customers, to Company when Executive's employment relationship with Company terminates or otherwise on demand and, at that time Executive will certify to Company, in writing and under oath, that Executive has complied with this Agreement. Executive shall not retain any copies or reproductions of correspondence, memoranda, reports, notebooks, drawings, photographs, databases, diskettes, or other documents or electronically stored information of any kind relating in any way to the business, potential business or affairs of Company and its clients and customers.

(E) Executive acknowledges receipt of the following notice under the Defend Trade Secrets Act: An individual will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret if he/she (i) makes such disclosure in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney and such disclosure is made solely for the purpose of reporting or investigating a suspected violation of law; or (ii) such disclosure was made in a complaint or other document filed in a lawsuit or other proceeding if such filing is made under seal.

(F) Notwithstanding the foregoing or anything else contained herein to the contrary, this Agreement shall not preclude the Executive from disclosing Confidential Information to a governmental body or agency or to a court if and to the extent that a restriction on such disclosure would limit the Executive from exercising any protected right afforded the Executive under applicable law, including the ability to receive an award for information provided to a governmental body.

5.02 Obligations to Other Persons. Executive does not have any non-disclosure or other obligations to any other individual or entity (including without limitation, any previous company) concerning proprietary or confidential information that Executive learned of during any previous employment or associations that would conflict with the Executive's obligations to Company under this Agreement. Executive shall not disclose to Company or induce Company to use any secret or confidential information or material belonging to others, including, without limitation, Executive's former employers, if any. Executive does not have any non-competition agreements, non-solicitation agreements or other restrictive covenants with any previous company or other individual or entity that would conflict with the Executive's obligations to Company under this Agreement.

5.03 Covenants Against Competition and Solicitation.

Executive acknowledges and understands that, Executive's position with Company affords Executive extensive access to Confidential Information of the Company. Executive therefore agrees that during the course of Executive's employment with Company and for twelve (12) months after termination of Executive's employment with Company (for any reason or no reason) (collectively, "Restricted Period"), Executive shall not: (i) anywhere within the United States of America or any other country in which the Company then conducts or proposes to conduct business, either directly or indirectly, as an owner, stockholder, member, partner, joint venturer, officer, director, consultant, independent contractor, agent or executive, engage in any business or other commercial activity which is engaged in or is seeking to engage in a "Competitive Business." As used in this Agreement, "Competitive Business" shall mean any individual or enterprise engaged in (x) cleansing of body cavities, tubular structures or other orafices or devices added on or attached to endoscopes or (y) any other business directly competitive with the business of the Company on the date of termination.

Executive further agrees that, during the Restricted Period, Executive shall not, directly or indirectly, either on Executive's own behalf or on behalf of any other individual or commercial enterprise: (i) contact, communicate, solicit or transact any business with or assist any third party in contacting, communicating, soliciting or transacting any business with (A) any of the customers or clients of the Company, (B) any prospective customers or clients of the Company, or (C) any individual or entity who or which was within the most recent twelve (12) month period a customer or client of Company, for the purpose of inducing such customer or client or potential customer or client to be connected to or benefit from any competitive business or to terminate its or their business relationship with the Company; (ii) solicit, induce or assist any third party in soliciting or inducing any individual or entity who is then (or was at any time within the preceding twelve (12) months an employee or full-time consultant, independent contractor or agent of Company) to leave the employment of the Company or cease performing services for the Company; (iii) hire or engage or assist any third party in hiring or engaging, any individual or entity that is or was (at any time within the preceding twelve (12) months) an employee or full-time consultant, independent contractor or agent of the Company, or (iv) solicit, induce or assist any third party in soliciting or inducing any other person or entity (including, without limitation, any third-party service provider or distributor) to terminate its relationship with the Company or otherwise interfere with such relationship. A "prospective customer or client" is any individual or entity with respect to whom or which Company was engaged in a solicitation at any time during the twelve (12) months preceding termination of Executive's employment with Company and in which solicitation Executive was in any way involved, or about whom or which Executive had access to Confidential Information.

5.04 Cooperation With Investigations/Litigation. Executive agrees, upon Company's request, to reasonably cooperate both during and after Executive's employment with Company in any Company investigation, litigation, arbitration, or regulatory proceeding regarding events that occurred during Executive's tenure with Company. Executive will make himself reasonably available to consult with Company's counsel, to provide information, and to appear to give testimony. Company will reimburse Executive for reasonable out-of-pocket expenses Executive incurs in extending such cooperation, so long as Executive provides advance written notice of Executive's request for reimbursement and provides satisfactory documentation of the expenses.

5.05 Reasonable Restrictions/Damages Inadequate Remedy. The Parties to this agreement acknowledge that the restrictions contained in this Article are reasonable and necessary to protect the legitimate business interests of Company and that any breach by Executive of any provision contained in this Article may result in immediate irreparable injury to Company for which a remedy at law would be inadequate. Accordingly, the Parties shall be entitled to temporary or permanent injunctive or other equitable relief (without being obligated to post a bond or other collateral) in the event of any breach or threatened breach of the provisions of this Article, in addition to any other remedy that may be available whether at law or in equity.

5.06 Separate Covenants. In the event that an arbitrator or any court of competent jurisdiction shall determine that any one or more of the provisions contained in this Article shall be unenforceable in any respect, then such provision shall be deemed limited and restricted to the extent that the adjudicator shall deem the provision to be enforceable. It is the intention of the Parties to this Agreement that the covenants and restrictions in this Article be given the broadest interpretation permitted by law. The invalidity or unenforceability of any provision of this Article shall not affect the validity or enforceability of any other provision hereof. If, in any judicial or arbitration proceedings, a court of competent jurisdiction or arbitration panel should refuse to enforce all of the separate covenants and restrictions in this Article, then such unenforceable covenants and restrictions shall be eliminated from the provisions of this Agreement for the purpose of such proceeding to the extent necessary to permit the remaining separate covenants and restrictions to be enforced in such proceeding.

5.07 Ownership of Proprietary Rights

(A) Proprietary Rights. "Proprietary Rights" means all right, title and interest (including any copyrights, patent rights, trademarks, servicemarks and trade names) in and to, or associated with, or arising from, any and all notes, data, reference materials, sketches, drawings, memoranda, documentation, and any and all work product conceived, created, reduced to any medium of expression and/or produced as part of the activities of Executive for the Company, including all written, graphical, pictorial, visual, audio, and audiovisual elements relating thereto, software code or records in any way incorporating or reflecting any Confidential Information and any original works of authorship, derivative works, inventions, developments, concepts, know-how, improvements, trade secrets or ideas, whether or not fixed in a tangible medium of expression, that are conceived or developed in whole or in part by the Executive alone or in conjunction with others, whether or not conceived or developed during regular working hours by, or in association with, the Company that are made through the use of any Confidential Information or any of the Company's equipment, facilities, supplies, or trade secrets, or that relate to the Company's business or the Company's actual or demonstrably anticipated research and development, or that result from any work performed by the Executive for the Company.

(B) Ownership of Proprietary Rights. All Proprietary Rights shall belong exclusively to the Company, and the Executive agrees to assign and hereby assigns to the Company, all rights, title and interest throughout the world in and to all Proprietary Rights. The Executive agrees to promptly make full written disclosure to the Company, and will hold in trust for the sole right and benefit of the Company, all Proprietary Rights. Upon request of the Company and without any separate compensation, the Executive shall take such action and execute and deliver such documents and instruments as may be necessary or proper to vest in the Company all right, title and interest in and to all such Proprietary Rights. Without limiting the foregoing, the Executive further agrees that for any original works of authorship created by the Executive, the Company shall be deemed the author thereof under the United States Copyright Act; *provided*, *however*, that in the event and to the extent such works do not to constitute "works made for hire" as a matter of law, the Executive agrees to irrevocably assign and transfer, and hereby irrevocably assigns and transfers to the Company, all right, title and interest in and to such works, including but not limited to copyrights.

(C) Maintenance of Records. The Executive covenants and agrees to take commercially reasonable measures to keep and maintain adequate and current written records of all inventions and works of authorship made by the Executive (solely or jointly with others) during the term of the Executive's relationship with the Company. The records may be in the form of notes, sketches, drawings, flow charts, electronic data or recordings, laboratory notebooks, and any other format. The records will be available to and remain the sole property of the Company at all times. The Executive agrees not to remove such records from the Company's place of business except as expressly permitted by the Company policy, which may, from time to time, be revised at the sole election of the Company. The Executive agrees to return all such records (including any copies thereof) to the Company at the time of termination of services with the Company.

(D) Recordation of Rights. The Executive covenants and agrees to assist the Company, or its designee, at the Company's expense, in every proper way to secure the Company's, or its designee's, rights in the inventions and any copyrights, patents, trademarks, servicemarks, moral rights, or other intellectual property rights relating thereto in any and all countries, including the disclosure to the Company or its designee of all pertinent information and data with respect thereto, the execution of all applications, specifications, oaths, assignments, recordations, and all other instruments that the Company or its designee shall deem necessary in order to apply for, obtain, maintain and transfer such rights, or if not transferable, waive such rights, and in order to assign and convey to the Company or its designee and any successors, assigns and nominees the sole and exclusive rights, title and interest in and to such inventions, and any copyrights, patents or other intellectual property rights relating thereto. The Executive further agrees that the obligation to execute or cause to be executed, when it is in the Executive's power to do so, any such instrument or papers shall continue after the termination of this Agreement until the expiration of the last such intellectual property right to expire in any country of the world. If the Company or its designee is unable because of the Executive's mental or physical incapacity or unavailability or for any other reason to secure the Executive's signature to apply for or to pursue any application for any United States or foreign patents, copyrights, or other registrations covering inventions or works of authorship assigned or to be assigned to the Company or its designee as above, then the Executive hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as the Executive's agent and attorney-in-fact, to act for and on the Executive's behalf and stead to execute and file any such applications and to do all other lawfully permitted acts to further the application for, prosecution, issuance, maintenance or transfer of letters patent, copyright or other registrations thereon with the same legal force and effect as if originally executed by the Executive. The Executive hereby waives and irrevocably quitclaims to the Company or its designee any and all claims, of any nature whatsoever, that the Executive now or hereafter has for infringement of any and all proprietary rights assigned to the Company or such designee.

ARTICLE VI
MISCELLANEOUS

6.01 Benefit of Agreement and Assignment. This Agreement shall inure to the benefit of Company, its affiliates and their respective successors and assigns (including, without limitation, the purchaser of all or substantially all of the assets of Company and/or any of its affiliates) and shall be binding upon Company and its successors and assigns. This Agreement also shall inure to the benefit of and be binding upon Executive and Executive's heirs, administrators, executors and assigns. Executive may not assign or delegate Executive's duties under this Agreement, without the prior written consent of Company.

6.02 Notices. All notices, requests, demands and other communications required or permitted hereunder shall be given in writing and shall be deemed to have been duly given (i) on the date delivered if personally delivered, (ii) upon receipt by the receiving party of any notice sent by registered or certified mail (first-class mail, postage pre-paid, return receipt requested), (iii) by email, or (iv) on the date targeted for delivery if delivered by nationally recognized overnight courier or similar courier service, addressed in the case of Company to:

Motus GI Holdings, Inc.,

1301 East Broward Blvd
Fort Lauderdale, Florida 33301

Attn: Chief Executive Officer

With a copy which, itself, shall not constitute notice, to:
Lowenstein Sandler LLP
One Lowenstein Drive
Roseland, NJ 07068
Attn: Steven M. Skolnick, Esq.

and in the case of Executive to:

Andrew Taylor
816 Winter Road
Rydal, PA 19046

Any Party may notify the other Party in writing of the change in address by giving notice in the manner provided in this Section 6.02. Service of process in connection with any suit, action or proceeding (whether arbitration or otherwise) may be served on each Party hereto anywhere in the world by the same methods as are specified for the giving of notices under this Agreement.

6.03 Non-Disparagement. During the Term and at all times thereafter, Executive agrees that Executive shall not knowingly disparage, criticize or otherwise make any derogatory statements regarding Company or its past, present and future directors, officers, shareholders, employees, or agents. Upon conclusion of the Term, the Company agrees to instruct the Board and its senior officers not to knowingly disparage, criticize or otherwise make any derogatory statements concerning the Executive. Nothing herein shall preclude either Party from making truthful statements that are reasonably necessary to comply with applicable law, regulation or legal process or to defend or enforce a Party's rights under this Agreement.

6.04 Indemnification. The Company shall indemnify Executive to the maximum extent provided in the Company's Bylaws and organizational documents, as currently in effect. Executive shall be entitled to coverage under the directors and officers liability insurance on terms no less favorable to him in any respect than the coverage then being provided to any other current or former director or officer of the Company and which the Company shall maintain with minimum coverage of $1 million.

6.05 Arbitration. With the exception of the Company's right to seek injunctive relief in a court of competent jurisdiction to enforce Article V, any dispute or controversy arising out of or relating to this Agreement or Executive's performance thereunder shall be exclusively settled by arbitration before a single arbitrator to be held in Florida in accordance with the rules then in effect of the American Arbitration Association to the maximum extent permitted by applicable law. The decision of the arbitrator shall be final, conclusive and binding on the Parties to the arbitration. Judgment may be entered on the arbitrator's decision in any court having jurisdiction. The Company and the Executive shall separately pay their own counsel fees and expenses. The arbitrator shall apply the laws of the State of Florida with respect to interpretation, construction or enforcement of this Agreement without giving effect to the principles of conflicts of law.

6.06 Entire Agreement. This Agreement, including the exhibits, contains the entire agreement of the Parties with respect to the terms and conditions of Executive's employment during the Term and activities following termination of this Agreement and Executive's employment with Company and supersedes any and all prior agreements and understandings, whether written or oral, between the Parties with respect to the subject matter of this Agreement. This Agreement may not be changed or modified except by an instrument in writing, signed by both the Company and the Executive.

6.07 Representation and Warranties. Executive and Company each respectively represent and warrant to the other that (a) he/it has the legal capacity to execute and perform this Agreement, (b) this Agreement is a valid and binding agreement enforceable against the Parties according to its terms, and (c) the execution and performance of this Agreement by him/it does not violate or conflict with the terms of any existing agreement or understanding to which Executive or Company is a party or by which Executive or Company may be bound.

6.08 No Attachment. Except as required by law, no right to receive payments under this Agreement shall be subject to anticipation, commutation, alienation, sale, assignment, encumbrance, charge, pledge, or hypothecation or to execution, attachment, levy, or similar process or assignment by operation of law, and any attempt, voluntary or involuntary, to effect any such action shall be null, void and of no effect; *provided, however*, that nothing in this Section 6.08 shall preclude the assumption of such rights by executors, administrators or other legal representatives of Company or Executive's estate and their assigning any rights hereunder to the person or persons entitled thereto.

6.09 Source of Payment. All payments provided for under this Agreement shall be paid in cash from the general funds of Company. The Company shall not be required to establish a special or separate fund or other segregation of assets to assure such payments, and, if Company shall make any investments to aid it in meeting its obligations hereunder, Executive shall have no right, title or interest whatever in or to any such investments except as may otherwise be expressly provided in a separate written instrument relating to such investments. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind, or a fiduciary relationship, between Company and Executive or any other person. To the extent that any person acquires a right to receive payments from Company hereunder, such right, without prejudice to rights which Executives may have, shall be no greater than the right of an unsecured creditor of Company.

6.10 No Waiver. The waiver by any Party of a breach of any provision of this Agreement shall not operate or be construed as a continuing waiver or as a consent to or waiver of any subsequent breach hereof.

6.11 Headings. The Article and Section headings in this Agreement are for the convenience of reference only and do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

6.12 Validity. The invalidity or enforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision or provisions of this Agreement, which shall remain in full force and effect.

6.13 Executive Withholdings and Deductions. All payments to Executive hereunder shall be subject to such withholding and other Executive deductions as may be required by law.

6.14 Counterparts. This Agreement may be executed in one more counterparts, each of which shall be deemed to be an original but all of which together will constitute one and the same instrument.

6.15 Agreement to Take Actions. Each Party shall execute and deliver such documents, certificates, agreements and other instruments, and shall take all other actions, as may be reasonably necessary or desirable in order to perform his or its obligations under this Agreement.

6.16 Survival. The terms of Section 4.02 and Articles V and VI of this Agreement shall survive the termination of this Agreement and Executive's employment hereunder.

6.17 Section 409A Compliance.

(A) This Agreement is intended to comply with the requirements of Section 409A of the Code ("Section 409A") and regulations promulgated thereunder. To the extent that any provision in this Agreement is ambiguous as to its compliance with Section 409A, the provision shall be read in such a manner so that all payments due under this Agreement shall comply with Section 409A. For purposes of section 409A, each payment made under this Agreement shall be treated as a separate payment. In no event may Executive, directly or indirectly, designate the calendar year of payment. Notwithstanding anything contained herein to the contrary, Executive shall not be considered to have terminated employment with Company for purposes of Section 4.02 of this Agreement unless Executive would be considered to have incurred a "termination of employment" from Company within the meaning of Treasury Regulation §1.409A-1(h)(1)(ii).

(B) All reimbursements provided under this Agreement shall be made or provided in accordance with the requirements of Section 409A, including, where applicable, the requirement that (i) any reimbursement is for expenses incurred during Executive's lifetime (or during a shorter period of time specified in this Agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred, and (iv) the right to reimbursement is not subject to liquidation or exchange for another benefit.

(C) Executive acknowledges that, while the Parties endeavor to have this Agreement comply with the requirements of Section 409A, any tax liability incurred by Executive under Section 409A is solely the responsibility of Executive.

6.18 Legal Counsel. Executive represents that Company has previously recommended that Executive engage counsel to assist Executive in reviewing this Agreement. Executive acknowledges that, prior to executing this Agreement, Executive has been given a reasonable opportunity to review the Agreement and to consult with counsel as to its content and is entering into this Agreement freely and voluntarily.

[Signatures appear on the following page]

IN WITNESS WHEREOF, Company and Executive have duly executed this Agreement as of the date first written above.

COMPANY:

Motus GI Holdings, Inc.

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

EXECUTIVE:

/s/ Andrew Taylor
Andrew Taylor

[*Signature Page to Andrew Taylor First Amended Employment Agreement*]

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement of Motus GI Holdings, Inc. on Form S-8 (No. 333-224003) of our report dated March 26, 2019, on our audit of the consolidated financial statements as of December 31, 2018 and for the year then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 26, 2019. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern.

/s/ *EisnerAmper LLP*

EISNERAMPER LLP
Philadelphia, PA
March 26, 2019

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement of Motus GI Holdings, Inc. on Form S-8 (No. 333-224003) of our report dated March 28, 2018 (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the substantial doubt as to the Company's ability to continue as a going concern), on our audit of the consolidated financial statements as of, and for the year ended, December 31, 2017, which report is included in this Annual Report on Form 10-K filed on March 26, 2019.

/s/ *Brightman Almagor Zohar & Co.*

Brightman Almagor Zohar & Co.
Certified Public Accountants
Member of Deloitte Touche Tohmatsu Limited

Tel Aviv, Israel
March 26, 2019

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Timothy P. Moran, certify that:

1. I have reviewed this annual report on Form 10-K for the period ended December 31, 2018 of Motus GI Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 26, 2019

/s/ Timothy P. Moran
Timothy P. Moran
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew Taylor, certify that:

1. I have reviewed this annual report on Form 10-K for the period ended December 31, 2018 of Motus GI Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 26, 2019

/s/ Andrew Taylor
Andrew Taylor
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

Certification Pursuant to
18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Annual Report on Form 10-K of Motus GI Holdings, Inc. for the year ended December 31, 2018 (the "Annual Report"), each of the undersigned hereby certifies in his capacity as an officer of Motus GI Holdings, Inc. (the "Company") that to such officer's knowledge:

(1) The Annual Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 26, 2019

By: */s/ Timothy P. Moran*
Timothy P. Moran
Chief Executive Officer
(Principal Executive Officer)

Dated: March 26, 2019

By: */s/ Andrew Taylor*
Andrew Taylor
Chief Executive Officer
(Principal Executive Officer)

This Certification is being furnished solely to accompany the Annual Report pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.