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, 2020

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

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchanged on Which Registered
Common Stock, $0.0001 par value per share	MOTS	The Nasdaq Capital Market

As of June 30, 2020, 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 $34,315,900 based on the closing price of the registrant's Common Stock on June 30, 2020.

The number of shares outstanding of the registrant's Common Stock, par value of $0.0001 per share, as of March 11, 2021 was 46,748,113.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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

For the Year Ended December 31, 2019

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;
- 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 separately 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
- our ability to adequately support growth; and
- our ability to project in the short term the hospital medical device environment considering the global pandemic and strains on hospital systems

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 anticipated 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"). In June 2019, the 510(k) premarket notification for the second-generation of the Pure-Vu System was reviewed and cleared by the FDA. The second-generation of our Pure-Vu System has received 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. 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 Medicare Severity Diagnostic Related Group (a "MS-DRG"). Based on our review and analysis of 2019 market data and 2021 projections for the U.S. and Europe, as obtained from iData Research Inc., we estimate that during 2021 approximately 1.5 million inpatient colonoscopy procedures will be performed in the U.S. and approximately 4.8 million inpatient colonoscopy procedures will be performed worldwide. The Pure-Vu System does not currently have a unique reimbursement code with any private or governmental third-party payors in any country. We began commercialization in the fourth quarter of 2019, with the first commercial placements of our second generation Pure-Vu System as part of our initial U.S. market launch targeting early adopter hospitals. We do not expect to generate significant revenue from product sales until the COVID-19 pandemic has subsided and we expand our commercialization efforts for the Pure-Vu System, which is subject to significant uncertainty.

Recent Developments

Due to the recent outbreak around the world of the highly transmissible and pathogenic coronavirus COVID-19, the extent and duration of which is difficult to predict, our sales efforts with targeted early adopter hospitals continue to be disrupted. This disruption is specifically related to our limited on-site access at hospital accounts, an overall reduction in GI procedures, and physician and clinician time primarily being focused on care for COVID-19 patients. This has presented a temporary slow-down in commercial activities, but we expect a recovery as broader vaccination occurs in particular with front-line healthcare workers. Projecting when new technology evaluations and non-critical hospital procedures will normalize is challenging, and the ability of hospital systems to make capital investments in new medical technologies remains impacted. In addition to sales disruptions, we have also experienced an overall slowdown in clinical program activities.

We completed the move of the manufacturing of our loading fixture from RMS Company to Sanmina Corporation during 2020. As part of the move, we also incorporated some enhancements in the loading fixture based on feedback from the initial launch of our second-generation of the Pure-Vu System that can further reduce the time of setup. Over time, this switch has the potential to improve our overall efficiency as the Workstation component of our Pure-Vu System is already being manufactured by Sanmina Corporation.

Due to nationwide COVID-19 lockdowns in Israel, our research & development activity were disrupted in the second quarter of 2020 and early part of the third quarter of 2020, but we are now moving forward at a steady pace. In our Israeli innovation center, we are using a flexible in office work plan to reduce the risk of future work disruption should any employee contract the virus. To date we have had no issues in our facility.

Our clinical research efforts are focused on critical patient populations such as acute lower GI bleeds, where time to a successful colonoscopy can be clinically impactful. We are working with a major hospital system on a study that has recently received IRB approval focused on rapid examination of significant lower GI bleed patients. In this study the patients will not ingest any purgative based preparation and only receive two tap water enemas prior to the procedure.

At this date, we cannot fully predict the impact of the COVID-19 outbreak on our financial results and operations and we continue to closely monitor the situation. We have been encouraged by an increase in GI procedural volume, as well as an uptake in hospital access and physician availability in certain parts of the United States where the prevalence of COVID-19 has lessened. We intend to continue to be nimble in our commercial approach and explore all options with respect to how we can best minimize the negative impact of COVID-19 on our business.

In an effort to manage the lack of in-person access to U.S. hospitals as a result of the pandemic, in June 2020, we officially launched the Motus GI mobile app that provides end-users with on-demand access to a full spectrum of Pure-Vu System support and educational resources. This new mobile interface provides Pure-Vu System users instant access to on-demand video support and training resources, including demo and intra-procedural videos, live set-up tutorials, and case studies. The app can be customized to individual hospitals, enabling the administration and healthcare teams to share and track protocols and upload external materials specific to their respective endoscopy department. It is available to all Pure-Vu System users via the '*imsmart'* umbrella in the App store. This new mobile solution is a part of a larger effort to diversify and digitize much of the go-to-market content for the Pure-Vu System, which is being adopted by a growing number of U.S. hospitals. If there are additional waves of COVID-19 in the Unites States, we intend to continue to leverage these new digital tools to ensure commercial efforts and training continues with minimal interruption.

Market Overview

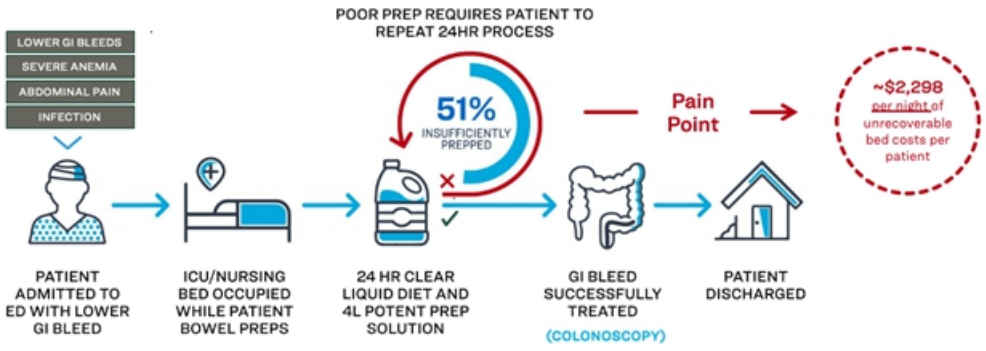
Colonoscopies are one of the most frequently performed medical procedures with over 20 million colonoscopies performed in the United States each year and close to 55 million worldwide, per 2019 iData Research Inc. Based on our review and analysis of this market data as well as 2021 projections for the U.S. and Europe, as obtained from iData Research Inc., we estimate that during 2021 approximately 1.5 million inpatient colonoscopy procedures in a hospital setting will be performed in the U.S. and approximately 4.8 million worldwide. A majority of total colonoscopies in the U.S. and worldwide are performed as outpatient procedures at an ambulatory endoscopy center and/or hospital outpatient departments. Some colonoscopies are performed to help diagnose and treat lower gastrointestinal (GI) bleeding, irritable bowel syndrome (IBS), inflammatory bowel disease (IBD), anemia or infection, with the bulk of procedures performed to detect and prevent colorectal cancer (CRC). CRC is the third most common cancer diagnosed in the U.S. with approximately 150,000 new cases anticipated to be diagnosed and more than 50,000 deaths anticipated in 2021, according to the American Cancer Society. According to the CDC (2018), approximately 31% of eligible patients are still not current with their CRC screening in the U.S. Over the past few decades, CRC has been demonstrated to be one of the most preventable cancers through the use of colonoscopies.

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. 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. 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, each of which results in increased healthcare costs. 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 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, as noted by Harwood et al., American Journal of Gastroenterology (2002). Further, it is estimated by HRA Healthcare Research & Analytics (2015) that approximately 23% of outpatients present with inadequately prepped colons, resulting in a number of colonoscopies that yield poor diagnostic accuracy or failed colonoscopies that must be repeated. For inpatients, this figure jumps to approximately 51% according to a recently published study by the Cleveland Clinic. It has also been 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., per Lieberman D.A. et.al., American Society for Gastrointestinal Endoscopy (2005).

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 the MS-DRG payment groupings, 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 700 MS-DRGs ("Medicare Severity – Diagnostics 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), MSDRGs 395, 394 or 393 would apply which pay between $3,861 (without complications or major comorbidities) and $9,421 (with major complications and comorbidities), which are average figures subject to adjustment. 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 generally 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 by the Cleveland Clinic that showed an inadequate preparation rate of 51% in the study population of 8,819 inpatients. The study noted that the 51% of the study population that were inadequately prepped stayed one day extra in the hospital compared to patients with adequate preparation. Another study, from Northwestern University Hospital System, 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 potentially reducing the time to a successful colonoscopy, minimizing delayed and incomplete procedures, and improving the quality of an exam.



Our Pure-Vu Solution

Our system consists of a workstation controller and a single-use, disposable sleeve that fits over most standard and slim 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 the disposable over-sleeve to the workstation. The over-sleeve is treated with a hydrophilic lubricious coating that reduces friction and allows for smooth advancement through the colon. 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 smart sense suction (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 received special 510(k) clearance from the FDA in the fourth quarter of 2017 for our first generation Pure-Vu System 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.

In June 2019, the 510(k) premarket notification for the second-generation (“Gen 2”) of the Pure-Vu System was reviewed and cleared by the FDA. We received the initial approval to affix the CE Mark to the Gen 2 Pure-Vu System in March 2020 and obtained an additional approval with all the latest upgrades in January 2021.

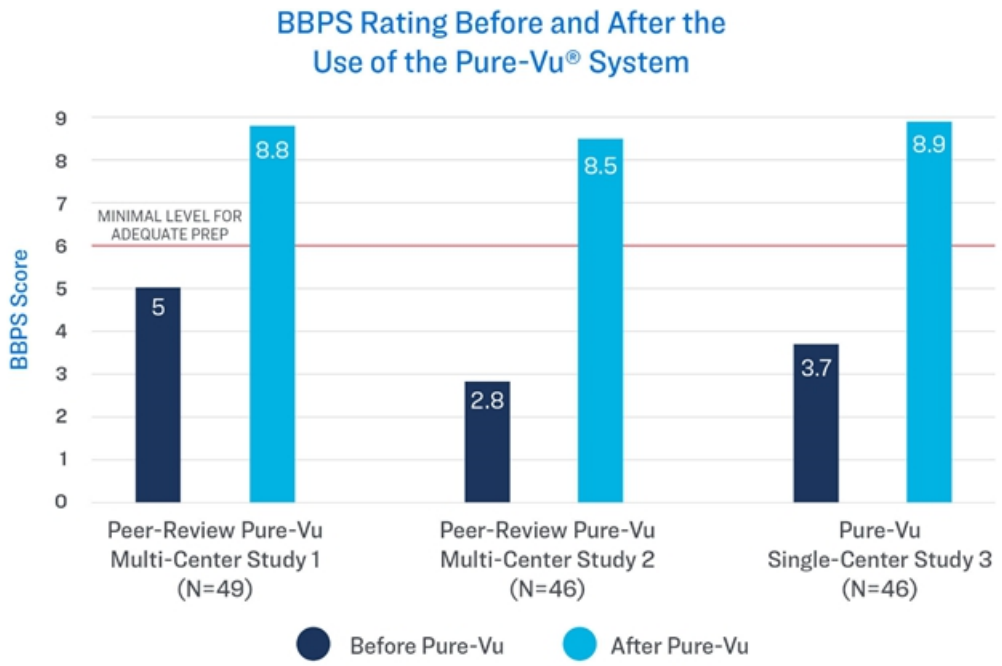
The Gen 2 Pure-Vu System includes two versions of the oversleeve for compatibility with both standard and slim colonoscopes. The Gen 2 Pure-Vu System has also been designed to improve the mobility and logistics in the setup of the system and retains all the same functionality as the first generation of the Pure-Vu System in terms of how it cleanses the colon. The Gen 2 Pure-Vu System Workstation has a reduced footprint and is 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.

Pre-Clinical and Clinical Data & Safety

The Pure-Vu System has been studied in multiple clinical trials in patients receiving a reduced prep regime as well as a trial focused on the inpatient population. The Pure-Vu System was used in two multi-center clinical studies in the EU and Israel, and also 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 the 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.

The third clinical study in the outpatient setting was presented at the American College of Gastroenterology ("ACG") Annual Meeting in October 2018. This study was performed in the United States and showed that 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 chart below shows the outcome of the primary endpoint using the BBPS both pre and post use of the Pure-Vu System in a side by side fashion. It can be seen from the data that the high cleansing level achieved with the Pure-Vu System is consistent across the various studies.



REDUCE Study

At the Digestive Disease Week (DDW) conference in May of 2019 the results of the REDUCE study ("Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement"), a multi-center inpatient prospective trial designed to evaluate Pure-Vu System's ability to consistently and reliably improve bowel preparation to facilitate a successful colonoscopy in a timely manner in patients who were indicated for a diagnostic colonoscopy, was presented. The study enrolled 95 hospitalized patients on schedule regardless of their level of pre-procedural bowel preparation. The primary endpoint for the study was improvement of bowel preparation from baseline to post procedure as assessed by the Boston Bowel Preparation Scale ("BBPS"), which assesses the cleanliness of the each of the three segments of the colon on a 0 to 3 scale and requires a minimum score of 2 or better per segment to be considered adequately prepped.

For inpatients that received the Pure-Vu System, adequate bowel preparation improved from a baseline of 38% to 96% in segments evaluated. The analysis from the REDUCE study showed statistically significant improvement in every segment of the colon after Pure-Vu System use. The per segment BBPS improved from an average baseline of 1.74, 1.74 and 1.5 to 2.89, 2.91 and 2.86 respectively with a statistically significant p value of ..001 for all three segments of the colon. The primary indication for patients enrolled in the study (68%) was a GI bleed. Acute GI bleeds can lead to hemodynamic instability and is a critical population to treat in an urgent fashion. Physicians were able to achieve a successful clinical outcome in 98% of patients in the study.

Current Clinical Studies

Our current clinical research efforts are focused on critical patient populations such as acute lower GI bleeds, where time to a successful colonoscopy can be clinically impactful. We are working with a major hospital system on a study that has recently received IRB approval focused on rapid examination of significant lower GI bleed patients. In this study the patients will not ingest any purgative based preparation and only receive two tap water enemas prior to the procedure. We are also evaluating additional studies focused on critical populations in both the inpatient and outpatient markets. As an example, studying the ability of the Pure-Vu System to impact outpatients that have a history of poor preparation that cannot get a quality exam and have to come back on a shortened surveillance interval may be of interest.

Intellectual Property

Our IP position comprises a portfolio covering highly innovative technologies rooted in systems and methods for cleaning body cavities with or without the use of an endoscope. Currently we have twelve granted or allowed patents in the U.S., fourteen patents in Asia (Japan, China and Hong Kong), and seven patents in the EU, with patent protection until at least 2036. In addition, we have 24 pending patent applications in various regions of the world with a focus on the U.S., EU and Japan. We also have one Patent Cooperation Treaty (PCT) worldwide patent application pending which can lead to additional National Phase applications in the above jurisdictions. We have registered trademarks for Motus GI and for the Pure-Vu System in the US, EU and other international jurisdictions. We also have a pending trademark application in the US to MICRO-PREP.

Our portfolio of patents and patent applications focuses on cleaning body cavities in a safe and efficient manner, insertion, 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. Coverage includes critical aspects of our system that we believe are key to effectively and efficiently clean the colon or other cavities in the body. These aspects 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 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 identified and potentially 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 Corp, Pentax Medical, Fujifilm Medical) as well as some smaller equipment manufacturers (i.e., Medivators, Erbe) sell a lesser powered irrigation pump that can pump fluid through the auxiliary water jet or working channel of a colonoscope. Potentially competitive is an intra-procedural device under development by Medjet Ltd. MedJet's device goes through the working channel of a scope, is used mostly for spot cleaning a small amount of debris and does not have the capability to fully clean the colon of large amounts of fecal matter. The MedJet product also requires the physician to remove it from the working channel during the procedure if they need to remove significant debris, polyps or take a biopsy, impacting the workflow of the procedure. There is also a device under development by a company named OTTek Ltd. The device is called the FIOT (Flow in Over Tube). The tube is noted as being able to create a channel between the endoscope and the inside of the over tube to facilitate the removal of debris. The competitive products mentioned are not currently separately 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 sectors, 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 Corp, who controls a majority of the market, with Pentax Medical and FujiFilm Medical taking most of the rest of the U.S. colonoscope market. Boston Scientific, Medtronic GI Solutions, Conmed Corporation, Cantel Medical, Ambu A/S, 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 Corp. 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, 2020, 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 $1.407 million (assuming no increase, per the IIA Regulations, as described below). As of December 31, 2020, 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 4% (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 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 relevant grant applications submitted to the IIA. Furthermore, the IIA Regulations require that the know-how 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. We received a general approval for such transfer. The transfer outside of Israel of manufacturing which is connected with the IIA-funded knowhow at a greater scope than the scope set forth in the general approval will result in a higher royalty repayment rate and may further result in increased royalties (up to three times the aggregate amount of the IIA grants plus interest thereon). 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 generally required to ensure that all rights in the IIA-backed product are retained by them. This means that, generally, 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 CMOs, and our collaborators to manufacture and supply our product for our initial U.S. market launch targeting early adopter hospitals and for our broader commercialization. Currently, the workstation and loading fixture component of our Pure-Vu System is manufactured by Sanmina Corporation at their facilities in Israel. 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 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, at their facilities in China. 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 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

Our initial launch strategy in the United States is focused on the acute care hospital market. Our focus is on building clinical champions amongst key Gastroenterologists, and other GI and nursing floor leadership and staff. Additionally, we 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 seek to work within the Value Analysis Committee approval process, currently utilized within most U.S. hospitals and integrated delivery networks (IDNs). Following successful implementation at the flagship location within an IDN, we then seek to gain further expansion of the Pure-Vu System within sister hospital locations. We support our customers with robust training on the effective use of our Pure-Vu System technology through our training and in-servicing programs.

In addition to working with a third-party logistics provider specializing in medical devices to provide front and back office support to successfully fulfill customer orders, 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. Our primary focus of the initial product launch is on gaining system placements in the acute care hospital market, driving utilization of our Pure-Vu System disposable sleeve, growing top line revenues and appropriately scaling the commercial organization.

Market Expansion Opportunities

Our resources are currently focused on the initial U.S. market launch targeting early adopter hospitals. However, we have identified several follow-on market expansion opportunities that are currently being evaluated, including the upper GI endoscopy and high medical need outpatient markets, as described below.

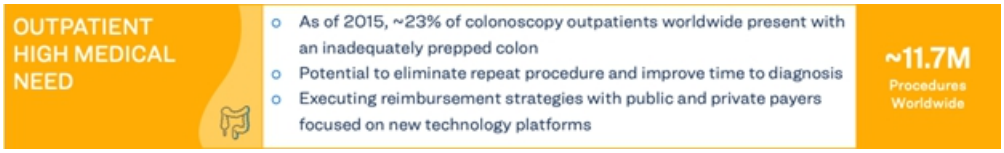
Upper GI Endoscopy Market

Upper GI bleeds occurred at a rate of approximately 400,000 cases per year in 2019 in the United States, according to iData Research Inc. The mortality rate of this condition can reach up to approximately 10%, as noted in Thad Wilkins, MD, et al., American Family Physician (2012).Removing adherent blood clots from the field of view is a significant need in allowing the physician the ability to find and treat the bleed. We believe the Pure-Vu System has the potential to be adapted and used during upper GI endoscopy procedures to remove clots and debris in order to provide a clear field of view for the endoscopist. This additional indication for the use of the Pure-Vu System would require a 510(k) clearance by the FDA.

High Medical Need Outpatient Market

The high medical need outpatient colonoscopy market presents a large potential commercial market opportunity for the Pure-Vu System. Based on our review and analysis of 2019 market data and 2021 projections for the U.S. and Europe, as obtained from iData Research Inc., and estimates from HRA Healthcare Research & Analytics - Market Research, May 2015, we believe there are ~4.7M high medical need outpatient colonoscopies performed in the US each year and ~11.7M worldwide. These colonoscopy patients can often times 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 high medical need outpatient colonoscopy market. We may seek to obtain reimbursement coverage for this market through exploration of programs with both private and public payers focused on new technology platforms.

Additionally, if we choose to explore either market, we may be able to leverage our existing hospital and physician relationships developed through our inpatient colonoscopy sales force to facilitate such expansion.



Strategic Partnerships

We intend to explore potential strategic relationships to accelerate and scale our US commercialization effort, and to initiate sales in the EU, Japan, China and other markets in the future.

Employees

As of December 31, 2020, we had 24 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 governing certain matters such as 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 the 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, expansion 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 good and positive relationships with our employees are a significant part of our operations.

Israeli law generally requires the payment of severance pay by employers upon the retirement, death or dismissal of an employee. We fund our ongoing Israeli severance obligations by making monthly payments to the employees' respective insurance policies. All of our current employees in Israel have agreed, as part of their employment agreements, 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.

Similar requirements may be applicable in other countries and jurisdictions including the European Union, the European Economic Area, and the United Kingdom.

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. Medical device manufacturers intending to market medical devices in the European Union/ and the European Economic Area (the "EU/EEA"), are required to affix the CE Mark to their medical devices, often after the intervention of a notified body and the issuing of a CE Certificate of Conformity. Many other countries, such as Australia, India, New Zealand, Pakistan and Sri Lanka, accept CE Certificates of Conformity or FDA clearance or approval, although others, such as Brazil, Canada and Japan require separate regulatory filings.

In the EU and the EEA, medical devices are currently required to comply with the essential requirements of the EU Medical Devices Directive. Compliance with these requirements would entitle us to affix the CE 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 mark we must undergo a conformity assessment procedure, which procedure varies according to the type of medical device and its classification. Apart from 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 by an EU Member States' accreditation body to conduct conformity assessments. The Notified Body would typically audit and examine the quality system for the manufacture, design and final inspection of our medical devices before issuing a CE Certificate of Conformity. After receiving the CE Certificate of Conformity from the Notified Body we can draw up a CE Declaration of Conformity which allows us to affix the CE Mark to our products.

Apart from 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 by an EU Member States' accreditation body to conduct conformity assessments. The Notified Body would typically audit and examine the quality system for the manufacture, design and final inspection of our medical devices before issuing a CE Certificate of Conformity. After receiving the CE Certificate of Conformity from the notified body 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 and industry codes 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.

On May 26, 2021, the EU Medical Devices Regulation will become applicable which will repeal the EU Medical Devices Directive. Notified bodies will have to be accredited by the EU Member States' accreditation bodies to conduct assessment procedures for medical devices. There are currently a relatively small number of notified bodies that have been accredited to conduct conformity assessment to the Regulation. This may delay our conformity assessment procedures in the future. The Medical Devices Regulation imposes a number of new requirements on manufacturers of medical devices. This may have also impact our activities in the EU, the EEA and the UK, the renewal of our existing CE Certificates of Conformity and conformity assessment related to future bodies.

On March 29, 2017, the United Kingdom formally notified the EU of its intention to withdraw from the Union pursuant to Article 50 of the Lisbon Treaty, commonly referred to as Brexit. The United Kingdom and EU have now agreed on the terms of the exit deal, which will include a transitional period following the United Kingdom's exit which occurred on January 31, 2020. The transitional period will continue until December 31, 2020 during which the EU and the United Kingdom will seek to negotiate new arrangements for the period from January 1, 2021. During the transitional period most obligations imposed by EU legislation will remain applicable to and in the United Kingdom. Since a significant proportion of the regulatory framework in the United Kingdom is derived from EU directives and regulations, the "hard" withdrawal of the United Kingdom from the EU (where no deal is agreed for the period after the transitional period ending December 31, 2020) could materially impact the regulatory regime with respect to our CE Certificates of Conformity in the United Kingdom. CE Certificates of Conformity issued by a notified body accredited in the EU may no longer by recognized in the UK. Similarly, notified bodies accredited in the UK will no longer be able to issue CE Certificates of Conformity. Obtaining new CE Certificates of Conformity or certification for the UK may have a significant impact on our activities.

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 separately reimbursable through private or governmental third-party payors in any country. Significant uncertainty exists as to whether coverage and separate reimbursement of the Pure-Vu System will develop; but we intend to seek separate 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 Medicare 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 will 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, restrictions under applicable federal and state healthcare laws and regulations include, but are not limited to, the following:

- The federal 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, or in return for, the purchase, lease, recommendation, order, or arranging for the purchase, lease, or order, of any health care product or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced-price items and services. 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. There are a number of statutory exceptions and regulatory safe harbors protecting from prosecution some common activities like discounts, or engaging health care professionals as speakers or consults; however, those exceptions and safe harbors are drawn narrowly, and there is no exception or safe harbor for many common business activities like educational grants or reimbursement support programs. In November 2020, the federal government finalized a regulation creating new safe harbors for, among other things, certain value-based arrangements and patient engagement tools, and that modifying and clarifying the scope of existing safe harbors for warranties and personal service agreements. The Biden Administration has temporarily paused implementation of the final rule. Whether the rule will go into effect and the impact of the regulation on our current or contemplated operations remains to be seen.

- The federal civil False Claims Act imposes liability, 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, knowingly making, using, or causing to be made or used a false statement or record material to an obligation to pay money to the government, or knowingly concealing or knowingly and improperly 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 significant mandatory penalties per false claim or statement for violations 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 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.

- The Health Insurance Portability and Accountability Act of 1996, Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations (collectively, "HIPAA") imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers; knowingly and willfully embezzling or stealing from a healthcare benefit program; willfully obstructing a criminal investigation of a healthcare offense; and knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. HIPAA, as amended by the HITECH and its implementing regulations, also imposes certain obligations, including contractual terms and technical safeguards, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

- HITECH also created new tiers of civil monetary penalties 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.

  On December 12, 2018, HHS issued a request for information (RFI) seeking input from the public on how the HIPAA regulations, and the Privacy Rule in particular, could be modified to amend existing, or impose additional, obligations relating to the processing of PHI. Subsequent to the RFI, on January 21, 2021, HHS published a notice of proposed rulemaking (NPRM) containing potential modifications to the Privacy Rule addressing standards that may impede the transition to value-based health care. The Company is monitoring the NPRM process. If modifications to the Privacy Rule are adopted, they may impact the Company's compliance obligations under HIPAA

- The federal Physician Payments Sunshine 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, and payments or other "transfers of value" to such physician owners. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives.

- 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 and local laws that require manufacturers to report information related to payments and other transfers of value to health care providers and state and local laws that require manufacturers to implement compliance programs or marketing codes. 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"—certain persons or entities that create, receive, maintain or transmit protected health information in connection with providing a specified service or performing a function on behalf of a covered entity.

Further, the legislative and regulatory landscape for privacy and data security continues to evolve, and there has been an increasing amount of focus on privacy and data security issues with the potential to affect our business. Congress and state legislatures also have been considering and enacting new legislation relating to privacy and data protection. For example, on June 28, 2018, the California legislature passed the California Consumer Privacy Act (CCPA), which was effective January 1, 2020. The CCPA created new transparency requirements and granted California residents several new rights with regard their personal information. In addition, in November 2020, California voters approved the California Privacy Rights Act ("CPRA") ballot initiative which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency ("CPPA"). The amendments introduced by the CPRA go into effect on January 1, 2023, and new implementing regulations are expected to be introduced by the CPPA. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or potential statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with certain types of incidents. These claims may result in significant liability and potential damages. We implemented processes to manage compliance with the CCPA and continues to assess the impact of the CPRA, and other state legislation, on our business as additional information and guidance becomes available.

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, decisions of the European Court of Justice have increased uncertainty around compliance with EU privacy law requirements. As a result of the decision in the Schrems case (Case C-362/14 Maximillian Schrems v. Data Protection Commissioner), 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,, 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." However, on July 16, 2020, the European Court of Justice ruled the EU-US Privacy Shield to be an invalid data transfer mechanism, confirmed that the Model Clauses remain valid, and left unaddressed some issues regarding supplementary measures that may need to be taken to support transfers. As a result, organizations are no longer able to use the Privacy Shield framework to transfer personal data.

Adherence to the Privacy Shield is not, however, mandatory. US-based companies are permitted to rely on 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.

For example, in March 2010, the Patient Protection and Affordable Care Act (the "Affordable Care Act") was enacted. The Affordable Care Act has substantially changed the way healthcare is financed by both governmental and private insurers and has significantly affected the health care industry. Certain provisions of the Affordable Care Act have been subject to judicial challenges as well as efforts to repeal or replace them or to alter their interpretation and implementation. For example, the Tax Cuts and Jobs Act (TCJA) enacted on December 22, 2017, included a provision that eliminated the tax-based shared responsibility payment for individuals who fail to maintain minimum essential coverage under Section 5000A of the Internal Revenue Code of 1986, commonly referred to as the "individual mandate," effective January 1, 2019. Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible, but the nature and extent of such potential changes or challenges are uncertain at this time. The implications of the Affordable Care Act, and efforts to repeal, replace, or otherwise modify, or invalidate, the Affordable Care Act or its implementing regulations, or portions thereof, or the political uncertainty surrounding any repeal, replacement, or other modification to the Affordable Care Act for our business and financial condition, if any, are not yet clear. We will continue to evaluate the effect that the Affordable Care Act as well as its possible repeal, replacement, modification, or invalidation, in whole or in part, has on our business.

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, or to any employee of a public international organization, 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.

Compliance with the FCPA is expensive and resource-intensive, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the medical device and pharmaceutical industries, 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. In recent years, there has been a trend of increasing government investigations and litigations against companies operating in our industry, both in the United States and around the world. We may become involved in government investigations that arise in the ordinary course of our business.

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.

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, LLC (formerly Motus GI, Inc.), a Delaware limited liability company. Motus GI, Inc. was converted from a Corporation into a Limited Liability Company effective January 1, 2021.

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, 2020 were prepared under the assumption that we will continue as a going concern. The independent registered public accounting firm that audited our 2020 financial statements, in their report, included an explanatory paragraph referring to our recurring losses since inception and expressing management's assessment and conclusion that there is 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. See Note 2 to our Consolidated Financial Statements for further details.

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 initial U.S. market launch targeting early adopter hospitals, we have generated limited revenue from our Pure-Vu System, but we do not expect to generate significant revenue from product sales until we expand our commercialization efforts for the Pure-Vu System, 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, 2020 and December 31, 2019 was approximately $19.3 million and $23.1 million, respectively. As of December 31, 2020, we had an accumulated deficit of approximately $103.7 million.

Our indebtedness to Silicon Valley Bank may limit our flexibility in operating our business and adversely affect our financial health and competitive position. Our obligations to Silicon Valley Bank are secured by substantially all of our assets, excluding our intellectual property assets. If we default on these obligations, Silicon Valley Bank could foreclose on our assets, which could have a materially adverse effect on our business.

In December 2019, we entered into a Loan and Security Agreement with Silicon Valley Bank, as subsequently amended from time to time (the "Loan Agreement"). All obligations under the Loan Agreement are secured by a first priority lien and security interests in substantially all of our assets (excluding all of our intellectual property, which is subject to a negative pledge). The security interests in substantially all of our assets includes a stock pledge on not more than sixty-five percent of our equity interests in Motus GI Medical Technologies LTD, our direct wholly-owned subsidiary.

In order to service this indebtedness and any additional indebtedness we may incur in the future, we will need to generate cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. If we are unable to generate sufficient cash to repay our debt obligations when they become due and payable, either when they mature, or in the event of a default, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our business operations and financial condition.

The Loan Agreement restricts our ability, among other things, to:

- sell, transfer or otherwise dispose of any of our business assets or property, subject to limited exceptions;
- make material changes to our business or management;

- enter into transactions resulting in significant changes to the voting control of our stock;
- make certain changes to our organizational structure;
- consolidate or merge with other entities or acquire other entities;
- incur additional indebtedness or create encumbrances on our assets;
- pay dividends, other than dividends paid solely in our common shares, or make distributions on and, in certain cases, repurchase our capital stock;
- enter into certain transactions with our affiliates;
- repay subordinated indebtedness; or
- make certain investments.

In addition, we are required under the Loan Agreement to comply with various affirmative covenants. The covenants and restrictions and obligations in the Loan Agreement, as well as any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. Our ability to comply with these covenants may be affected by events beyond our control, and we may not be able to meet those covenants.

If we breach any the covenants or default on any of our obligations under the Loan Agreement, a default interest rate of an additional 4.0% per annum may be applied to the outstanding indebtedness, and all of the outstanding indebtedness under the Loan Agreement could become immediately due and payable, which would harm our business, financial condition and results of operations and could require us to reduce or cease operations.

In certain circumstances, procedures by Silicon Valley Bank could result in a loss by us of all of our equipment and inventory, which are included in the collateral granted under the Loan Agreement. If our indebtedness under the Loan Agreement were to be accelerated, there can be no assurance that our assets would be sufficient to repay in full that indebtedness. In addition, upon any distribution of assets pursuant to any liquidation, insolvency, dissolution, reorganization or similar proceeding, Silicon Valley Bank will be entitled to receive payment in full from the proceeds of the collateral which secures our indebtedness before the holders of other indebtedness or holders of our common stock receive any distribution with respect thereto.

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 in order to be in compliance with the liquidity covenant of our Loan Agreement with Silicon Valley Bank and 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. The independent registered public accounting firm that audited our 2020 financial statements, in their report, included an explanatory paragraph referring to our recurring losses since inception and expressing management's assessment and conclusion that there is substantial doubt in our ability to continue as a going concern. At December 31, 2020, we had a cash and cash equivalents balance of approximately $20.8 million.

We will need to raise additional capital or generate substantial revenue in order to ensure compliance with the liquidity covenant contained in our Loan Agreement with Silicon Valley Bank and to support our development and commercialization efforts. If adequate funds are not available to us on a timely basis, or at all, we may breach our liquidity covenant (the "Liquidity Covenant") under the Loan Agreement, in which case, we would be required to immediately pledge to the bank and thereafter maintain in a separate account, unrestricted and unencumbered cash in an amount equal to the amount then outstanding under the Loan Agreement. Based on our current business plan, we believe our cash and cash equivalents balance as of December 31, 2020, will be sufficient to ensure compliance with the liquidity covenant under the Loan Agreement into the first quarter of 2022.

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.

Except for our Loan Agreement with Silicon Valley Bank, we have no 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, which, except for limited circumstances, would require the prior written consent of Silicon Valley Bank pursuant to our Loan Agreement, 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 GI Medical Technologies LTD, and the holders of all issued and outstanding shares of capital stock of Motus GI 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 GI Medical Technologies LTD (the "Share Exchange Transaction") and Motus GI 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 credits 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 Code 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, Code 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.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security ("CARES") Act was enacted in response to the COVID-19 pandemic. The CARES Act provides relief to corporate taxpayers by permitting a five year carryback of net operating losses incurred in the 2018, 2019 and 2020 tax years, permitting net operating loss carrybacks and carryovers to offset 100% of taxable income for tax years beginning before 2021, and accelerating refunds for minimum tax credit carryforwards, among other provisions. Among other significant changes, the TCJA reduced the corporate federal income tax rate from 35% to 21%. The carryback of net operating losses under the CARES Act to pre-TCJA years will generate an income tax benefit due to the differential in income tax rates. During the year ended December 31, 2020, no material adjustments were made to provision amounts recorded as a result of the enactment of the CARES Act.

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, and we also must take into account newly emerging risks associated with medical devices such as cybersecurity vulnerabilities. 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 Certificate of Conformity. The first-generation and second-generation of our Pure-Vu System have received CE Mark approval in the European Economic Area, and we intend to target countries with a regulatory approval process with similar requirements to the EU and EEA. 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 and the 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 or, from May 26, 2021, compliance with the Medical Device Regulation. Until May 26, 2021, the Notified Body will assess the changes in accordance with the Medical Device Directive and verify whether they affect the products' conformity with the essential requirements set forth in the 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 Medical Devices Directive. If the assessment is not completed by May 26, 2021 we will be required to undertake the assessment procedure in accordance with the provisions of the Medical Devices Regulation. This may oblige us to undertake future clinical and technical procedures and provide information in addition to that provided to support conformity assessment under the Medical Devices Directive.

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 separately 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 separately reimbursable through private or governmental third-party payors in any country. We intend to seek separate reimbursement through private or governmental third-party payors, 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/hospital 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.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

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.

For example, in March 2010, the Affordable Care Act was enacted. The Affordable Care Act has substantially changed the way healthcare is financed by both governmental and private insurers and has significantly affected the health care industry. Certain provisions of the Affordable Care Act have been subject to judicial challenges as well as efforts to repeal or replace them or to alter their interpretation and implementation. For example, the Tax Cuts and Jobs Act (TCJA) enacted on December 22, 2017, included a provision that eliminated the tax-based shared responsibility payment for individuals who fail to maintain minimum essential coverage under Section 5000A of the Internal Revenue Code of 1986, commonly referred to as the "individual mandate," effective January 1, 2019. Additional legislative changes, regulatory changes, and judicial challenges related to the Affordable Care Act remain possible, but the nature and extent of such potential changes or challenges are uncertain at this time. The implications of the Affordable Care Act, and efforts to repeal, replace, or otherwise modify, or invalidate, the Affordable Care Act or its implementing regulations, or portions thereof, or the political uncertainty surrounding any repeal, replacement, or other modification to the Affordable Care Act for our business and financial condition, if any, are not yet clear. It is possible that the Affordable Care Act as well as its possible repeal, replacement, modification, or invalidation, in whole or in part, could negatively impact our business.

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. For a fuller discussion of the applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations applicable to our business, see Item 1 "Description of Business - Other Healthcare Laws and Compliance Requirements".

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.

The failure to comply with anti-corruption laws could materially adversely affect our business and result in civil and/or criminal sanctions.

The U.S. Foreign Corrupt Practices Act (FCPA) and similar anti-corruption laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to government officials for the purpose of obtaining or retaining business. Because of the predominance of government-administered healthcare systems in many jurisdictions around the world, many of our customer relationships outside of the U.S. are with governmental entities and are therefore potentially subject to such laws.

Global enforcement of anti-corruption laws has increased in recent years, including investigations and enforcement proceedings leading to assessment of significant fines and penalties against companies and individuals. Our international operations create a risk of unauthorized payments or offers of payments by one of our employees, consultants, sales agents, or distributors. We maintain policies and programs to implement safeguards to educate our employees and agents on these legal requirements, and to prevent and prohibit improper practices. However, existing safeguards and any future improvements may not always be effective, and our employees, consultants, sales agents or distributors may engage in conduct for which we could be held responsible. In addition, regulators could seek to hold us liable for conduct committed by companies in which we invest or that we acquire. Any alleged or actual violations of these regulations may subject us to government scrutiny, criminal or civil sanctions and other liabilities, including exclusion from government contracting, and could disrupt our business, adversely affect our reputation and result in a material adverse effect on our business, results of operations, financial condition and cash flows.

Laws and regulations governing international business operations could adversely impact our business.

The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC), and the Bureau of Industry and Security at the U.S. Department of Commerce (BIS), administer certain laws and regulations that restrict U.S. persons and, in some instances, non-U.S. persons, in conducting activities, transacting business with or making investments in certain countries, governments, entities and individuals subject to U.S. economic sanctions. Our international operations subject us to these laws and regulations, which are complex, restrict our business dealings with certain countries, governments, entities, and individuals, and are constantly changing. Further restrictions may be enacted, amended, enforced or interpreted in a manner that materially impacts our operations. Violations of these regulations are punishable by civil penalties, including fines, denial of export privileges, injunctions, asset seizures, debarment from government contracts and revocations or restrictions of licenses, as well as criminal fines and imprisonment. We have established policies and procedures designed to assist with our compliance with such laws and regulations. However, there can be no assurance that our policies and procedures will prevent us from violating these regulations in every transaction in which we may engage, and such a violation could adversely affect our reputation, business, financial condition, results of operations and cash flows.

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 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 first generation and second generation Pure-Vu System and began commercialization in fourth quarter of 2019, with the first commercial placements of our second generation Pure-Vu System as part of our initial U.S. market launch targeting early adopter hospitals. 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 separate 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;
- rapid technological change may make our Pure-Vu System obsolete; and
- our inability to project in the short term the hospital medical device environment considering the global pandemic and strains on hospital systems.

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 separate 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 separate 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.

We rely on the proper function, availability and security of our information technology systems to operate our business and a cyber-attack or other breach or disruption of these systems could have a material adverse effect on our business and results of operations.

We rely on information technology systems to process, transmit and store electronic information in our day-to-day operations. The form and function of such systems may change over time as our business needs change. The nature of our business involves the receipt and storage of personal and financial information regarding our customers. We use our information technology systems to manage or support a variety of business processes and activities, including sales, shipping, billing, customer service, procurement and supply chain, manufacturing and accounts payable. In addition, we use enterprise information technology systems to record, process, and summarize transactions and other financial information and results of operations for internal reporting purposes and to comply with regulatory financial reporting, legal, and tax requirements. Our information technology systems may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. Any failure by us to maintain or protect our information technology systems and data integrity, including from cyber-attacks, intrusions, disruptions or shutdowns, could result in the unauthorized access to customer data, theft of intellectual property or other misappropriation of assets or the loss of key data and information, or otherwise compromise our confidential or proprietary information and disrupt our operations. If our information technology systems are breached or suffer severe damage, disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may be materially and adversely affected.

If our efforts to maintain the privacy and security of our customer, employee, supplier or Company information are not successful, we could incur substantial additional costs and become subject to litigation, enforcement actions and reputational damage.

Our business, like that of most medical device companies, involves the receipt, storage and transmission of customer information and payment and reimbursement information, our employees, our suppliers and our Company. Our information systems are vulnerable to an increasing threat of continually evolving cybersecurity risks. Unauthorized parties may attempt to gain access to our systems or information through fraud or other means of deceiving our employees, business acquisitions, or third-party service providers. Hardware, software or applications we develop or obtain from third parties may contain defects in design or manufacture or other problems that could unexpectedly compromise information and device security. Hardware or software applications developed by our business acquisitions may face risks associated with defects and vulnerabilities in their systems, or difficulties with the integration of the acquisitions into our information systems. The methods used to obtain unauthorized access, disable or degrade service or sabotage systems are also constantly changing and evolving, and may be difficult to anticipate or detect for long periods of time. The ever-evolving threats mean we must continually evaluate and adapt our systems and processes, and our efforts may not be adequate to safeguard against all data security breaches, misuse of data or sabotage of our systems. Any future significant compromise or breach of our data security, whether external or internal, or misuse of customer, employee, supplier or Company data, could result in additional significant costs, lost sales, fines, lawsuits and damage to our reputation. In addition, as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, with new and constantly changing requirements applicable to our business, compliance with those requirements could also result in additional costs. Further, many of our employees are working remotely in response to the COVID-19 pandemic and related government actions, which could expose us to greater risks related to cybersecurity and our information systems.

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 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 relevant grant applications submitted to the IIA. Furthermore, the IIA Regulations require that the know how 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. We received a general approval for such transfer. The transfer outside of Israel of manufacturing which is connected with the IIA-funded knowhow at a greater scope than the scope set forth in the general approval will result in a higher royalty repayment rate and may further result in increased royalties (up to three times the aggregate amount of the IIA grants plus interest thereon). 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, generally required to ensure that all rights in the IIA-backed product are retained by them. This means that, generally, 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, 2020, we had 24 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 products through clinical trials and to expand our development, regulatory and commercial 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.

Global or regional pandemics, including outbreaks of communicable diseases, may materially and adversely affect our business, financial condition, revenues, and results of operations.

We may face risks related to health epidemics or outbreaks of communicable diseases. For example, the recent outbreak around the world of the highly transmissible and pathogenic coronavirus COVID-19. The outbreak of such communicable diseases could result in a widespread health crisis that could adversely affect general commercial activity and the economies and financial markets of many countries.

The continued impact resulting from the COVID-19 outbreak where we and our business partners have operations, or the perception that such an outbreak could occur, and the measures taken by our business partners, including restrictions with respect to business or hospital procedures, restrictions with respect to our access to our business partners, and/or restrictions imposed by the regulatory bodies or governments of countries or regions affected, could adversely affect our business, financial condition, revenues, and results of operations.

For example, the COVID-19 outbreak, or other similar outbreaks, could have an adverse effect on the overall productivity of our workforce and we may be required to take extraordinary measures to ensure the safety of our employees and those of our business partners. These measures could require that our employees refrain from traveling to their normal workplace for extended periods of time, which we have already experienced in certain locations as a result of the COVID-19 outbreak, which in turn could result in a decrease in our commercial activities, or result in higher costs or other inefficiencies.

Any serious disruption with our suppliers or customers due to such outbreaks could impair our ability to meet and/or generate demand for our product, which may negatively impact our revenue, financial condition and commercial operations. Such outbreaks could also result in delays in or the suspension of our business partners manufacturing operations, which we have already experienced as a result of the COVID-19 outbreak, including the loss of our contract manufacturing relationship with RMS Company, the contract manufacturer who manufactured the loading fixture for our Pure-Vu System, our research and product development activities, which we have begun to scale back as a result of the impact of COVID-19 on our business, our regulatory work streams, our clinical studies, which we have already experienced as a result of the COVID-19 outbreak, including that we will no longer pursue the RESCUE study, and other important commercial functions.

Additionally, our business may be harmed if, in connection with an outbreak, our customers seek to limit or prevent access by our sales and clinical support teams to their facilities, which we have already experienced in certain locations as a result of the COVID-19 outbreak, or if our customers postpone elective procedures while their resources are diverted to addressing such an outbreak, or if capital spending by hospitals is curtailed or delayed in connection with such an outbreak, which we have already experienced as a result of the COVID-19 outbreak. An outbreak may also result in restrictions on domestic and international travel, which could have a negative impact on our customer engagement efforts, including through the cancellation or postponement of third-party conferences, trade shows and similar events, each of which we have already experienced as a result of the COVID-19 outbreak.

In addition to the risks identified above, we may face the risk of a resurgence of an outbreak, including a resurgence of the ongoing COVID-19 outbreak, in locations where we and our business partners have operations that were initially showing signs of improvement from such outbreak. Such resurgence may result in the recurrence of each of the risks and restrictions identified above, as well as new or unforeseen risks or restrictions imposed by our business partners, including with respect to our business partners operations or procedures and/or our access to such business partners, or imposed by the regulatory bodies and/or governments of countries or regions affected, all of which could adversely affect our business, financial condition, revenues, and results of operations.

Further, in our operations as a public company, prolonged government disruptions, global pandemics and other natural disasters or geopolitical actions could affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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 20.25% of our outstanding capital stock as of February 18, 2021. 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 initial U.S. market launch targeting early adopter hospitals, we have generated limited revenue from our Pure-Vu System, but we do not expect to generate significant revenue from product sales until we expand our commercialization efforts for the Pure-Vu System, 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 we fail to maintain compliance with the requirements of The Nasdaq Capital Market for continued listing, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is listed for trading on The Nasdaq Capital Market. There can be no assurance that we will be able to continue to maintain compliance with the Nasdaq continued listing requirements, and if we are unable to maintain compliance with the continued listing requirements, including the $1.00 Minimum Bid Price Requirement set forth in Nasdaq Listing Rule 5550(a)(2), our securities may be delisted from Nasdaq, which could reduce the liquidity of our common stock materially and result in a corresponding material reduction in the price of our common stock. In the past, we have received notification from Nasdaq that we failed to maintain the $1.00 Minimum Bid Price Requirement set forth in Nasdaq Listing Rule 5550(a)(2), however, we were able to regain compliance with the requirement but we may not be able to obtain such compliance in the future. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and business development opportunities. Such a delisting likely would impair your ability to sell or purchase our common stock when you wish to do so. Further, if we were to be delisted from Nasdaq, our common stock may no longer be recognized as a "covered security" and we would be subject to regulation in each state in which we offer our securities. Thus, delisting from Nasdaq could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly impact the ability of investors to trade our securities and would negatively impact the value and liquidity of our common stock.

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, subject to a royalty cap amount per calendar year of $30 million. 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, subject to a royalty cap amount per calendar year of $30 million. The royalties will be payable up to the later of (i) the latest expiration date for our current patents (which is currently May 2036), 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 4 employees, and 2 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.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline. 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. We will also be required to disclose changes made in our internal control and procedures on a quarterly basis.

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.

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.

We are an "emerging growth company" as defined in the JOBS Act. For as long as we remain an emerging growth company, we are permitted and intend to take advantage of the exemptions contained in the JOBS Act, including that 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 of the Sarbanes Oxley 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. In the past, we have identified material weaknesses in our controls which we subsequently remediated. We cannot assure investors that we will not have other material weaknesses in our internal control over financial reporting in the future.

If we identify material weaknesses in our internal control over financial reporting in the future or if we are unable to successfully remediate the identified material weaknesses or, if we are unable to comply with the requirements of Section 404 in a timely manner or 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, or other regulatory authorities, which could require additional financial and management resources.

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 some of our employees 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 and rank 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, 2020, 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 $1.407 million (assuming no increase, per the IIA Regulations, as described below). As of December 31, 2020, 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 4% (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% (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 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 relevant grant applications submitted to the IIA. Furthermore, the IIA Regulations require that the know-how 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. We received a general approval for such transfer. The transfer outside of Israel of manufacturing which is connected with the IIA-funded knowhow at a greater scope than the scope set forth in the general approval will result in a higher royalty repayment rate and may further result in increased royalties (up to three times the aggregate amount of the IIA grants plus interest thereon). 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 generally required to ensure that all rights in the IIA-backed product are retained by them. This means that, generally, 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 affect 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. The lease was set to expire on December 31, 2019. On July 4, 2019, we exercised the option to extend the lease expiration to December 31, 2022.

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. In January 2020, we entered into a license agreement with Orchestra BioMed, Inc., formerly a greater than 5% holder of our Common Stock, pursuant to which we granted a license to Orchestra BioMed, Inc. for the use of portions of the office space not being used by us in our leased facility in Fort Lauderdale, Florida (the "Premises"), and a proportionate share of common areas of such Premises, which compromises approximately 35% of the Premises as of January 2020 and will expand incrementally to approximately 60 to 70% of the Premises by September 2024.

On March 11, 2020, we entered into a lease with 720 UNIVERSITY PROPERTY, LLC, a Delaware limited liability company (the "Landlord") for a facility in Norwood, Massachusetts (the "Massachusetts Lease"), which we intended to begin to occupy on the date the Landlord substantially completed construction of the premises, which was expected to be on or about June 11, 2020. The facility consists of 7,684 square feet. The term was intended to run for six years and two months from the date we would have taken occupancy. Annual base rent ranged from approximately $198 thousand per year to approximately $244 thousand per year.

On March 30, 2020, we executed a Lease Termination Agreement with Landlord (the "Massachusetts Lease Termination Agreement") to terminate the Massachusetts Lease effective as of March 30, 2020. A termination fee of $170,000 was paid to Landlord on March 30, 2020, in connection with the Massachusetts Lease Termination Agreement.

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 February 18, 2021, we had approximately 159 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.

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 (the "Pure-Vu System"), a medical device that has received 510(k) clearance from the U.S. Food and Drug Administration (the "FDA"). In June 2019, the 510(k) premarket notification for the second-generation of the Pure-Vu System was reviewed and cleared by the FDA. The second-generation of our Pure-Vu System has received 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. 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 Medicare Severity Diagnostic Related Group (a "MS-DRG"). Based on our review and analysis of 2019 market data and 2021 projections for the U.S. and Europe, as obtained from iData Research Inc., we estimate that during 2021 approximately 1.5 million inpatient colonoscopy procedures will be performed in the U.S. and approximately 4.8 million inpatient colonoscopy procedures will be performed worldwide. The Pure-Vu System does not currently have a unique reimbursement code with any private or governmental third-party payors in any country. We began commercialization in the fourth quarter of 2019, with the first commercial placements of our second generation Pure-Vu System as part of our initial U.S. market launch targeting early adopter hospitals. We do not expect to generate significant revenue from product sales until the COVID-19 pandemic has subsided and we expand our commercialization efforts for the Pure-Vu System, which is subject to significant uncertainty.

Financial Operations Overview

We have generated limited revenues to date from the sale of products. We have never been profitable and have incurred significant net losses each year since our inception, including a loss of $19.3 million for the year ended December 31, 2020, and we expect to continue to incur net operating losses for the foreseeable future. As of December 31, 2020, we had $20.8 million in cash and cash equivalents and an accumulated deficit of $103.7 million. We expect our expenses to increase 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. Furthermore, the extent of the impact and effects of the recent outbreak of the coronavirus COVID-19 on the operation and financial performance of our business will depend on future developments, including the duration and spread of the outbreak, related travel advisories and restrictions, production delays, or the uncertainty with respect to the accessibility of additional liquidity or capital markets, all of which are highly uncertain and cannot be predicted. If the demand for our second generation system is impacted by this outbreak for an extended period, our results of operations may be materially adversely affected.

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 in connection with our ongoing activities, as we:

- continue commercialization which began in the fourth quarter of 2019, with the first commercial placements of our Pure-Vu System as part of our initial U.S. market launch targeting early adopter hospitals;
- scale manufacturing with our contracted partners for both the workstation and disposable portions of the Pure-Vu System;
- develop future generations of the Pure-Vu System to improve user interface, optimize handling and reduce the cost structure;
- raise sufficient funds 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 Significant Judgement and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 3 to our consolidated financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue recognition

We generate revenue from the sale or lease of our Pure-Vu System Workstation ("Workstation") and from the sale of our single-use disposable sleeves ("Disposables"), and related services, which are primarily support and maintenance services on our Workstations. See Note 3 for further discussion of revenue recognition.

Sales of our Workstation and Disposables are accounted for in accordance with ASC Topic 606 - Revenue from Contracts with Customers to depict the transfer of control to our customers in an amount reflecting the consideration to which we expect to be entitled to. Revenue from the sale of a Workstation is recognized after a customer commits to purchase the Workstation and the Workstation is delivered, which is when title is transferred. Disposables are identified as a separate performance obligation, and therefore, revenue from the sale of Disposables is recognized when the Disposables are delivered to the customer and title is transferred.

For contracts outside the scope of ASC 606, we determine income for proposed supply arrangements with an embedded lease in accordance with ASC 842 and certain components of sales within the proposed supply arrangement in accordance with ASC 606. We allocate the transaction price to the performance obligations within the proposed supply arrangements using the total estimated purchases method for both (i) arrangements that contain minimum purchase commitments and (ii) those arrangements that do not contain a minimum purchase commitment, but instead offer a volume discount for purchases that exceed a specified tier.

Inventory

Inventory is accounted for at lower of cost and net realizable value using the weighted average cost method and is evaluated at least annually for impairment. Write-downs for potentially obsolete or excess inventory are made based on management's analysis of inventory levels, historical obsolescence and future sales forecasts.

Share-Based Compensation

Our share-based compensation programs grant awards that have included stock options, warrants, and restricted stock units. Grants are awarded to employees and non-employees, including directors.

We account for our stock-based compensation awards in accordance with ASC Topic 718, Compensation—Stock Compensation, or ASC 718. ASC 718 requires all stock-based payments to employees and non-employee directors, including grants of employee stock options and restricted stock units and modifications to existing stock options, to be recognized in the consolidated statements of operations and comprehensive loss based on their fair values.

We account for forfeitures as they occur instead of estimating forfeitures at the time of grant and revising those estimates in subsequent periods if actual forfeitures differ from its estimates. Share-based compensation expense recognized in the financial statements is based on awards for which performance or service conditions are expected to be satisfied.

Prior to the adoption of ASU No. 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, or ASU 2018-07, on July 1, 2018, the measurement date for non-employee awards was generally the date the services were completed, resulting in financial reporting period adjustments to stock-based compensation during the vesting terms for changes in the fair value of the awards. After adoption of ASU 2018-07, the measurement date for non-employee awards is the date of grant without changes in the fair value of the award.

Our share-based awards are subject to service or performance-based vesting conditions. Compensation expense related to awards to employees, directors and non-employees with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term.

We expense restricted stock unit awards to employees based on the fair value of the award on a straight-line basis over the associated service period of the award.

We estimate the fair value of our option awards to employees, directors and non-employees using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including (i) the expected stock price volatility, (ii) the calculation of expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of complete company-specific historical and implied volatility data for the full expected term of the stock-based awards, we base our estimate of expected volatility on a representative group of publicly traded companies in addition to our own volatility data. For these analyses, we selected companies with comparable characteristics to our own, including enterprise value, risk profiles, position within the industry and with historical share price information sufficient to meet the expected life of the stock-based awards. We compute historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. We have estimated the expected term of our employee stock options using the "simplified" method, whereby, the expected term equals the arithmetic average of the vesting term and the original contractual term of the option due to its lack of sufficient historical data. The risk-free interest rates for periods within the expected term of the option are based on the U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. We have never paid, and do not expect to pay, dividends in the foreseeable future.

Contingent Royalty Obligation

We estimate and record a contingent royalty obligation in relation to our royalty obligation, which is payable over the life of certain patents after certain conditions are met. Forecasted revenue over an expected life of the product is the largest driver of the estimated obligation, with other factors being growth rate, patent expiration assessments, and the discount rate. All these drivers are subject to a high degree of uncertainty which we determine at present based on a very limited-commercialized product.

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.

Recent Accounting Pronouncements

Refer to Note 3, "Significant Accounting Policies and Basis of Presentation", in the accompanying notes to the consolidated financial statements for a discussion of recent accounting pronouncements.

Results of Operations

Comparison of Year Ended December 31, 2020 and 2019

Revenue

As of December 31, 2020, as part of our initial launch, we have generated a small amount of revenue from the sales of products. We do not expect to generate significant revenue from product sales until we expand our commercialization efforts for the Pure-Vu System, which is subject to significant uncertainty.

Revenue totaled $98.0 thousand for the year ended December 31, 2020, compared to $107.0 thousand for the year ended December 31, 2019. The decrease of $9.0 thousand was largely driven by the impact of COVID-19 on the commercial launch of the Pure-Vu System in U.S. hospitals during 2020.

Cost of Revenue

Cost of revenue for the year ended December 31, 2020 totaled $496.0 thousand, compared to $136.0 thousand for the year ended December 31, 2019. The increase of $360.0 thousand was primarily attributable to the net increase of inventory reserves and obsolete inventory of $344.0 thousand, due to the lengthening of sales cycles and lower than anticipated sales volume in light of COVID-19, and an increase to the cost of our system disposable evaluation and commercial units of $16.0 thousand.

Research and Development

Research and development expenses consist of costs 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.

Research and development expenses for the year ended December 31, 2020 totaled $5.6 million, compared to $9.0 million for the year ended December 31, 2019. The decrease of $3.4 million was primarily attributable to decreases of $2.1 million in salaries and other personnel related costs, $0.9 million in material costs and clinical costs, $0.3 million in travel, and $0.1 million in share-based compensation as we shifted our focus to expanding our commercialization efforts for the Pure-Vu System.

Sales and Marketing

Sales and marketing expenses consist of costs primarily related to our sales and marketing personnel and infrastructure supporting the commercialization of the second generation Pure-Vu System.

Sales and marketing expenses for the year ended December 31, 2020 totaled $3.5 million, compared to $4.9 million for the year ended December 31, 2019. The decrease of $1.4 million was primarily attributable to decreases of $1.0 million in salaries and other personnel related cost and professional services and $0.2 million in travel, and $0.2 million in promotional items as we implemented our 2020 cost reduction strategy.

General and Administrative

General and administrative expenses consist primarily of costs associated with our overall operations and being a public company. These costs include personnel, legal and financial professional services, insurance, investor relations, compliance related fees, and expenses associated with obtaining and maintaining patents.

General and administrative expenses for the year ended December 31, 2020 totaled $9.6 million, compared to $9.5 million for the year ended December 31, 2019.

Other Income and Expenses

Other expense, net for the year ended December 31, 2020 totaled $0.2 million compared to other income, net of $0.4 million for the year ended December 31, 2019. The change of $0.6 million in other income and expenses, net was primarily attributable to a change of $0.7 million from finance income to finance expense offset by an increase of $0.1 million from the gain on the change in estimated fair value of contingent royalty obligation.

Liquidity and Capital Resources

To date, we have generated minimal revenues, experienced negative operating cash flows and have incurred substantial operating losses from our activities. We expect operating costs will increase significantly as we incur costs associated with commercialization activities related to the Pure-Vu System. We expect to continue to fund our operations primarily through utilization of our current financial resources, future product sales, and through the issuance of debt or equity.

In December 2019, we entered into a Loan and Security Agreement, as subsequently amended from time to time (the "Loan Agreement"), for $8.0 million with Silicon Valley Bank (the "Bank" or "SVB"). Under the terms of the Loan Agreement we must maintain unrestricted cash in accounts held at SVB of at least $10.0 million (the "Liquidity Covenant"). We will need to raise additional capital or generate substantial revenue in order to ensure compliance with the Liquidity Covenant to support our development and commercialization efforts. If adequate funds are not available to us on a timely basis, or at all, we may breach the Liquidity Covenant, in which case, we would be required to immediately pledge to the bank and thereafter maintain in a separate account, unrestricted and unencumbered cash in an amount equal to the amount then outstanding under the Loan Agreement.

On September 1, 2020 we entered into a securities purchase agreement (the "Securities Purchase Agreement") under which we sold and issued to an institutional investor (the "Holder"), in a registered direct offering, an aggregate of 3,200,000 shares of our common stock par value $0.0001 per share (the "Common Stock"), and pre-funded warrants to purchase an aggregate of 5,533,625 shares of Common Stock (the "Pre-Funded Warrants"). The offering price was $1.145 for each share of Common Stock and $1.144 for each Pre-Funded Warrant. The Pre-Funded Warrants were immediately exercisable at a price of $0.001 per share of Common Stock. Pursuant to the Securities Purchase Agreement, in a concurrent private placement, we also agreed to issue to the Holder warrants to purchase up to 8,733,625 shares of Common Stock (the "Private Placement Warrants"). These warrants were immediately exercisable at an exercise price of $1.30 per share and expire on the fifth anniversary of the date of issuance. In connection with the closing of the offering, we received gross proceeds of $10.0 million before deducting placement agent fees and other offering expenses of $0.8 million, from the issuance of the Common Stock, the Pre-Funded Warrants and the Private Placement Warrants.

On January 27, 2021, we entered into a Warrant Exercise Agreement (the "Exercise Agreement") with the Holder, at which time 8,000,000 of the Private Placement Warrants remained outstanding, due to the prior exercise of 733,625 of the Private Placement Warrants on January 22, 2021. Pursuant to the Exercise Agreement, in order to induce the Holder to exercise all of its remaining outstanding 8,000,000 Private Placement Warrants for cash, we agreed to issue to the Holder, new warrants (the "New Warrants") to purchase 0.75 shares of Common Stock for each share of Common Stock issued upon such exercise of the remaining 8,000,000 Private Placement Warrants pursuant to the Exercise Agreement, or an aggregate of 6,000,000 New Warrants. The terms of the New Warrants are substantially similar to those of the Private Placement Warrants, except that the New Warrants will have an exercise price of $2.12, will be immediately exercisable and will expire five years from the date of the Exercise Agreement. In addition, the Holder paid a cash payment of $0.10 for each New Warrant issued to the Holder, for an aggregate of $600,000 to the Company. We received aggregate gross proceeds before expenses of approximately $11.0 million from the exercise of all of the remaining 8,000,000 outstanding Private Placement Warrants held by the Holder and the payment of the purchase price for the New Warrants.

In connection with the Exercise Agreement, we entered into a financial advisory agreement (the "Letter Agreement") with A.G.P./Alliance Global Partners ("A.G.P."), pursuant to which A.G.P. acted as exclusive financial advisor to us in this transaction and received a cash fee of $300,000 upon full cash exercise of the Private Placement Warrants. As additional compensation, A.G.P. will receive a cash fee equal to $200,000 upon the cash exercise in full of the New Warrants.

Since March 2020, we have been evaluating the actual and potential business impacts related to the COVID-19 pandemic. While the full impact of the pandemic continues to evolve, the financial markets have been subject to significant volatility that adversely impacts our ability to enter into, modify, and negotiate favorable terms and conditions relative to equity and debt financing initiatives. The uncertain financial markets, potential disruptions in supply chains, mobility restraints, and changing priorities could also affect our ability to enter into key agreements. The outbreak and government measures taken in response to the pandemic have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, have spiked, while demand for other goods and services have fallen. The future progression of the outbreak and its effects on our business and operations are uncertain. We and our third-party contract manufacturers, contract research organizations, and clinical sites may also face disruptions in procuring items that are essential to our research and development activities, including, for example, medical and laboratory supplies, in each case, that are sourced from abroad or for which there are shortages because of ongoing efforts to address the outbreak.

At the end of the first quarter of 2020, we adopted a cost reduction plan (the "2020 Plan") in response to the ongoing disruptions from the COVID-19 outbreak, and to better align our cost structure with the resources required to more efficiently and effectively execute on our commercial strategy of creating a strong foundation in the market by establishing national and regional hospital networks as Pure Vu reference centers. Most significantly, the 2020 Plan resulted in the reduction of our overall headcount by 50%, including a significant reduction of our commercial team in the US, the implementation of tighter expense controls, and the termination of the lease of our planned corporate office facility in Norwood, Massachusetts. These activities were initiated in the first quarter of 2020, of which the majority were completed in the second quarter of 2020.

Our ability to continue as a going concern for the next twelve months from the issuance of our Annual Report on Form 10K, depends on our ability to execute our business plan, increase revenue and reduce expenditures. As of December 31, 2020, we had cash and cash equivalents of $20.8 million and an accumulated deficit of $103.7 million. We will need to raise significant additional capital to continue to fund operations and to maintain the Liquidity Covenant under our existing debt facility. 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 shareholders and certain of 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. The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our product and clinical development programs as well as 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 including those associated with our planned product development, clinical trial and commercial efforts.

These factors raise substantial doubt about our ability to continue as a going concern. For more information, refer to note 2 to our consolidated financial statements included elsewhere in this Annual Report.

Cash Flows

The following table provides information regarding our cash flows for each of the periods below:

	Years Ended December 31,	
	2020	2019
	(in thousands)	
Net cash used in operating activities	$ (16,993)	$ (19,915)
Net cash provided by (used in) investing activities	8,115	(5,623)
Net cash provided by financing activities	9,169	28,016
Net increase in cash and cash equivalents	$ 291	$ 2,478

Operating Activities

During the year ended December 31, 2020, operating activities used $17.0 million of cash, due to our net loss of $19.3 million, offset by non-cash expenses principally related to share based compensation expense of $2.9 million, depreciation and amortization of $0.4 million, impairment of inventory of $0.4 million, issuance of common stock for board of directors' compensation of $0.1 million, offset by the gain on the change in estimated fair value of contingent royalty obligation of $0.3 million, and offset by changes in net working capital items principally related to the decrease in inventory of $0.6 million, the decrease in accounts payable and accrued expenses of $0.5 million, and the increase in prepaid expenses and other current assets of $0.1 million.

During the year ended December 31, 2019, operating activities used $19.9 million of cash, due to our net loss of $23.1 million, offset by non-cash expenses of $3.7 million principally related to share based compensation expense of $3.2 million, depreciation and amortization of $0.2 million, the write-down of obsolete inventory of $0.1 million, and non-cash operating lease expense of $0.2 million partially offset by the gain on the change in estimated fair value of contingent royalty obligation of $0.1 million, and cash used by the change in net working capital items of $0.5 million principally related to the increase in inventory of $1.0 million and the decrease in operating lease liabilities of $0.2 million, partially offset by the increase in accounts payable and accrued expenses of 0.6 million and the decrease of prepaid and other current assets of $0.1 million.

Investing Activities

During the year ended December 31, 2020, net cash used in investing activities was $8.1 million, principally related to the proceeds from the sale of available-for-sale securities of $8.2 million, offset by the purchase of fixed assets of $0.1 million.

During the year ended December 31, 2019, net cash used in investing activities was $5.6 million, principally related to the purchase of available-for-sale securities of $9.6 million and the purchase of fixed assets of $0.5 million, offset with $4.5 million of proceeds from the sale of available for sale securities.

Financing Activities

During the year ended December 30, 2020, net cash provided by financing activities was $9.2 million, consisting primarily of the to $10.0 million in proceeds received from an offering, partially offset by $0.8 million paid for financing fees related to the equity financing.

During the year ended December 30, 2019, net cash provided by financing activities was $28.0 million, consisting primarily of the proceeds received from public offerings and the exercise of over-allotment options of $21.9 million, proceeds obtained from debt financing of $8.0 million, partially offset by $1.9 million paid for financing fees.

Shelf Registration Statement

On March 26, 2019, we filed a shelf registration statement with the Securities and Exchange Commission, which was declared effective on April 24, 2019, that allows us to offer, issue and sell up to a maximum aggregate offering price of $75.0 million of any combination of our common stock, preferred stock, warrants, debt securities, subscription rights and/or units from time to time, together or separately, in one or more offerings. Each issuance under the shelf registration statement will require the filing of a prospectus supplement identifying the amount and terms of the securities to be issued. As of December 31, 2020, we have sold approximately $31.8 million of securities under our shelf registration statement. Our ability to issue securities is subject to market conditions and other factors including, in the case of our debt securities, our credit ratings.

Contractual Obligations and Commitments

For Operating Leases and Other Commitments

For further information, refer to Note 5 and Note 7 of the Notes to the Consolidated Financial Statements included in Pages F-15 through F-17 of this Annual Report of Form 10-K.

Off-Balance Sheet Arrangements

As of December 31, 2020, we do not have any off-balance sheet arrangements, as defined under applicable SEC rules.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements required to be filed pursuant to this Item 8 are found on pages F-1 through F-25.

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

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, 2020. 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 our management, including our 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. Our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2020.

Management's Annual Report on Internal Control Over Financial Reporting

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. Based on the results of this evaluation, management has concluded that the Company's internal control over financial reporting was effective at the reasonable assurance level as of December 31, 2020.

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 on Form 10-K 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 of Material Weakness in Internal Control over Financial Reporting

As of December 31, 2020, we have remediated the previously reported material weakness in our internal control over financial reporting related to the operation of internal controls related to the accounting for non-routine complex transactions.

In connection with the review of our third quarter 2018 consolidated financial statements and the audit of our annual 2018 consolidated financial statements, we identified a material weakness in our internal control over financial reporting related to the accounting for non-routine complex transactions. The material weakness was initially identified when management did not appropriately identify the proper accounting treatment related to a contract that included 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 Annual Report on Form 10-K.

We began remediation efforts in the fourth quarter of 2018 for our accounting of non-routine complex transactions controls 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 third-party specialists, we have implemented additional controls related to contract evaluation. Additionally, there is a renewed emphasis on our process 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. After redesigning and operating related controls during the third and fourth quarters of 2019, we completed a remediation test plan with our third-party internal control consulting firm. Based on the results of testing, Management concluded that controls associated with our remediation efforts were adequately designed as of December 31, 2019. However, we identified a lack of documentation in a fourth quarter 2019 technical accounting memo to support the depth and breadth of analysis performed by management and our third-party technical accounting specialists, and therefore we were unable to conclude that the controls associated with our remediation efforts were operating effectively at December 31, 2019. During 2020 we continued to implement the corrective actions described above and we completed a remediation test plan with our third-party internal control consulting firm. Based on the results of testing Management concluded that controls associated with our remediation efforts were operating effectively at the reasonable assurance level at December 31, 2020.

We believe these measures remediated the material weakness in internal control over financial reporting described above. The related modified and new controls are adequately designed and have operated for a sufficient period of time; therefore, management has concluded, through testing, that such controls are operating effectively at the reasonable assurance level at December 31, 2020.

Changes in Internal Control over Financial Reporting

Other than the changes 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, 2020 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	49	Chief Executive Officer and Director
Mark Pomeranz	59	President, Chief Operating Officer and Director
Andrew Taylor	50	Chief Financial Officer
David Hochman	45	Chairman of the Board
Darren Sherman	49	Director
Gary Jacobs (1)	63	Director
Samuel Nussbaum	72	Director
Shervin Korangy	46	Director
Gary J. Pruden	59	Director

(1) Gary Jacobs resigned as a director effective January 6, 2020.

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 and has served on the board of directors of Angel Medical Systems, Inc. since 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 and licensing efforts, and implementation of capital and operating budgets. From 2005 to 2007, Mr. Taylor was a Practice Leader for AC Lordi Consulting (now part of BDO USA, LLP), 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., 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 earned a B.A. in Political Science and Economics at McGill University and his MBA in Finance at Northeastern University, and is CFA Program Level II Candidate.

On December 31, 2018, Angel Medical Systems, Inc. filed a voluntary petition for relief under Chapter 11 of Title 11 of the United States Bankruptcy Code in the U.S. Bankruptcy Court for the District of Delaware (the "Bankruptcy Court"). On February 11, 2019, the conditions of the Chapter 11 Plan of Reorganization (the "Bankruptcy Plan") for Angel Medical Systems, Inc. were confirmed by the Bankruptcy Court. On March 29, 2019, the Bankruptcy Plan became effective and Angel Medical Systems, Inc. emerged from its Chapter 11 reorganization as a private company.

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 the Chairman of our board of directors 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 bringing high-impact procedure-based therapeutic innovations to life through risk-reward sharing partnerships. From 2006 until 2019, he served as Managing Partner of Orchestra Medical Ventures, LLC, an investment firm that employed 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 previously managed by Orchestra Medical Ventures, LLC, and now a wholly owned subsidiary of Orchestra BioMed, Inc. Mr. Hochman has over twenty-four years of medical innovation, entrepreneurial, venture capital and investment banking experience. Mr. Hochman served as a board member of Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP), a clinical-stage drug development company pioneering transformative medicines that target the endocannabinoid system, from 2013 until 2020. 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 served as a director of Adgero Biopharmaceuticals Holdings, Inc until 2020 when it was acquired by Kintara Therapeutics, Inc. (NASDAQ: KTRA). Prior to joining Orchestra Medical Ventures LLC, Mr. Hochman was Chief Executive Officer of Spencer Trask Edison Partners, LLC, an investment partnership focused on development 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 2011 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 bringing high-impact procedure-based therapeutic innovations to life through risk-reward sharing partnerships. 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. From 2009 until December 2019, Mr. Sherman served as Managing Partner of Orchestra Medical Ventures, LLC, an investment firm that employed 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, from 2008 to 2019, and now a wholly owned subsidiary of Orchestra BioMed, Inc. From 2009 until March 2018, Mr. Sherman served as Chief Executive Officer and a director of Caliber Therapeutics, Inc., from 2012 until March 2019 served as Chief Executive Officer and a director of FreeHold Surgical, Inc., and from 2009 until March 2019 he served as a director of BackBeat Medical, Inc., each of which entities are now wholly owned subsidiary of Orchestra BioMed, 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 had been a director of Motus GI Medical Technologies Ltd., our wholly owned subsidiary, since 2011 and had served on our board of directors since December 2016. Mr. Jacobs resigned as a member of our board of directors effective January 6, 2020. Mr. Jacobs is the Founder and Managing Director at Jacobs Investment Company LLC, and served as Chief Executive Officer of DermTech, Inc. He served as Chairman of DermTech International from 2006-2019, NGT New Generation Technologies Ltd., and Galilee Tech Management 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, Global Healthcare Private Capital, and Ontario Teachers Pension Plan. 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, PhyMed Healthcare Group, a physician led and owned leader of anesthesia and pain management services, Progenity, Inc. (NASDAQ: PROG), a biotechnology and molecular diagnostics company focused on women's health, Atrio Health Plans, Oregon-based Medicare Advantage Health Plans and the Able Channel, a streaming digital health platform. 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 Board of Directors 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 President and Chief Executive Officer of BVI Medical, Inc., a leading global developer, manufacturer and marketer of specialized surgical devices for the ophthalmic marketplace. Prior to his appointment as CEO of BVI, he served as the Chief Financial Officer and Head of Strategy of BVI. 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 strategy committee and member 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 has also served on the Advisory Board of the McNulty Center for Leadership and Change Management at The Wharton School of the University of Pennsylvania, since January 2019. 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 distributor 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 board experience, 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 FDA. 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 serves as an independent board member for Lantheus Holdings, Inc. (NASDAQ: LNTH) (and serves as a member of its Audit and Compensation committees), OSSIO Inc, (and serves as a member of its Audit committee) and Avisi Technologies Inc. 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 global management and regulatory experience with medical device and pharmaceutical products and his financial experience in leading a large business.

Family Relationships

There are no family relationships among any of the members of our board of 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. Pruden and Dr. Nussbaum, with Mr. Hochman serving as the Chairman of the Compensation Committee. Our board of directors has determined that the three 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. Pruden, 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.

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, 2020, our two other most highly compensated executive officers who were serving as executive officers as of December 31, 2020, 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, 2019. 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 ($) (2)	Option Awards ($) (1)	All Other Compensation ($)	Total ($)
Timothy P. Moran (3)	2020	475,000	262,200	224,035	408,685	558,930(6)	1,928,850
Chief Executive Officer	2019	475,000	213,750	41,679	79,171	849,756(7)	1,659,356
Mark Pomeranz (4)	2020	385,000	174,213	87,126	160,766	18,015(8)	825,120
President and Chief Operating Officer	2019	385,000	153,038	185,242	351,632	16,236(8)	1,091,148
Andrew Taylor (5)	2020	310,000	112,220	99,572	178,695	25,596(9)	726,083
Chief Financial Officer	2019	307,500	92,768	101,883	193,980	23,099(9)	719,230

(1) Amounts reflect the grant date fair value of option awards granted in 2020 and 2019 in accordance with Accounting Standards Codification Topic 718. For information regarding assumptions underlying the valuation of equity awards, see Note 11 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) Amounts reflects the grant date fair value of stock awards granted in 2020 and 2019 computed in accordance with Accounting Standards Codification Topic 718. For information regarding assumptions underlying the valuation of equity awards, see Note 11 to our Consolidated Financial Statements.

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

(4) 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.

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

(6) $533,333 reflects Employment Buy-Out Payments (as defined below), the remainder relates to corporate and health benefits.

(7) $826,667 reflects Employment Buy-Out Payments (as defined below), the remainder relates to corporate and health benefits.

(8) Amounts relate to corporate and health benefits.

(9) Amounts relate to corporate and health benefits.

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 our board of directors 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 our board of directors determines the objectives have been achieved. Thereafter, subsequent payout parameters will be determined by our board of directors based upon parameters set by our board of directors 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 our board of directors 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 received 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.

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 our board of directors 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 our board of directors determines that he has met the target objectives communicated to him. Payout parameters for the Pomeranz Performance Bonus will be determined by our board of directors based upon parameters set by our board of directors 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 our 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 our board of directors 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, as subsequently amended on March 15, 2021, 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, for any bonus period subsequent to December 31, 2019, an annual bonus payment (the "Taylor Performance Bonus") in an amount equal to up to forty percent (40%) of the Taylor Base Salary if our board of directors determines that he has met the target objectives communicated to him. Payout parameters for the Taylor Performance Bonus will be determined by our board of directors based upon parameters set by our board of directors 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 our 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 our board of directors 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 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 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 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 – 2020

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, 2020.

	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options		Option Exercise	Option Expiration	Number of Shares or Units of Stock That Have Not	Market Value of Shares or Units of Stock That Have Not
Name	Exerciseable	Unexerciseable	Price ($)	Date	Vested	Vested ($)
Timothy P. Moran (CEO)	330,000	165,000	$ 3.78(1)	November 8, 2028	165,714(11)	157,428
	16,884	12,060	$ 4.32(2)	February 13, 2029		
	15,125	88,595	$ 2.16(3)	February 6, 2030		
	-	200,000	$ 1.17(4)	June 11, 2030		
	-	190,000	$ 0.74(5)	November 11, 2030		
Mark Pomeranz (COO)	67,238	-	$ 2.38(6)	April 2, 2024	54,373(12)	51,654
	511,113	-	$ 4.50(7)	May 3, 2027		
	75,040	53,601	$ 4.32(8)	February 13, 2029		
	10,083	30,253	$ 2.16(3)	February 6, 2030		
	-	80,000	$ 1.17(4)	June 11, 2030		
	-	75,000	$ 0.74(5)	November 11, 2030		
Andrew Taylor (CFO)	240,000	-	$ 4.50(9)	September 29, 2027	47,840(12)	45,448
	41,272	29,481	$ 4.32(10)	February 13, 2029		
	11,526	34,572	$ 2.16(3)	February 6, 2030		
	-	90,000	$ 1.17(4)	June 11, 2030		
	-	78,000	$ 0.74(5)	November 11, 2030		

(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 February 13, 2019 with an exercise price of $4.32 per share. The shares underlying the option vest in a series of twelve (12) successive equal quarterly installments commencing on May 1, 2019 and continuing on the first day of each third month thereafter.

(3) Represents options to purchase shares of our Common Stock granted on February 6, 2020 with an exercise price of $2.16 per share. The shares underlying the option vest in a series of twelve (12) successive equal quarterly installments commencing on May 1, 2020 and continuing on the first day of each third month thereafter.

(4) Represents options to purchase shares of our Common Stock granted on June 11, 2020 with an exercise price of $1.17 per share. The shares underlying the option vest on the first anniversary of the date of grant.

(5) Represents options to purchase shares of our Common Stock granted on November 11, 2020 with an exercise price of $0.74 per share. The shares underlying the option vest on the first anniversary of the date of grant.

(6) Represents options to purchase shares of our Common Stock granted on April 2, 2014, under the Motus GI 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.

(7) 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.

(8) Represents options to purchase shares of our Common Stock granted on February 13, 2019 with an exercise price of $4.32 per share. The shares underlying the option vest in a series of twelve (12) successive equal quarterly installments commencing on May 1, 2019 and continuing on the first day of each third month thereafter.

(9) 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.

(10) Represents options to purchase shares of our Common Stock granted on February 13, 2019 with an exercise price of $4.32 per share. The shares underlying the option vest in a series of twelve (12) successive equal quarterly installments commencing on May 1, 2019 and continuing on the first day of each third month thereafter.

(11) Represents RSUs granted on October 1, 2018, February 13, 2019, and February 6, 2020. The shares underlying the RSUs granted on October 1, 2018 and February 13, 2019 vest in a series of sixteen (16) successive equal quarterly installments commencing on January 1, 2019 and May 1, 2019 and continuing on the first day of each third month thereafter. The shares underlying the RSUs granted on February 6, 2020 vest in a series of twelve (12) successive equal quarterly installments commencing on May 1, 2020 and continuing on the first day of each third month thereafter.

(12) Represents RSUs granted on February 13, 2019 and February 6, 2020. The shares underlying the RSUs granted on February 13, 2019 vest in a series of sixteen (16) successive equal quarterly installments commencing on May 1, 2019 and continuing on the first day of each third month thereafter. The shares underlying the RSUs granted on February 6, 2020 vest in a series of twelve (12) successive equal quarterly installments commencing on May 1, 2020 and continuing on the first day of each third month thereafter.

Director Compensation

The following table sets forth information concerning the compensation paid to certain of our non-employee directors during 2020.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($) (7)	Option Awards ($) (1)	Total ($)
David Hochman (2)	18,250	96,076	29,240	143,566
Darren Sherman (3)	9,875	56,626	18,275	84,776
Samuel Nussbaum (4)	9,000	54,002	18,275	81,277
Shervin Korangy (5)	9,000	54,002	18,275	81,277
Gary Pruden (6)	9,625	58,876	18,275	86,776

(1) Amounts reflect the aggregate grant date fair value of each stock option granted in 2020 in accordance with the Accounting Standards Codification Topic 718. For information regarding assumptions underlying the valuation of equity awards, see Note 11 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, 2020 held by Mr. Hochman was 235,000.

(3) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2020 held by Mr. Sherman was 137,500.

(4) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2020 held by Dr. Nussbaum was 87,500.

(5) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2020 held by Mr. Korangy was 102,500.

(6) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2019 held by Mr. Pruden was 87,500.

(7) Represents the value of Common stock issued to the board in lieu of cash compensation in 2020 and the FV of RSU's issued in 2020.

Non-Employee Director Compensation

Our board of directors approved a director compensation policy for our directors, effective February 2021. This policy provides for the following cash compensation:

- each director is entitled to receive a quarterly fee of $6,500;
- the chairman of our board of directors will receive a quarterly fee of $9,000 through December 31, 2020, and a quarterly fee from us of $6,450 thereafter;
- the chair of the Audit Committee will receive a quarterly fee of $2,500;
- each chair of any other board of director committee will receive a quarterly fee of $1,500;
- each non-employee director sitting on more than two of our board of directors 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 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. Effective May 2020, our Board approved a temporary modification to the non-employee director compensation policy to permit payment of the Fees in grants of our common stock, in lieu of cash compensation, for the quarters ending June 30, 2020, September 30, 2020 and December 31, 2020. Effective February 2021, our Board approved a temporary modification to the non-employee director compensation policy to permit payment of the entire 2021 Fees in a single grant of our common stock, in lieu of cash compensation, for the quarters ending March 31, 2021, June 30, 2021, September 30, 2021 and December 31, 2021 (the "2021 Fee Grant"). The 2021 Fee Grant was made to each non-employee director on February 17, 2021. 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

2016 Equity Incentive Plan

General

On December 14, 2016, our board of directors adopted our 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"), subject to stockholder approval, which was received on December 20, 2016.

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.

The following table provides information with respect to our compensation plans under which equity compensation was authorized as of December 31, 2020.

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)(4)
Equity compensation plans approved by security holders(1)	5,367,044(2)	$ 3.00(3)	387
Equity compensation plans not approved by security holders	-	$ -	-
Total	5,367,044	$ 3.00	387

(1) The amounts shown in this row include securities under the 2016 Plan.
(2) Includes 5,029,119 shares of common stock issuable upon exercise of outstanding options and 337,925 shares of common stock issuable pursuant to outstanding restricted stock units
(3) The weighted average exercise price does not take into account the shares issuable pursuant to outstanding restricted stock units, which have no exercise price.
(4) In accordance with the "evergreen" provision in our 2016 Plan, an additional 1,936,339 shares were automatically made available for issuance on the first day of 2021, which represents 6% of the number of shares outstanding on December 31, 2020; 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, February 18, 2021 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 46,626,876 shares of Common Stock issued and outstanding as of February 18, 2021 plus any shares issuable upon exercise of options or warrants that are exercisable on or within 60 days after February 18, 2021 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)	647,821	1.37%
Mark Pomeranz (2)	725,081	1.53%
David Hochman (3)	467,513	1.00%
Darren Sherman (4)	197,297	*
Samuel Nussbaum (5)	140,605	*
Shervin Korangy (6)	165,605	*
Andrew Taylor (7)	333,694	*
Gary Pruden (8)	199,469	*
Directors and Officers as a Group (8 persons)	2,877,085	5.88%
5% Stockholders		
Perceptive Life Sciences Master Fund Ltd. (9)	2,906,597	6.20%
Larry N. Feinberg (10)	3,806,666	8.16%

1. Includes 451,963 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of February 18, 2021. Does not include 706,701 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of February 18, 2021. Includes 142,525 shares of our Common Stock pursuant to restricted stock unit awards which have vested as of February 18, 2021, or which will be vested within sixty days of February 18, 2021. Does not include 276,843 shares of our Common Stock issuable upon the vesting of restricted stock units that will not vest within sixty days of February 18, 2021.
2. Includes 677,555 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of February 18, 2021. Does not include 289,773 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of February 18, 2021. Includes 34,885 shares of our Common Stock pursuant to restricted stock unit awards which have vested as of February 18, 2021, or which will be vested within sixty days of February 18, 2021. Does not include 113,331 shares of our Common Stock issuable upon the vesting of restricted stock units that will not vest within sixty days of February 18, 2021.
3. Includes (i) 16,572 shares of our Common Stock held by NSH 2008 Family Trust, a family trust of which Mr. Hochman is a co-trustee and beneficiary and (ii) 110,000 shares of our Common Stock held by DPH 2008 Trust, a trust of which Mr. Hochman is a co-trustee and beneficiary. Includes 221,666 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of February 18, 2021. Does not include 53,334 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of February 18, 2021. Does not include 50,000 shares of our Common Stock issuable upon the vesting of restricted stock units that will not vest within sixty days of February 18, 2021. Includes (i) 904 shares of our Common Stock issuable upon the exercise of warrants, held directly by Mr. Hochman, that are exercisable within sixty days of February 18, 2021 and (ii) 3,785 shares of our Common Stock issuable upon the exercise of warrants, held by NSH 2008 Family Trust, a family trust of which Mr. Hochman is a co-trustee and beneficiary, that are exercisable within sixty days of February 18, 2021.
4. Includes 129,166 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of February 18, 2021. Does not include 38,334 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of February 18, 2021. Does not include 36,250 shares of our Common Stock issuable upon the vesting of restricted stock units that will not vest within sixty days of February 18, 2021. Includes 300 shares of our Common Stock issuable upon the exercise of warrants, held directly by Mr. Sherman, that are exercisable within sixty days of February 18, 2021.
5. Includes 79,166 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of February 18, 2021. Does not include 38,334 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of February 18, 2021. Does not include 36,250 shares of our Common Stock issuable upon the vesting of restricted stock units that will not vest within sixty days of February 18, 2021.
6. Includes 94,166 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of February 18, 2021. Does not include 38,334 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of February 18, 2021. Does not include 36,250 shares of our Common Stock issuable upon the vesting of restricted stock units that will not vest within sixty days of February 18, 2021.

7. Includes 302,536 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of February 18, 2021. Does not include 282,315 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of February 18, 2021. Does not include 102,524 shares of our Common Stock issuable upon the vesting of restricted stock units that will not vest within sixty days of February 18, 2021.
8. Includes 79,166 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of February 18, 2021. Does not include 38,334 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of February 18, 2021. Does not include 36,250 shares of our Common Stock issuable upon the vesting of restricted stock units that will not vest within sixty days of February 18, 2021.
9. Based on the information provided in the Schedule 13G/A filed with the SEC on January 27, 2021 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 February 18, 2021, 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.
10. Based on the information provided in the Schedule 13G/A filed with the SEC on February 16, 2021 by Larry N. Feinberg with respect to himself, Oracle Partners, LP ("Partners") which holds 2,711,402 shares of our Common Stock, Oracle Institutional Partners, LP ("Institutional Partners") which holds 379,566 shares of our Common Stock, Oracle Ten Fund, LP ("Ten Fund" which holds 550,698 shares of our Common Stock, and, together with Partners and Institutional Partners, the "Oracle Partnerships"), Oracle Investment Management, Inc. Employees' Retirement Plan (the "Retirement Plan") which holds 135,000 shares of our Common Stock, The Feinberg Family Foundation (the "Foundation") which holds 30,000 shares of our Common Stock, Oracle Associates, LLC ("Oracle Associates"), which serves as the general partner of the Oracle Partnerships, and may be deemed to indirectly own, by virtue of the foregoing relationship, the Shares directly owned by the Oracle Partnerships, Oracle Investment Management, Inc. (the "Investment Manager"), which serves as the investment manager of the Oracle Partnerships and the plan administrator to the Retirement Plan, and may be deemed to indirectly own the Shares directly owned by the Oracle Partnerships and the Retirement Plan. Mr. Larry N. Feinberg ("Mr. Feinberg"), serves as the managing member of Oracle Associates and as the sole shareholder, director and president of the Investment Manager, and the trustee of the Foundation and may be deemed to indirectly own, by virtue of the foregoing relationships, the Shares directly owned by the Oracle Partnerships, the Retirement Plan and the Foundation (collectively, the "Oracle Reporting Persons"). 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 INDEPENDENCE

Other than compensation arrangements for our named executive officers and directors, we describe below each transaction or series of similar transactions, since January 1, 2019 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 of directors, (ii) Ten Percent Warrants to purchase 300 shares of our Common Stock to Darren Sherman, a member of our board of 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., former 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 former 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, a former member of our board of directors, who resigned as a member of our board of directors effective January 6, 2020, 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 of directors, (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, a member of our board of 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., former 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 former 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, a former member of our board of directors, who resigned as a member of our board of directors effective January 6, 2020, 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 May 2036). 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.

Between December 12, 2019 and February 24, 2020, we consented to the transfer of Royalty Payment Rights Certificates representing an aggregate of 53.01% of the aggregate royalty amount payable to the holders of the Royalty Payment Rights Certificates from certain of our directors and certain of our existing stockholders, including stockholders affiliated with certain of our directors including (i) David Hochman, the Chairman of our board of directors, (ii) Darren Sherman, a member of our board of directors, (iii) Ascent Biomedical Ventures II, L.P. and Ascent Biomedical Ventures Synecor, L.P., former beneficial owners of more than five percent of our Common Stock, (iv) Orchestra Medical Ventures II, L.P., a former beneficial owner of more than five percent of our Common Stock, (v) Orchestra MOTUS Co-Investment Partners, LLC, a former beneficial owner of more than five percent of our Common Stock, (vi) Perceptive Life Sciences Master Fund Ltd., a beneficial owner of more than five percent of our Common Stock, and (vii) certain other holders of our Royalty Payment Rights Certificates to Orchestra BioMed, Inc., formerly a greater than 5% holder of our Common Stock and entity in which David Hochman, the Chairman of our board of directors, serves as the Chairman of the board of directors and as chief executive officer, and Darren Sherman, a member of our board of directors, serves as a director and as president and chief operating officer, pursuant to a private transaction between such parties.

Participation in July 2019 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 2,022,665 shares of our Common Stock in our July 2019 Offering, completed July 2019, at the public offering price of $3.00 per share, including (i) Perceptive Life Sciences Master Fund Ltd., a greater than 5% shareholder, which purchased 1,000,000 shares, (ii) the Oracle Reporting Persons, greater than 5% holders of our Common Stock, which purchased an aggregate 991,666 shares, (iii) DPH 2008 Trust, an trust in which David Hochman, the Chairman of our board of directors, serves as co-trustee and of which he is a beneficiary, which purchased 10,000 shares, (iv) Gary Pruden, a member of our board of directors, who purchased 8,333 shares, (v) Jacobs Investment Company LLC, an investment firm in which Gary Jacobs, a former member of our board of directors, who resigned as a member of our board of directors effective January 6, 2020, serves as Founder and Managing Director, which purchased 8,333 shares, (vi) Timothy P. Moran, our chief executive officer, who purchased 3,333 shares, and (vii) Mark Pomeranz, our President and Chief Operating Officer, who purchased 1,000 shares.

License Agreement with Orchestra BioMed, Inc.

In January 2020, we entered into a license agreement (the "License Agreement") with Orchestra BioMed, Inc., formerly a greater than 5% holder of our Common Stock and entity in which David Hochman, the Chairman of our board of directors, serves as the Chairman of the board of directors and as chief executive officer, and Darren Sherman, a member of our board of directors, serves as a director and as president and chief operating officer, pursuant to which we granted a license to Orchestra BioMed, Inc. for the use of portions of the office space not being used by us in our leased facility in Fort Lauderdale, Florida (the "Premises"), and a proportionate share of common areas of such Premises, which compromises approximately 35% of the Premises as of January 2020 and will expand incrementally to approximately 60 to 70% of the Premises by September 2024. In January 2020, Orchestra BioMed, Inc. paid us a one-time fee of $28.5 thousand, upon entering into the License Agreement and will continue to pay a monthly license fee to us until the expiration of the License Agreement in September 2024. Aggregate license fees will generally range from approximately $162 thousand to approximately $198 thousand in any given calendar year during the term of the License Agreement.

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 (who resigned from our board of directors effective January 6, 2020), 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

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	2020	2019
Audit Fees	$ 186,704	$ 242,162
Audit-Related Fees	$ -	$ -
Tax Fees	$ 33,540	$ 42,110
All Other Fees	$ -	$ -
Total Fees	$ 220,244	$ 284,272

Audit Fees

"Audit fees" consist of approximately $171,000 and $185,000 in 2020 and 2019, respectively, of fees for professional services provided in connection with the audit of our annual audited financial statements and the review of our quarterly financial statements, and approximately $16,000 and $57,000 in 2020 and 2019, respectively, of fees for consents and comfort letters provided in connection with the offerings of our Common Stock.

Tax Fees

"Tax fees" consist of approximately $25,000 and $23,000, in 2020 and 2019, respectively, for services related to tax preparation and filing, and $9,000 and $19,000, in 2020 and 2019, respectively, for 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 2020 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 our 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-26 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	Certificate of Amendment to the Certificate of Incorporation, dated August 13, 2020	8-K	001-38389	3.1	8/14/2020	
3.4	Bylaws	S-1	333-222441	3.3	1/5/2018	
3.5	Certificate of Designations of Series A Convertible Preferred Stock	S-1	333-222441	3.4	1/5/2018	
3.6	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	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
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	
4.15	Description of Registrants Securities					X
4.16	Form of Pre-Funded Warrant	8-K	001-38389	4.1	8/28/2020	
4.17	Form of Common Warrant	8-K	001-38389	4.2	8/28/2020	
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	Amendment to the Motus GI Holdings, Inc. 2016 Equity Incentive Plan, dated February 6, 2020	8-K	001-38389	10.1	8/14/2020	
10.6 †	Form of Incentive Stock Option Agreement	S-1	333-222441	10.5	1/5/2018	
10.7 †	Form of Non-Qualified Stock Option Agreement	S-1	333-222441	10.6	1/5/2018	
10.8 †	Form of Restricted Stock Agreement	S-1	333-222441	10.7	1/5/2018	
10.9 †	Form of Assumed Options to Israeli Employees and Directors Agreement	S-1	333-222441	10.8	1/5/2018	
10.10	Form of Assumed Options to Israeli Non-Employees and Controlling Shareholders Agreement	S-1	333-222441	10.9	1/5/2018	
10.11 †	Form of Israeli Option Grant to Israeli Employees and Directors Agreement	S-1	333-222441	10.10	1/5/2018	
10.12	Form of Israeli Option Grant to Israeli Non-Employees and Controlling Shareholders Agreement	S-1	333-222441	10.11	1/5/2018	
10.13 †	Employment Agreement, dated December 22, 2016, between the Company and Mark Pomeranz	S-1	333-222441	10.12	1/5/2018	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.14	Lease, dated April 13, 2017, between Company and Victoriana Building, LLC	S-1	333-222441	10.13	1/5/2018	
10.15	Form of Subscription Agreement for Convertible Notes Offering	S-1	333-222441	10.14	1/5/2018	
10.16	Finders Agreement, dated October 14, 2016, between the Company and Aegis Capital Corporation	S-1	333-222441	10.15	1/5/2018	
10.17	Finders Agreement, dated December 22, 2016, between the Company and Aegis Capital Corporation	S-1	333-222441	10.16	1/5/2018	
10.18 †	Form of Indemnification Agreement	S-1	333-222441	10.17	1/5/2018	
10.19 †	Employment Agreement, dated August 16, 2017, between the Company and Andrew Taylor	S-1	333-222441	10.18	1/5/2018	
10.20 #	Supply Agreement, dated September 1, 2017, between Motus GI Technologies Ltd. and Polyzen, Inc.	S-1/A	333-222441	10.19	2/7/2018	
10.21 †	Amended and Restated Employment Agreement, effective September 24, 2018, between the Company and Mark Pomeranz	8-K	001-38389	10.2	9/25/2018	
10.22 †	Employment Agreement, effective October 1, 2018, between the Company and Timothy P. Moran	8-K	001-38389	10.1	9/25/2018	
10.23	Form of Restricted Stock Unit Award Agreement	10-K	001-38389	10.22	3/26/2019	
10.24 †	Amended and Restated Employment Agreement, effective March 26, 2019, between the Company and Andrew Taylor	10-K	001-38389	10.23	3/26/2019	
10.25 †	First Amendment to Amended and Restated Employment Agreement, dated March 15, 2021, between the Company and Andrew Taylor					X
10.26	Loan and Security Agreement, dated as of December 13, 2019 between Silicon Valley Bank and Motus GI Holdings, Inc.	8-K	001-38389	10.1	12/18/2019	
10.27	Joinder and First Amendment to Loan and Security Agreement, dated as of February 7, 2020 between Silicon Valley Bank and Motus GI Holdings, Inc.	10-K	001-38389	10.25	3/30/2020	
10.28	Second Amendment to Loan and Security Agreement, dated as of February 25, 2020 between Silicon Valley Bank and Motus GI Holdings, Inc.	10-K	001-38389	10.26	3/30/2020	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.29	Third Amendment to Loan and Security Agreement, dated as of January 4, 2021 between Silicon Valley Bank and Motus GI Holdings, Inc.					X
10.30	Lease Agreement, effective as of March 11, 2020, by and between Motus GI Holdings, Inc. and 720 UNIVERSITY PROPERTY, LLC.	8-K	001-38389	10.1	3/11/2020	
10.31	Lease Termination Agreement, effective as of March 30, 2020, by and between Motus GI Holdings, Inc. and 720 UNIVERSITY PROPERTY, LLC.	10-K	001-38389	10.28	3/30/2020	
10.32	Deferral Agreement, dated as of April 10, 2020, effective as of April 2, 2020, by and between Silicon Valley Bank, Motus GI Holdings, Inc. and Motus GI, Inc.	8-K	001- 38389	10.1	4/13/2020	
10.33	U.S. Small Business Administration Paycheck Protection Program Note, dated as of April 10, 2020, by and between Silicon Valley Bank and Motus GI Holdings, Inc.	8-K	001-38389	10.1	4/28/2020	
10.34	Placement Agency Agreement, dated August 28, 2020, by and between A.G.P./Alliance Global Partners and Motus GI Holdings, Inc.	8-K	001-38389	10.1	8/28/2020	
10.35	Form of Securities Purchase Agreement, dated August 28, 2020, by and between Motus GI Holdings, Inc. and each Purchaser thereto	8-K	001-38389	10.2	8/28/2020	
21.1	List of Subsidiaries of the Company					X
23.1	Consent of EisnerAmper LLP					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 16, 2021

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

Date: March 16, 2021

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 16, 2021
/s/ Andrew Taylor Andrew Taylor	Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2021
/s/ David Hochman David Hochman	Chairman of the Board	March 16, 2021
/s/ Mark Pomeranz Mark Pomeranz	President, Chief Operating Officer, and Director	March 16, 2021
/s/ Darren Sherman Darren Sherman	Director	March 16, 2021
/s/ Samuel Nussbaum Samuel Nussbaum	Director	March 16, 2021
/s/ Shervin Korangy Shervin Korangy	Director	March 16, 2021
/s/ Gary Pruden	Director	March 16, 2021

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CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Motus GI Holdings, Inc. and Subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of comprehensive loss, changes in shareholders' equity, and cash flows for each of the years 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, 2020 and 2019, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has generated minimal revenues, experienced negative cash flows from operations 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.

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 audits. 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 audits 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 audits 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 audits 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 audits 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 audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Contingent Royalty Obligation
As described in Note 4 to the consolidated financial statements, the Company estimates the fair value of its contingent royalty obligation using the discounted cash flow method. Management estimates the contingent royalty obligation primarily by estimating of the future projected revenues of the Company, with other factors being growth rate, patent expiration assessments and a discount rate. The fair value of the contingent royalty obligation was approximately $1,617,000 as of December 31, 2020.

We identified the valuation of the contingent royalty obligation as a critical audit matter because the valuation inputs involve the application of significant judgement and estimation on the part of management, which led to a high degree of auditor subjectivity. We also applied significant judgment in performing our audit procedures and involved a valuation specialist to evaluate the reasonableness of management's valuation model, as well as the inputs used within the model.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. Our procedures included, among other things, (i) obtaining an understanding of management's process and evaluating the design of controls related to the valuation of the contingent royalty obligation; (ii) assessing the reasonableness of management's projected revenue by inquiring of management regarding its process for developing the projections and evaluating assumptions utilized for reasonableness; (iii) performing a sensitivity analysis of the assumptions in the calculation to evaluate the potential material effects of any changes in assumptions; and (iv) with the assistance of our valuation specialists, we (1) evaluated the reasonableness of management's valuation methodology; (2) evaluated the reasonableness of the discount rate used by management by developing an independent weighted average cost of capital and compared it to the rate used by management; and (3) tested the mathematical accuracy of the discounted cash flow calculation.

/s/ EisnerAmper LLP

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

EISNERAMPER LLP
Philadelphia, PA
March 16, 2021

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 20,819	$ 20,528
Investments	-	8,203
Accounts receivable	35	65
Inventory	805	1,014
Prepaid expenses and other current assets	448	339
Related party receivable	-	18
Total current assets	22,107	30,167
Fixed assets, net	1,178	1,056
Right-of-use assets	766	1,021
Other non-current assets	13	13
Total assets	$ 24,064	$ 32,257
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,333	$ 2,999
Operating lease liabilities - current	238	321
Other current liabilities	60	270
Term debt, net of debt discount of $21 and $246, respectively	7,979	7,754
Total current liabilities	10,610	11,344
Contingent royalty obligation	1,617	1,872
Operating lease liabilities - non-current	547	713
Total liabilities	12,774	13,929
Commitments and contingent liabilities (Note 9)		
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 shares issued and outstanding	-	-
Common Stock $0.0001 par value; 115,000,000 and 50,000,000 shares authorized as of December 31, 2020 and December 31, 2019, respectively; 32,272,309 and 28,811,087 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	3	3
Additional paid-in capital	115,008	102,789
Accumulated deficit	(103,721)	(84,464)
Total shareholders' equity	11,290	18,328
Total liabilities and shareholders' equity	$ 24,064	$ 32,257

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

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

	Years Ended December 31,	
	2020	**2019**
Revenue	$ 98	$ 107
Operating expenses:		
Costs of revenue - sales	95	79
Costs of revenue - impairment of inventory	401	57
Research and development	5,555	9,013
Sales and marketing	3,532	4,897
General and administrative	9,562	9,497
Total costs and expenses	19,145	23,543
Operating loss	(19,047)	(23,436)
Gain on change in estimated fair value of contingent royalty obligation	255	81
Finance income (expense), net	(464)	273
Foreign currency loss	(1)	(4)
Loss before income taxes	(19,257)	(23,086)
Net loss	$ (19,257)	$ (23,086)
Basic and diluted loss per common share	$ (0.60)	$ (0.92)
Weighted average number of common shares outstanding, basic and diluted	32,120,017	25,133,190

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

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

	Common Stock		Additional paid-in	Accumulated	Total shareholders'
	Shares	Amount	capital	deficit	equity
Balance at December 31, 2018	21,440,148	$ 2	$ 79,893	$ (61,378)	$ 18,517
Issuance of common shares upon public offering, net of offering costs of $1,759	6,666,667	1	18,240	-	18,241
Issuance of common shares upon exercise of overallotments, net of offering costs of $156	648,333	-	1,789	-	1,789
Issuance of common shares upon exercise of options	416	-	2	-	2
Issuance of common shares upon vesting of restricted stock units	55,523	-	-	-	-
Share based compensation	-	-	2,865	-	2,865
Net loss	-	-	-	(23,086)	(23,086)
Balance at December 31, 2019	28,811,087	3	102,789	(84,464)	18,328
Issuance of common shares upon public offering, net of offering costs of $849	3,200,000	-	9,145	-	9,145
Issuance of common stock upon exercise of warrants	50,000	-	58	-	58
Issuance of common stock for board of directors' compensation	103,404	-	111	-	111
Issuance of common shares upon vesting of restricted stock units	107,818	-	-	-	-
Share based compensation	-	-	2,905	-	2,905
Net loss	-	-	-	(19,257)	(19,257)
Balance at December 31, 2020	32,272,309	$ 3	$ 115,008	$ (103,721)	$ 11,290

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

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

	Years Ended December 31,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (19,257)	$ (23,086)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	377	223
Amortization of debt issuance costs	25	4
Gain on change in estimated fair value of contingent royalty obligation	(255)	(81)
Share based compensation	2,905	3,205
Issuance of common stock for board of directors' compensation	168	-
Impairment of inventory	401	76
Unrealized gain on investments	-	(5)
Impairment of fixed assets	18	35
Non-cash operating lease expense	255	220
Changes in operating assets and liabilities:		
Accounts receivable	30	(60)
Related party receivable	18	(18)
Inventory	(621)	(975)
Prepaid expenses and other current assets	(109)	155
Accounts payable and accrued expenses	(489)	629
Operating lease liabilities - current and non-current	(249)	(216)
Other current and non-current liabilities	(210)	(21)
Net cash used in operating activities	(16,993)	(19,915)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of fixed assets	(88)	(468)
Purchase of available-for-sale securities	-	(9,655)
Proceeds from sale of available-for-sale securities	8,203	4,500
Net cash provided by (used in) investing activities	8,115	(5,623)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Gross proceeds from offering	9,994	20,000
Proceeds from exercise of over-allotment options	-	1,945
Proceeds from issuance of debt	-	8,000
Proceeds from exercise of options	-	2
Proceeds from exercise of warrants	58	-
Financing fees from equity offering	(849)	(1,931)
Financing fees from debt	(34)	
Net cash provided by financing activities	9,169	28,016
NET INCREASE IN CASH AND CASH EQUIVALENTS	291	2,478
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	20,528	18,050
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 20,819	$ 20,528
SUPPLEMENTAL CASH FLOW INFORMATION:		
CASH PAID FOR:		
Interest	$ 433	$ -
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING AND INVESTING ACTIVITIES:		
Financing fees included in accounts payable and accrued expenses	$ -	$ 234
Financing fees extinguished previously included in accounts payable and accrued expenses	$ 200	$ -
Reclassification of inventory to fixed assets	$ 430	$ -

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

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"). In June 2019, the 510(k) premarket notification for the second-generation of the Pure-Vu System was reviewed and cleared by the FDA. The second-generation of our Pure-Vu System has received 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. The Company believes that the technology may be useful in the future as a tool to help reduce user dependency on conventional pre-procedural bowel prep regimens. 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 Medicare Severity Diagnostic Related Group (a "MS-DRG"). Based on the Company's review and analysis of 2019 market data and 2021 projections for the U.S. and Europe, as obtained from iData Research Inc., we estimate that during 2021 approximately 1.5 million inpatient colonoscopy procedures will be performed in the U.S. and approximately 4.8 million inpatient colonoscopy procedures will be performed worldwide. The Pure-Vu System does not currently have a unique reimbursement code with any private or governmental third-party payors in any country. The Company began commercialization in the fourth quarter of 2019, with the first commercial placements of its second generation Pure-Vu System as part of its initial U.S. market launch targeting early adopter hospitals. The Company does not expect to generate significant revenue from product sales until the COVID-19 pandemic has subsided and it expands its commercialization efforts for the Pure-Vu System, which is subject to significant uncertainty.

Note 2 – Going Concern

To date, the Company has generated minimal revenues, experienced negative operating cash flows and has incurred substantial operating losses from its activities. The Company expects operating costs will increase significantly as it incurs costs associated with commercialization activities related to the Pure-Vu System. Management expects the Company to continue to fund its operations primarily through utilization of its current financial resources, future product sales, and through the issuance of debt or equity. Since March 2020, we have been evaluating the actual and potential business impacts related to the COVID-19 pandemic. While the impact of the pandemic continues to evolve, the financial markets have experienced periods of volatility that may adversely impact the Company's ability to enter into, modify, and negotiate favorable terms and conditions relative to equity and debt financing initiatives. The uncertain financial markets, potential disruptions in supply chains, mobility restraints, and changing priorities could also affect the Company's ability to enter into key agreements. The outbreak and government measures taken in response to the pandemic have also had a significant impact, both direct and indirect, on businesses and commerce in general, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as certain medical services and supplies, have spiked, while demand for other goods and services have fallen. While not all of these have impacted the Company directly, the future progression of the outbreak and its effects on the Company's business and operations remain uncertain. The Company and its third-party contract manufacturers, contract research organizations, and clinical sites may also face disruptions in procuring items that are essential to the Company's research and development activities, including, for example, medical and laboratory supplies, in each case, that are sourced from abroad or for which there are shortages because of ongoing efforts to address the outbreak. These disruptions have negatively impacted the Company's sales, its results of operations, financial condition, and liquidity in 2020.

In December 2019, the Company entered into a Loan and Security Agreement as amended from time to time (the "Loan Agreement"), for $8.0 million with Silicon Valley Bank (the "Bank" or "SVB"). Under the terms of the Loan Agreement the Company must maintain unrestricted cash in accounts held at SVB of at least $10.0 million (the "Liquidity Covenant"). The Company will need to raise additional capital or generate substantial revenue in order to ensure compliance with the Liquidity Covenant to support its development and commercialization efforts. If adequate funds are not available to the Company on a timely basis, or at all, the Company may breach the Liquidity Covenant, in which case, the Company would be required to immediately pledge to the bank and thereafter maintain in a separate account, unrestricted and unencumbered cash in an amount equal to the amount then outstanding under the Loan Agreement.

On September 1, 2020 the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") under which the Company sold and issued to an institutional investor (the "Holder"), in a registered direct offering, an aggregate of 3,200,000 shares of the Company's common stock par value $0.0001 per share (the "Common Stock"), and pre-funded warrants to purchase an aggregate of 5,533,625 shares of Common Stock (the "Pre-Funded Warrants"). The offering price was $1.145 for each share of Common Stock and $1.144 for each Pre-Funded Warrant. The Pre-Funded Warrants were immediately exercisable at a price of $0.001 per share of Common Stock. Pursuant to the Securities Purchase Agreement, in a concurrent private placement, the Company also agreed to issue to the Holder warrants to purchase up to 8,733,625 shares of Common Stock (the "Private Placement Warrants"). These warrants were immediately exercisable at an exercise price of $1.30 per share and expire on the fifth anniversary of the date of issuance. In connection with the closing of the offering, the Company received gross proceeds of $10.0 million before deducting placement agent fees and other offering expenses of $0.8 million, from the issuance of the Common Stock, the Pre-Funded Warrants and the Private Placement Warrants.

On January 27, 2021, the Company entered into a Warrant Exercise Agreement (the "Exercise Agreement") with the Holder, at which time 8,000,000 of the Private Placement Warrants remained outstanding, due to the prior exercise of 733,625 of the Private Placement Warrants on January 22, 2021. Pursuant to the Exercise Agreement, in order to induce the Holder to exercise all of its remaining outstanding 8,000,000 Private Placement Warrants for cash, the Company agreed to issue to the Holder, new warrants (the "New Warrants") to purchase 0.75 shares of Common Stock for each share of Common Stock issued upon such exercise of the remaining 8,000,000 Private Placement Warrants pursuant to the Exercise Agreement, or an aggregate of 6,000,000 New Warrants. The terms of the New Warrants are substantially similar to those of the Private Placement Warrants, except that the New Warrants will have an exercise price of $2.12, will be immediately exercisable and will expire five years from the date of the Exercise Agreement. In addition, the Holder paid a cash payment of $0.10 for each New Warrant issued to the Holder, for an aggregate of $600,000 to the Company. The Company received aggregate gross proceeds before expenses of approximately $11.0 million from the exercise of all of the remaining 8,000,000 outstanding Private Placement Warrants held by the Holder and the payment of the purchase price for the New Warrants.

Management's plan, inclusive of its cost reduction plan (the "2020 Plan") in 2020 (see note 13), 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.

Such conditions, as well as the terms of its Liquidity Covenant and the uncertainty of the impact of the COVID-19 pandemic, raise substantial doubts about the Company's ability to continue as a going concern. These consolidated 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 and Basis of Presentation

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

Basis of presentation and use of estimates

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. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification, or ASC, and Accounting Standards Updates, or ASUs, of the Financial Accounting Standards Board.

The preparation of the 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 consolidated 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.

Investments

The Company accounts for investments held as "available-for-sale" in accordance with ASC 320, "Investments - Debt and Equity Securities". The Company has one equity investment in a mutual fund and classifies this investment as a current asset and carries it at fair value. Unrealized gains and losses are recorded in finance income (expense), net on the consolidated statement of comprehensive loss. Realized gains or losses on mutual fund transactions are reported in the consolidated statement of comprehensive loss. The mutual fund is maintained at one financial institution.

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

Sales contracts executed for the second generation Pure-Vu System is accounted for in accordance with ASC Topic 606 - Revenue from Contracts with Customers ("ASC 606") to depict the transfer of control to the Company's customers in an amount reflecting the consideration to which the Company expects to be entitled to. The Pure-Vu System consists of a Workstation (a "Workstation") and single use disposable sleeve (a "Disposable").

ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases and collaboration arrangements. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (1) identify the contract with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract and (5) recognize revenue when a performance obligation is satisfied.

Commercial placements of the second generation system include the Workstation, sale of the Disposables, and a service plan. The Workstation is operational without any significant customization and modification and the Disposables are specialized consumables that are readily available for purchase from the Company. Therefore, revenue from the sale of a Workstation is recognized after the customer commits to purchase the Workstation and the Workstation is delivered, which is when title is transferred. Disposables are identified as a separate performance obligation, and therefore, revenue from the sale of Disposables is recognized when the Disposables are delivered to the customer and title is transferred.

A free one-year service plan is included with the purchase of any second generation Pure-Vu Workstation. An extended service plan with varying support and maintenance of the Workstation is offered for sale after the free one-year service plan period. In the case of the free one-year service plan, a portion of the Workstation sales price is deferred and recognized ratably over the one-year service plan term based upon the relative standalone value. The standalone selling price of the Workstation is set at the beginning of the contract based on observable prices from standalone sales of the Workstation, however, at times, the Company has offered discounts from that price to certain customers. The standalone sales price of the one year service plan is based on the expected costs of replacement parts and direct costs to perform the service plus a standard margin, as set by the Company. The standard margin assumed is consistent with the margin expected in pricing the extended service plan. Revenue for the extended service plans is recognized ratably over the term of the service plan contract period.

At times, the Company may include a limited time free trial to potential customers to evaluate the Workstation for a period of up to 6 months and in certain instances extend the period to an aggregate of up to 11 months. The Company considers the 6-11 month usage period as a non-contiguous limited trial period because the total length of the free trial is still less than one year. In scenarios where the Company continues to provide the Workstation to a customer for a usage period of greater than one year, the arrangement falls outside of the scope of ASC 606, as described below. Management does not collect any upfront payments or deposits prior to commencing a free trial period. No revenue is recognized for the Workstation during the duration of a free trial, however, any Disposables purchased by the evaluator are recognized when delivered, as described above.

For contracts outside the scope of ASC 606, the Company determines income for proposed supply arrangements under 1) ASC 842 as it pertains to an embedded lease of the Workstation within a proposed supply arrangement and 2) ASC 606 for the sale of the sleeves within the proposed supply arrangement. The Company allocates the transaction price to the performance obligations within the proposed supply arrangements using the total estimated purchases method for both (i) arrangements that contain minimum purchase commitments and (ii) those arrangements that do not contain a minimum purchase commitment, but instead offer a volume discount for purchases that exceed a specified tier.

During the year ended December 31, 2020, the Company recognized revenue of $98, which primarily consisted of revenue from the sales of Disposables. During the year ended December 31, 2019 the Company recognized revenue of $107, which consisted of $46 from the sale of a Workstation and the remaining revenue from the sales of Disposables.

Deferred revenue is de minimis at December 31, 2020 and 2019. Lease revenue was de minimis for the years ended December 31, 2020 and 2019.

Contract Costs

Incremental commissions, if applicable, above a base commission level, are paid to sales representatives upon certain eligible sales, which are paid upon execution of the sales agreement. The guidance within ASC 606 provides a practical expedient if the amortization period of the assets that the entity otherwise would have recognized is one year or less. The Company chose to apply the available practical expedient as the commission paid on eligible sales orders relates to the period in which the sales order was fulfilled. For the years ending December 31, 2020 and 2019, incremental commissions paid on eligible sales orders were $0 and $27, respectively.

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, 2020 and 2019, the allowance for doubtful accounts was $0.

Inventory

Inventory is stated at lower of cost and net realizable value using the weighted average cost method and is evaluated at least annually for impairment. The Company records an inventory reserve for losses associated with dated, expired, excess and obsolete items. Reserves and write-downs of inventory is based on management's current knowledge with respect to inventory levels, planned production, and extension capabilities of materials on hand. A significant change in the timing or level of demand for the Company's products compared to forecasted amounts may result in recording additional charges for excess and obsolete inventory in the future. The Company records charges for excess and obsolete inventory within cost of revenues.

Leases

Effective January 1, 2019, the Company adopted ASC 842- Leases ("ASC 842"). The lease standard provided a number of optional practical expedients in transition. The Company elected the package of practical expedients. As such, the Company did not have to reassess whether expired or existing contracts are or contain a lease; did not have to reassess the lease classifications or reassess the initial direct costs associated with expired or existing leases. The lease standard also provides practical expedients for an entity's ongoing accounting. The Company elected the short-term lease recognition exemption under which the Company will not recognize right-of-use ("ROU") assets or lease liabilities, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases. The Company elected the practical expedient to not separate lease and non-lease components for certain classes of assets (facilities).

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and short-term and long-term lease liabilities, as applicable. The Company does not have financing leases.

Operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. Prospectively, the Company will adjust the right-of-use assets for straight-line rent expense or any incentives received and remeasure the lease liability at the net present value using the same incremental borrowing rate that was in effect as of the lease commencement or transition date.

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	3-7 years
Leasehold improvements	Shorter of lease term or useful life

Share based compensation

The Company adopted Accounting Standards Update 2018-07 ("ASU 2018-07"), "Improvement to Nonemployee Share Based Payment Accounting", which expanded the scope of ASC 718 to include share- based payment transactions for acquiring goods and services from nonemployees. The guidance was applied prospectively to all new awards granted after the date of adoption. In addition, the guidance was applied to all existing equity-classified awards for which a measurement date has not been established under ASC 505-50 by the adoption date by remeasuring at fair value as of the adoption date, and recording a cumulative effect adjustment to opening accumulated deficit on January 1, 2019.

For the Company's equity-classified awards for which a measurement date has not been established under ASC 505-50, the fair value on January 1, 2019, the adoption date, approximated the value assigned on December 31, 2018, therefore no cumulative adjustment to opening accumulated deficit was required.

Under the revised guidance, the accounting for awards issued to non-employees will be similar to the model for employee awards, except that ASU 2018-07:

- allows the Company to elect on an award-by-award basis to use the contractual term as the expected term assumption in the option pricing model, and
- the cost of the grant is recognized in the same period(s) and in the same manner as if the grantor had paid cash.

Employee and Non-Employee Share 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 and equity awards issued to non-employees based on estimated fair values.

ASC 718-10 requires companies to estimate the fair value of equity-based option 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 consolidated statements of comprehensive loss. The Company recognizes share based award forfeitures as they occur.

The Company estimates the fair value of granted option 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.

Restricted Stock Units

The Company issues restricted stock units under its 2016 Equity Incentive Plan. The fair value of the restricted stock units is based on the closing stock price on the date of grant and is expensed as operating expense over the period during which the units vest. Each restricted stock unit entitles the grantee to one share of common stock to be received upon vesting up to four years after the grant date. Recipients of restricted stock units have no voting rights until the vesting of the award.

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. The shares of common stock into which the Pre-Funded Warrants may be exercised are considered outstanding for the purposes of computing earnings per share because the shares may be issued for little or no consideration, are fully vested, and are exercisable after the original issuance date. 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

Research and development expenses are charged to the consolidated statement of comprehensive loss as incurred.

Patent costs

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

Debt issuance costs

Debt issuance costs represent the costs associated with the issuance of a debt instrument and are amortized using the effective interest method over the life of the related debt instrument. The Company records debt issuance costs as a debt discount and is a reduction of the carrying amount of the debt liability.

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, 2020 and 2019, 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, 2020 or December 31, 2019.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), was signed into law to address the COVID-19 crisis. The CARES Act is an approximately $2 trillion emergency economic stimulus package that includes numerous U.S. federal income tax provisions, including various payroll tax incentives and the modification of: (i) net operating loss rules, (ii) the alternative minimum tax refund and (iii) business interest deduction limitations under Section 163(j) of the Internal Revenue Code. The impact of the CARES Act on the Company was not material.

For the years ended December 31, 2020 and 2019, 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, 2020 and 2019, due to a full valuation allowance to offset any deferred tax asset related to net operating loss carry forwards attributable to the losses.

Restructuring charges

Restructuring charges are comprised of severance costs related to workforce reductions and other costs directly related to the 2020 Plan, including lease exit and fixed asset impairment. The Company recognizes restructuring charges when the liability is incurred. Employee termination benefits are accrued at the date management has committed to a plan of termination and employees have been notified of their termination dates and expected severance payments, see note 13.

Fair value of financial instrument

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, 2020 and 2019.

New Accounting Pronouncements- Recently Adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed below, the Company does not believe that the adoption of recently issued standards have or may have a material impact on its consolidated financial statements and disclosures.

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. ASU 2018-13 removes, modifies, and adds certain disclosure requirements, and is effective for all entities for fiscal years ending after December 15, 2019. The Company adopted ASU 2018-13 on January 1, 2020. The adoption of ASU 2018-13 did not have a material impact on the Company’s financial position or results of operations.

In December 2019, the FASB issued ASU 2019-12, “Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes”, or ASU 2019-12, which is intended to simplify the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The new standard will be effective beginning January 1, 2021. The adoption of ASU 2019-12 did not have a material impact on the Company’s financial position or results of operations.

New Accounting Pronouncements- Not Yet Adopted

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. ASU 2016-13 replaces the current incurred loss impairment methodology with a methodology that reflects expected credit losses. In April 2019 and May 2019, the FASB issued ASU No. 2019-04, "Codification Improvements to Topic 326, Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments" and ASU No. 2019-05, "Financial Instruments-Credit Losses (Topic 326): Targeted Transition Relief" which provided additional implementation guidance on the previously issued ASU. In November 2019, the FASB issued ASU 2019-10, "Financial Instruments - Credit Loss (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842)," which defers the effective date for public filers that are considered small reporting companies ("SRC") as defined by the Securities and Exchange Commission to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Since the Company is an SRC, implementation is not needed until January 1, 2023. The Company will continue to evaluate the effect of adopting ASU 2016-13 will have on the Company's financial statements and disclosures.

Note 4 – Investments and Fair Value of Financial Instruments

Investments consist of available-for-sale equity securities, which are carried at fair value. Interest and dividends on investments are included in finance income (expense).

As of December 31, 2020, the Company did not have any investments. The following table summarizes, by major security type, the Company's investments as of December 31, 2019:

	December 31, 2019	
	Amortized Cost	Carrying Value
Mutual fund, available-for-sale	$ 8,198	$ 8,203
Total	$ 8,198	$ 8,203

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, 2020 and 2019:

	December 31, 2020			
	Level 1	Level 2	Level 3	Fair Value
Assets				
Investments	$ -	$ -	$ -	$ -
Liabilities				
Contingent royalty obligation	$ -	$ -	$ 1,617	$ 1,617

	December 31, 2019			
	Level 1	Level 2	Level 3	Fair Value
Assets				
Investments	$ 8,203	$ -	$ -	$ 8,203
Liabilities				
Contingent royalty obligation	$ -	$ -	$ 1,872	$ 1,872

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 9), the Company used the discounted cash flow method as of December 31, 2020 and 2019. 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, 2020 and 2019:

	Fair Value Measurements of Contingent Royalty Obligation (Level 3)
Balance at December 31, 2018	$ 1,953
Change in estimated fair value of contingent royalty obligation	(81)
Balance at December 31, 2019	1,872
Change in estimated fair value of contingent royalty obligation	(255)
Balance at December 31, 2020	$ 1,617

The contingent royalty obligation is re-measured at each balance sheet date using several assumptions, including the following: 1) estimated sales growth, 2) length of product cycle, 3) patent life, 4) discount rate (21% as of December 31, 2020 and 2019), and 5) rate of royalty payment (3% as of December 31, 2020 and 2019).

In accordance with ASC-820-10-50-2(g), the Company performed sensitivity analyses of the liability, which was classified as a Level 3 financial instrument. The contingent royalty obligation estimate may be significantly impacted by changes in assumptions used in these analyses. For example, 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 $260 and a 2% increase in the discount rate would decrease the liability by approximately $66.

Note 5 – Inventory

Inventory at December 31, 2020 and 2019 consisted of the following:

	December 31,	
	2020	2019
Raw materials	$ 333	$ 294
Work-in-process	211	124
Finished goods	529	596
Inventory reserve	(268)	-
Inventory, net	$ 805	$ 1,014

In addition to the inventory reserve shown above, for the years ended December 31, 2020 and 2019, an inventory write-down charge of $133 and $76, respectively, was recorded.

Note 6 – Fixed assets, net

Fixed assets, net, consists of the following:

	December 31,	
	2020	2019
Office equipment	$ 167	$ 148
Computers and software	299	335
Machinery	455	455
Lab and medical equipment	1,039	568
Leasehold improvements	185	180
Total	2,145	1,686
Less accumulated depreciation and amortization	(967)	(630)
Fixed assets, net	$ 1,178	$ 1,056

Depreciation and amortization expense for the years ended December 31, 2020 and 2019 was $377 and $223, respectively. The Company incurred a loss on the impairment of fixed assets in the amount of $18 and $35 for the years end December 31, 2020 and 2019, respectively.

Note 7 – Leases

The Company leases an office in Fort Lauderdale, Florida under an operating lease. The term expires November 2024. The annual base rent is subject to annual increases of 2.75%. As described within Note 10, the Company shares this space with a related party pursuant to the Shared Space Agreement, as defined below.

The Company leases an office in Israel under an operating lease. The term expires on December 31, 2022. The annual base rent is subject to increases of 4%.

The Company leases vehicles under operating leases that expire at various dates through 2022.

Many of these leases provide for payment by the Company, as the lessee, of taxes, insurance premiums, costs of maintenance and other costs which are expensed as incurred. Certain operating leases include escalation clauses and some of which may include options to extend the leases for up to 3 years.

An initial right-of-use asset of $1,065 was recognized as a non-cash asset and operating lease liabilities of $1,074 was recognized as a non-cash liability. An initial right-of-use asset and operating lease liability in the amount of $176 was recognized as a non-cash asset and liability upon the exercise of its option to extend the Israel lease. The components of lease cost and supplemental balance sheet information for the Company's lease portfolio were as follows:

	Year Ended December 31,	
	2020	2019
Lease Cost		
Operating lease cost, net of related party license fee	$ 176	$ 298
Variable lease cost	118	99
Total lease cost	$ 294	$ 397

	As of December 31,	
	2020	2019
Assets		
Operating lease, right-of-use- asset	$ 766	$ 1,021
Liabilities		
Current		
Operating lease liabilities	$ 238	$ 321
Non-current		
Operating lease liabilities, net of current portion	547	713
Total lease liabilities	$ 785	$ 1,034
Other information:		
Weighted average remaining lease term - operating leases	3.33 years	4.10 years
Weighted-average discount rate - operating leases	7.78%	7.67%

The Company records operating lease payments to lease expense using the straight-line method. The Company's lease expense was $294 and $397 for the years ended December 31, 2020 and 2019, respectively, included in general and administrative expenses which is net of the related party license fee of $172 and $18 for the years ended December 31, 2020 and 2019, respectively (see Note 10).

Future minimum lease payments under non-cancellable operating leases as of December 31, 2020 were as follows:

Year Ended December 31,	Amount
2021	$ 287
2022	273
2023	184
2024	141
Total future minimum lease payments	885
Imputed interest	(100)
Total liability	$ 785

The following table summarizes the cash paid for amounts included in the measurement of lease liabilities for the years ended December 31, 2020 and 2019:

	Years Ended December 31,	
	2020	2019
Cash paid for amounts included in measurement of lease liabilities:	$ (335)	$ (346)

Note 8 – Term Debt

On December 13, 2019 (the "Effective Date"), the Company entered into a Loan and Security Agreement (the "Loan Agreement") for $8,000 (the "Term Debt") with Silicon Valley Bank (the "Bank" or "SVB"). On April 10, 2020, the Company entered into a Deferral Agreement (the "Deferral Agreement") with SVB, effective April 2, 2020, which amends certain provisions of the Loan and Security Agreement, between the Company and SVB.

Pursuant to and among other changes effected by, the Deferral Agreement, as of April 2, 2020, the originally scheduled period of monthly interest-only payments under the Loan Agreement, and the originally scheduled maturity date of the Loan Agreement, have each been extended by six months. As a result, pursuant to the Deferral Agreement, the Loan Agreement now provides for monthly interest-only payments through June 30, 2022, followed by monthly payments of principal and interest until June 1, 2024.

The Term Debt of $8,000 bears an interest rate equal to the greater of (i) one-half of one percent (0.50%) above the Prime Rate and (ii) five and one-half percent (5.50%). At December 31, 2020, the interest rate was 5.69%. The Term Debt is collateralized by substantially all assets of the Company. Additionally, the Company has pledged 65% of the outstanding capital stock in the Company's foreign subsidiary, Motus GI Medical Technologies, Ltd., to collateralize the Term Debt.

Interest payments have commenced on January 1, 2020, following each month until the maturity date. Principal payments will commence July 1, 2022 and continuing for 24 consecutive months thereafter. The Company may prepay all, but not less than all, of the outstanding principal balance of the Term Debt subject to prepayment premium of $240, plus all other sums, if any, that shall have become due and payable.

The Company incurred $50 of debt issuance costs related to the Term Debt. For the years ended December 31, 2020 and 2019, $25 and $4 of debt issuance costs was amortized to interest expense, respectively, using the effective interest method. The effective interest rate on the Term Debt for the years ended December 31, 2020 and 2019 was 5.69% and 6.73%, respectively. The Company accounts for its bank indebtedness at amortized cost.

Further, under the terms of the agreement, the Company must maintain unrestricted cash in accounts with the Bank of at least $10,000. The covenant was met by the Company as of December 31, 2020. The Company's cash forecast indicates that it will need to raise additional funds during 2021, which is part of the current operating plan, in order to meet this liquidity requirement covenant during the coming year.

The Term Debt includes a subjective acceleration clause. Since March 2020, the Company has been evaluating the actual and potential business impacts related to the COVID-19 pandemic. In response to the pandemic, certain measures were taken by authorities that could result in adverse financial impacts to the Company, including requiring Company workers to stay home. The Company considered the probability of a further slow-down of its sales team and the related impact on the potential to trigger the Liquidity Covenant, along with the volatility of the capital markets, which could cause SVB to exercise the subjective acceleration clause in determining the classification of the Company's Term Debt. When considering these factors, the Company determined the likelihood of acceleration could be probable as the pandemic continues, and therefore the Company has classified the Term Debt in current liabilities.

Future maturities of the Term Debt are as follows:

Years Ending December 31,	**Amount**
2021	$ -
2022	2,000
2023	4,000
2024	2,000
Total	8,000
Less unamortized debt issuance costs	(21)
Total Term Debt, less debt issuance costs	$ 7,979

Note 9 – Commitments and Contingencies

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") for the financing of a portion of its research and development expenditures. The total amount that was received and recorded between the periods ending December 31, 2011 through 2016 was $1,332. No amounts were received during the years December 31, 2020 and 2019. The Company has a contingent obligation to the IIA for the total amount received along with the accumulated LIBOR interest to date in the amount of $1,407 and $1,396 as of December 31, 2020 and 2019, respectively. This obligation is repaid in the form of royalties on revenues generated in any fashion with a rate that is currently at 4% (which may be increased under certain circumstances). The Company may be obligated to pay up to 100% (which may be increased under certain circumstances) of the U.S. dollar-linked value of the grants received, 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 for the years ended December 31, 2020 and 2019, and an immaterial liability at December 31, 2020 and 2019.

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 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, 2020 and 2019 (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; and
- 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, 2020.

** 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 Certificate. The Company has not reached the Initial Licensing Proceeds Milestone as of December 31, 2020.

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 May 2036). 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 non-current liability at fair value in the consolidated balance sheets at December 31, 2020 and 2019 in the amount of $1,617 and $1,872, respectively. A gain on change in fair value of Contingent Royalty Obligation of $255 and $81 was recorded for the years ended December 31, 2020 and 2019, respectively.

Other Commitments and Contingencies

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 reason, 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.

Any serious disruption with the Company's operations due to the COVID-19 outbreak could impair the Company's ability to generate sufficient cash to repay its debt obligations when they become due and payable, either when they mature, or in the event of a default, which will cause the Company to breach its covenants and may negatively impact the Company's business operations, financial condition, and results of operations. The Company is unable to predict the outcome of these matters and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from an unfavorable outcome.

Note 10 – Related Party Transactions

Shared Space Agreement

In January 2020, the Company entered into a license agreement (the "Shared Space Agreement") with Orchestra BioMed, Inc., formerly a greater than 5% holder of the Company's common stock and entity in which David Hochman, the Chairman of the Company's board of directors, serves as the Chairman of the board of directors and Chief Executive Officer, and Darren Sherman, a member of the Company's board of directors, serves as a director and as President and Chief Operating Officer. During the year ended December 31, 2020 and 2019, the Company recorded license fee of $172 and $18, respectively, in relation to the Shared Space Agreement. This amount is netted with rent expense in general and administrative expenses.

Orchestra BioMed, Inc. will continue to pay a monthly license fee based on the shared space to the Company until the expiration of the Shared Space Agreement in September 2024. Aggregate license fees will range from $162 to $198 in any given calendar year during the term of the Shared Space Agreement.

Note 11 – Stock- based compensation

Issuance of Common Stock

Non-employee members of the Board of Directors were granted an aggregate of 103,404 shares of Common Stock as compensation, in lieu $111 of cash compensation, for service as directors during the year ended December 31, 2020. The Company recorded $56 in accrued expenses as of December 30, 2020, in relation to the service as directors for the three months ended December 31, 2020. On January 13, 2021, the non-employee members of the Board of Directors were granted an aggregate of 52,317 shares of Common Stock as compensation, in lieu of cash compensation, for service as directors during the fourth quarter of 2020, pursuant to the Company's non-employee director compensation policy. The number of shares granted to the Company's directors, in lieu of cash compensation, is determined by the dollar amount of quarterly fees due under the non-employee director compensation policy divided by the fair market value of a share of Common Stock as of the grant date.

On September 1, 2020 the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") under which it sold and issued to an institutional investor (the "Holder"), in a registered direct offering, an aggregate of 3,200,000 shares of the Company's common stock par value $0.0001 per share (the "Common Stock"), and pre-funded warrants to purchase an aggregate of 5,533,625 shares of Common Stock (the "Pre-Funded Warrants"). The offering price was $1.145 for each share of Common Stock and $1.144 for each Pre-Funded Warrant. The Pre-Funded Warrants were immediately exercisable at a price of $0.001 per share of Common Stock. The shares of common stock into which the Pre-Funded Warrants may be exercised are considered outstanding for the purposes of computing earnings per share because the shares may be issued for little or no consideration, are fully vested, and are exercisable after the original issuance date. Pursuant to the Securities Purchase Agreement, in a concurrent private placement, the Company has also agreed to issue to the purchaser warrants to purchase up to 8,733,625 shares of Common Stock (the "Private Placement Warrants"). These warrants were immediately exercisable at an exercise price of $1.30 per share and expire on the fifth anniversary of the date of issuance. In connection with the closing of the offering, the Company received gross proceeds of $9,994 before deducting placement agent fees and other offering expenses of $849, from the issuance of the Common Stock, the Pre-Funded Warrants and the Private Placement Warrants.

Issuance of Warrants to Purchase Common Stock

On January 1, 2019, the Company entered into an amended and restated consultant agreement to restate and replace the existing consultant agreement dated October 1, 2018 with a service provider which shall continue until September 30, 2019, unless and until sooner terminated by the Company or service provider by providing at least thirty days prior written notice. Pursuant to the agreement, the Company issued a fully-vested and nonforfeitable warrant on February 13, 2019 to purchase 50,000 shares of the Company's common stock, with an exercise price of $5.00 per share, and expires March 20, 2022. The Company recorded $90 as general and administrative expense in the accompanying consolidated statement of comprehensive loss for the year ended December 31, 2019.

On February 13, 2019, the Company issued to an existing service provider for past services rendered a fully-vested and nonforfeitable warrant to purchase 30,000 shares of the Company's common stock, with an exercise price of $5.00 per share, and expires March 20, 2022. The Company recorded $55 as general and administrative expense in the accompanying consolidated statement of comprehensive loss for the year ended December 31, 2019.

On February 6, 2020, the Company entered into a services agreement whereby it agreed to issue warrants to purchase 120,000 shares of common stock of the Company. The warrants will vest over a one-year period on a monthly basis and expire three years from the date of issuance. 60,000 of the granted warrants are exercisable at a price equal to $2.16 per share of common stock and 60,000 of the remaining warrants granted are exercisable at a price equal to $3.50 per share of common stock. The fair value of the warrants were valued on the date of grant at $112 using the Black-Scholes option-pricing model with the following parameters: (1) risk-free interest rate of 1.43%; (2) expected life in years of 3.0; (3) expected stock volatility of 74.82%; and (4) expected dividend yield of 0%. The Company recorded $102 as general and administrative expense in the accompanying consolidated statement of comprehensive loss in relation to the consulting agreement for the year ended December 31, 2020.

On June 11, 2020, the Company entered into a services agreement whereby it agreed to issue warrants to purchase 50,000 shares of common stock of the Company which vested immediately. The warrants are exercisable at $1.17 per share and expire three years from the date of issuance. The fair value of the warrants were valued on the date of grant at $28 using the Black-Scholes option-pricing model with the following parameters: (1) risk-free interest rate of 0.22%; (2) expected life in years of 3.0; (3) expected stock volatility of 73.06%; and (4) expected dividend yield of 0%. The Company recorded $28 as general and administrative expense in the accompanying consolidated statement of comprehensive loss in relation to the consulting agreement for the year ended December 31, 2020. On July 10, 2020 and August 3, 2020, the Company issued an aggregate of 50,000 shares of common stock upon exercise of the warrant which resulted in aggregate proceeds of approximately $59.

In connection with the Securities Purchase Agreement, as described above, the Company issued the Pre-Funded Warrants to purchase up to 5,533,625 shares of its common stock with the aggregate exercise price already being pre-funded to the Company on September 1, 2020 and, consequently, no additional consideration other than the nominal exercise price of $0.001 per warrant share shall be required to be paid to effect any exercise of the Pre-Funded Warrants. The Pre-Funded Warrants will be exercisable until it is exercised in full. Pursuant to the Securities Purchase Agreement, on September 1, 2020, the Company also issued the Private Placement Warrants to purchase 8,733,625 of its common stock at an exercise price of $1.30 per share that expires on September 1, 2025. The terms of both warrants include certain provisions related to fundamental transactions, a cashless exercise provision in the event registered shares are not available, and do not include any mandatory redemption provisions. Therefore, the warrants have been classified as equity upon issuance. As of February 16, 2021, the Pre-Funded Warrants for 5,533,625 shares of common stock and the Private Placement Warrants for 8,733,625 shares of common stock have been exercised.

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, 2019	2,629,468	$ 5.24	3.58	$ -
Granted	141,333	5.62		
Forfeited	(25,000)	7.39		
Outstanding at December 31, 2019	2,745,801	5.24	2.58	$ -
Granted	14,437,250	1.25		
Exercised	(50,000)	1.17		*
Forfeited	(75,000)	8.71		
Outstanding and exercisable at December 31, 2020	17,058,051	$ 1.86	5.78	$ -

* represents amount less than $1,000

As of December 31, 2020 17,048,051 shares of the Company's common stock were issuable upon exercise of outstanding warrants.

Stock Options

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, 2021, pursuant to an annual evergreen provision, the number of shares of common stock reserved for future grants was increased by 1,936,339 shares. Under the 2016 Plan, effective as of January 1, 2021, the maximum number of shares of the Company's common stock authorized for issuance is 7,592,663. As of December 31, 2020, there were 387 shares of common stock available for future grant under the 2016 Plan.

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, 2019	2,520,101	$ 4.32	8.72	$ -
Granted	1,242,144	4.02		
Exercised	(416)	3.78		*
Forfeited	(242,060)	4.24		
Outstanding at December 31, 2019	3,519,769	4.22	7.91	-
Granted	2,650,666	1.46		
Forfeited	(1,141,316)	3.17		
Outstanding at December 31, 2020	5,029,119	$ 3.00	7.96	$ -

* represents amount less than $1,000

The options granted during the years ended December 31, 2020 and 2019 were valued using the Black-Scholes option pricing model using the following weighted average assumptions:

	For the year ended December 31,	
	2020	2019
Expected term, in years	5.6	5.8
Expected volatility	82.70%	72.89%
Risk-free interest rate	0.86%	2.34%
Dividend yield	-	-
Grant date fair value	$ 1.83	$ 2.58

As of December 31, 2020, unamortized share based compensation for stock options was $2,131, with a weighted-average recognition period of 0.81 years.

As of December 31, 2020, outstanding options to purchase 2,537,941 shares of common stock were exercisable with a weighted-average exercise price per share of $4.18.

For the years ended December 31, 2020 and 2019, the Company recorded $2,299 and $2,393, respectively, for share based compensation expense related to stock options.

Restricted Stock Units

The Company recorded $476 and $280 as general and administrative expense in the accompanying consolidated statements of comprehensive loss for the years ended December 31, 2020 and 2019, respectively, in relation to the aggregate 501,265 restricted stock units issued to date to the executives and directors.

A summary of the Company's restricted stock unit awards activity is as follows:

	Number of Shares	Aggregate Weighted Average Grant Date Fair Value
Nonvested at January 1, 2019	165,000	$ 4.91
Granted	76,112	4.32
Vested	(55,523)	4.76
Nonvested at December 31, 2019	185,589	$ 4.71
Granted	260,154	2.16
Vested	(107,818)	3.59
Nonvested at December 31, 2020	337,925	$ 3.10

At December 31, 2020, unamortized stock compensation for restricted stock units was $897, with a weighted-average recognition period of 1.08 years.

Stock- based Compensation

The following table sets forth total non-cash share based compensation for the issuance of common stock, options to purchase common stock, warrants to purchase common stock, and restricted stock unit awards by operating statement classification for the years ended December 31, 2020 and 2019:

	December 31,	
	2020	2019
Research and development	$ 588	$ 697
Sales and marketing	340	325
General and administrative	1,977	2,183
Total	$ 2,905	$ 3,205

Note 12 – 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, 2020 and 2019.

As of December 31, 2020 and 2019, the Company had deferred tax assets of $22.3 million and $17.3 million, respectively, against which a full valuation allowance of $22.3 million and $17.3 million, respectively, had been recorded. The change in the valuation allowance for the year ended December 31, 2020 was an increase of $5.0 million. The increase in the valuation allowance for the year ended December 31, 2020 was mainly attributable to increases in net operating losses and non-deductible share based compensation, 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, 2020 and 2019 were as follows:

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards – Federal and state	$ 3,371	$ 2,183
Net operating loss carryforwards – Israel	16,323	12,680
Share based compensation	1,268	1,004
Capitalized research and development	734	731
Accrued liabilities and reserves	743	841
Total deferred tax assets	22,439	17,439
Deferred tax liabilities:		
Right of use asset	(132)	(168)
Other	(16)	(5)
Total deferred tax liabilities	(148)	(173)
Net deferred tax assets before valuation allowance	22,291	17,266
Valuation allowance	(22,291)	(17,266)
Net deferred tax assets after valuation allowance	$ -	$ -

A reconciliation of the federal statutory tax rate and the effective tax rates for the years ended December 31, 2020 and 2019 is as follows:

	For the Year Ended December 31,	
	2020	2019
U.S. federal statutory tax rate	21.0%	21.0%
State income taxes, net of federal benefit	4.2	0.9
U.S. vs. foreign tax rate differential	1.5	1.7
Non-deductible expenses	(0.6)	(1.4)
Change in valuation allowance	(26.1)	(22.2)
Effective tax rate	-%	-%

The Company had approximately $91.0 million and $71.0 million of gross net operating loss ("NOL") carryforwards (federal, state and Israel) as of December 31, 2020 and 2019, 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, 2020 and 2019 is as follows:

	December 31,	
	2020	2019
U.S. Federal NOL's	$ 10,724	$ 8,630
U.S. State NOL's	9,314	7,219
Israel NOL's	70,971	55,132
Total NOL's	$ 91,009	$ 70,981

The Company's federal and state NOL's of $3.3 million and $9.3 million, respectively, begin to expire after 2036 through 2040. The Company's federal NOL of $7.4 million, generated since 2018, and the Israel NOL of $71.0 million do not expire. A check the box election for Israel was made and accepted by the IRS as of January 1st, 2019. As such, approximately $21.2 million of Israeli NOLs are available for use in the U.S and have an indefinite life.

The Company follows guidance on accounting for uncertainty in income taxes which prescribes a minimum threshold a tax position is required to meet before being recognized in the financial statements. The Company does not have any liabilities as of December 31, 2020 and 2019 to account for potential income tax exposure. The Company is obligated to file income tax returns in the U.S. federal jurisdiction, several U.S. States and Israel. Since the Company had losses in the past, all prior years that generated net operating loss carry-forwards are open and subject to audit examination in relation to the net operating loss generated from those years. On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted in the United States, the impact of which was not material.

Note 13 – Restructuring

In March 2020, the Company adopted the 2020 Plan in response to the ongoing disruptions from the COVID-19 outbreak, and to better align its cost structure with the resources required to more efficiently and effectively execute on its commercial strategy of creating a strong foundation in the market by establishing national and regional hospital networks as Pure Vu reference centers. Most significantly, the 2020 Plan resulted in the reduction of the Company's overall headcount by approximately 50%, including a significant reduction of the Company's commercial team in the US, the implementation of tighter expense controls, and the termination of the lease of the Company's planned corporate office facility in Norwood, Massachusetts.

During the year ended December 31, 2020 the Company recorded charges of $624 related to the 2020 Plan, of which $445 were related to employee severance and other benefits included in sales and marketing expense and research and developments expense in the statement of comprehensive loss and $179 were related to lease termination and fixed asset impairments included in general and administrative expenses in the statement of comprehensive loss. There are no remaining unpaid liabilities related to restructuring charges as of December 31, 2020.

Note 14 – Subsequent Events

On January 27, 2021, the Company entered into a Warrant Exercise Agreement (the "Exercise Agreement") with the Holder, at which time 8,000,000 of the Private Placement Warrants remained outstanding, due to the prior exercise of 733,625 of the Private Placement Warrants on January 22, 2021. Pursuant to the Exercise Agreement, in order to induce the Holder to exercise all of its remaining outstanding 8,000,000 Private Placement Warrants for cash, the Company agreed to issue to the Holder, new warrants (the "New Warrants") to purchase 0.75 shares of Common Stock for each share of Common Stock issued upon such exercise of the remaining 8,000,000 Private Placement Warrants pursuant to the Exercise Agreement, or an aggregate of 6,000,000 New Warrants. The terms of the New Warrants are substantially similar to those of the Private Placement Warrants, except that the New Warrants will have an exercise price of $2.12, will be immediately exercisable and will expire five years from the date of the Exercise Agreement. In addition, the Holder paid a cash payment of $0.10 for each New Warrant issued to the Holder, for an aggregate of $600,000 to the Company. The Company received aggregate gross proceeds before expenses of approximately $11.0 million from the exercise of all of the remaining 8,000,000 outstanding Private Placement Warrants held by the Holder and the payment of the purchase price for the New Warrants.

In connection with the Exercise Agreement, the Company entered into a financial advisory agreement (the "Letter Agreement") with A.G.P./Alliance Global Partners ("A.G.P."), pursuant to which A.G.P. acted as exclusive financial advisor to the Company in this transaction and received a cash fee of $300,000 upon full cash exercise of the Private Placement Warrants. As additional compensation, A.G.P. will receive a cash fee equal to $200,000 upon the cash exercise in full of the New Warrants.

On January 20, 2021, the Company entered into a services agreement with a service provider whereby it agreed to issue warrants to purchase an aggregate 340,020 shares of common stock of the Company with an exercise price equal to $1.75 per share of common stock, which will vest over a one-year period on a monthly basis and will have an exercise period of three years from the date of issuance.

On February 17, 2021, the Company's Compensation Committee approved the issuance of 949,500 options, in the aggregate, to executives and employees which vest over a three-year period on a quarterly basis to purchase shares of the Company's common stock with an exercise price equal to $1.78 per share of common stock.

On February 17, 2021, the Company's Compensation Committee approved the issuance of 160,000 restricted stock unit awards to non-employee directors which vest on the first anniversary of the date of grant, and 266,000 restricted stock unit awards, to executives which vest over a three-year period on a quarterly basis.

On February 17, 2021, the Company's Compensation Committee approved the issuance of 160,000 options, in the aggregate, to non-employee directors which vest on the first anniversary of the date of grant to purchase shares of the Company's common stock with an exercise price equal to $1.78 per share of common stock.

On February 17, 2021, the Company's Compensation Committee approved a modification to the non-employee director compensation policy to permit payment of the fees for service as directors for 2021 in grants of the Company's common stock, in lieu of cash compensation. Non-employee members of the Board of Directors were granted an aggregate of 121,237 shares of common stock at a price equal to $1.78 per share of common stock, as compensation, in lieu of $216 of cash compensation, for service as directors for 2021.

Exhibit 4.15

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Motus GI Holdings, Inc. had one class of common stock registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

The following description of our common stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our certificate of incorporation, as amended, (the "Certificate of Incorporation") and our bylaws (the "Bylaws"), each of which is incorporated herein by reference as an exhibit to the Annual Report on Form 10-K filed with the Securities and Exchange Commission, of which this Exhibit 4.15 is a part. We encourage you to read our Certificate of Incorporation, our Bylaws and the applicable provisions of the General Corporation Law of the State of Delaware (the "DGCL") for additional information.

Description of Common Stock

Our authorized capital stock consists of:

- 115,000,000 shares of common stock, par value $0.0001 per share;
- 10,000,000 shares of preferred stock, par value $0.0001 per share.

The additional shares of our authorized capital stock available for issuance may be issued at times and under circumstances so as to have a dilutive effect on earnings per share and on the equity ownership of the holders of our common stock. The ability of our board of directors to issue additional shares of stock could enhance the board's ability to negotiate on behalf of the stockholders in a takeover situation but could also be used by the board to make a change-in-control more difficult, thereby denying stockholders the potential to sell their shares at a premium and entrenching current management. The following description is a summary of the material provisions of our common stock. You should refer to our Certificate of Incorporation and Bylaws, both of which are on file with the SEC as exhibits to previous SEC filings, for additional information. The summary below is qualified by provisions of applicable law.

Voting. The holders of our common stock are entitled to one vote for each share held of record on all matters on which the holders are entitled to vote (or consent to). When a quorum is present at any meeting of stockholders, any matter before any such meeting (other than an election of a director or directors) shall be decided by a majority of the votes properly cast on such matter, except where a different vote is required by our Certificate of Incorporation, by our Bylaws, by law, by the rules or regulations of any stock exchange applicable to us, or pursuant to any regulation applicable to us or our securities, in which case, such different vote shall apply. A majority in voting power of the shares entitled to vote at the meeting, present in person or represented by proxy, shall constitute a quorum at any meeting of stockholders.

Dividends. The holders of our common stock are entitled to receive, ratably, dividends only if, when and as declared by our board of directors out of funds legally available therefor and after provision is made for each class of capital stock having preference over our common stock.

Liquidation Rights. In the event of our liquidation, dissolution or winding-up, the holders of our common stock are entitled to share, ratably, in all assets remaining available for distribution after payment of all liabilities and after provision is made for each class of capital stock having preference over our common stock.

Conversion Right. The holders of our common stock have no conversion rights.

Preemptive and Similar Rights. The holders of our common stock have no preemptive or similar rights.

Redemption/Put Rights. There are no redemption or sinking fund provisions applicable to our common stock. All of the outstanding shares of our common stock are fully-paid and non-assessable.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Our Certificate of Incorporation and Bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or tender offers or delaying or preventing a change of control. These provisions are as follows:

- they provide that special meetings of stockholders may be called by the board of directors or at the request in writing by stockholders of record owning at least twenty (20%) percent of the issued and outstanding voting shares of our common stock;

- they do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes in our board of directors; and

- they allow us to issue, without stockholder approval, up to 10,000,000 shares of preferred stock that could adversely affect the rights and powers of the holders of our common stock.

We are subject to the provisions of Section 203 of the DGCL, an anti-takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in the following prescribed manner:

- prior to the time of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the stockholder owned at least eighty-five percent (85%) of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding; (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; and

- on or subsequent to the time of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least sixty-six and two-thirds percent (66 2/3%) of the outstanding voting stock which is not owned by the interested stockholder.

Generally, for purposes of Section 203, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns or, within three (3) years prior to the determination of interested stockholder status, owned fifteen percent (15%) or more of a corporation's outstanding voting securities.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our Bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee of our board of directors. These provisions may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed. These provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

Choice of Forum

Our Certificate of Incorporation 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 exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us, or any of our officers or Directors, arising pursuant to the DGCL, our Certificate of Incorporation or our Bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for the disputes listed above, which may discourage such lawsuits against us, or any of our officers or directors.

Potential Effects of Authorized but Unissued Stock

We have shares of common stock and preferred stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions or payment as a dividend on the capital stock.

The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, the board of directors has the discretion to determine designations, rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock, all to the fullest extent permissible under the DGCL and subject to any limitations set forth in our Certificate of Incorporation. The purpose of authorizing the board of directors to issue preferred stock and to determine the rights and preferences applicable to such preferred stock is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing desirable flexibility in connection with possible financings, acquisitions and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from acquiring, a majority of our outstanding voting stock.

Exhibit 10.25

AMENDMENT TO THE
FIRST AMENDED EMPLOYMENT AGREEMENT

AMENDMENT, dated as of March 15, 2021, to the First Amended Employment Agreement, dated March 26, 2019 (the "Employment Agreement"), between Motus GI Holdings, Inc., a Delaware corporation ("Company"), and Andrew Taylor ("Executive").

RECITALS

WHEREAS, the Employment Agreement sets forth the terms and conditions of Executive's employment with the Company, including, but not limited to, severance pay and benefits that will be payable to Executive if he experiences a covered termination;

WHEREAS, the Company desires to amend the Employment Agreement to increase certain severance benefits to Executive in the event that Executive's employment is terminated by the Company for a covered termination; and

WHEREAS, Section 6.06 of the Employment Agreement provides that the Employment Agreement may be amended pursuant to a written agreement between Executive and the Company.

NOW, THEREFORE, in consideration of the foregoing and other good and valuable consideration, the Company and Executive hereby agree that, effective the date hereof, the Employment Agreement is hereby amended as follows:

1. Section 4.02(B)(1) of the Employment Agreement is hereby amended in its entirety to read as follows:

"(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 twelve (12) 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 all respects not modified by this Amendment, the Employment Agreement is hereby ratified and confirmed.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Company and Executive agree to the terms of this Amendment, effective as of the date set forth above.

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 Amendment to the First Amended Employment Agreement*]

Exhibit 10.29

THIRD AMENDMENT TO LOAN AND SECURITY AGREEMENT AND ASSUMPTION AGREEMENT

This Third Amendment to Loan and Security Agreement and Assumption Agreement (this "**Assumption Agreement**") is entered into as of January 4, 2021, by and among (a) **SILICON VALLEY BANK**, a California corporation, with its principal place of business at 3003 Tasman Drive, Santa Clara, California 95054 and with a loan production office located at 275 Grove Street, Suite 2-200, Newton, Massachusetts 02466 ("**Bank**") and (b) (i) **MOTUS GI, INC.**, a Delaware corporation, with its principal place of business at 1301 East Broward Boulevard, 3rd Floor Fort Lauderdale, Florida 33301 ("**Existing Borrower**"), (ii) **MOTUS GI, LLC,** a Delaware limited liability company, with its principal place of business at 1301 East Broward Boulevard, 3rd Floor Fort Lauderdale, Florida 33301 ("**New Borrower**"), and (iii) **MOTUS GI HOLDINGS, INC.**, a Delaware corporation, with its principal place of business at 1301 East Broward Boulevard, 3rd Floor Fort Lauderdale, Florida 33301 ("**Holdings**").

Reference is made to that certain Loan and Security Agreement dated as of December 13, 2019, as amended by that certain Joinder and First Amendment to Loan and Security Agreement dated as of February 7, 2020 between Bank and Borrower, and as further amended by that certain Second Amendment to Loan and Security Agreement dated as of February 25, 2020 between Bank and Borrower (as may be further amended, affected, modified, restated, replaced, or supplemented from time to time, the "**Loan Agreement**"). All capitalized terms used herein without definitions shall have the meanings given such terms in the Loan Agreement.

1. Assumption. New Borrower is the successor entity to Existing Borrower. New Borrower hereby agrees to substitute itself as the "Borrower" under the Loan Agreement and each of the Loan Documents in lieu of Existing Borrower, and agrees to comply with and be bound by all of the terms, conditions and covenants of the Loan Agreement and the Loan Documents, as if it were originally named "Borrower" therein. Without limiting the generality of the preceding sentence, New Borrower hereby assumes and agrees to pay and perform when due all present and future indebtedness, liabilities and obligations of Existing Borrower under the Loan Agreement, including, without limitation, the Obligations. All references in the Loan Documents to "Borrower" shall be deemed to refer to New Borrower. Furthermore, all present and future obligations of Existing Borrower shall be deemed to refer to all present and future obligations of New Borrower. New Borrower acknowledges that the Obligations are due and owing to Bank from Existing Borrower, without any defense, offset or counterclaim of any kind or nature whatsoever as of the date hereof.

2. Grant of Security Interest. To secure the payment and performance in full of all of the Obligations, New Borrower hereby grants to Bank a continuing lien upon and security interest in all of New Borrower's now existing or hereafter arising rights and interest in such assets of New Borrower as are consistent with the description of the Collateral set forth on Exhibit A of the Loan Agreement (as if such Collateral were deemed to pertain to the assets of New Borrower), whether now owned or existing or hereafter created, acquired, or arising, and wherever located, and including, without limitation, all of New Borrower's assets (excluding Intellectual Property), and all of New Borrower's books relating to the foregoing and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing. New Borrower further covenants and agrees that by its execution hereof it shall provide all such information, complete all such forms, and take all such actions, and enter into all such agreements, in form and substance reasonably satisfactory to Bank that are reasonably deemed necessary by Bank in order to grant a valid, perfected first priority security interest to Bank in the Collateral. New Borrower hereby authorizes Bank to file financing statements, without notice to New Borrower, with all appropriate jurisdictions and filing offices in order to perfect or protect Bank's interest or rights hereunder, including a notice that any disposition of the Collateral, by either New Borrower or any other Person, shall be deemed to violate the rights of Bank under the Code. Any such financing statements may indicate the Collateral as "all assets of the Debtor" or words of similar effect, or as being of an equal or lesser scope, or with greater detail, all in Bank's discretion. Upon Borrower's written request, Bank shall provide Borrower with copies of the filed financing statements.

3. Representations and Warranties. New Borrower hereby represents and warrants to Bank that all representations and warranties in the Loan Documents made on the part of Existing Borrower are true and correct in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date) with respect to New Borrower, with the same force and effect as if New Borrower were named as the "Borrower" in the Loan Documents.

4. Delivery of Documents. New Borrower hereby agrees that the following shall be delivered to Bank prior to or concurrently with this Assumption Agreement, each in form and substance satisfactory to Bank:

A. a limited liability company borrowing certificate for New Borrower with respect to New Borrower's certificate of formation, operating agreement, incumbency and resolutions authorizing the execution and delivery of this Assumption Agreement and the other documents required by Bank in connection with this Assumption Agreement;

B. the Operating Documents and long-form good standing certificate of New Borrower certified by the Secretary of State Delaware as of a date no earlier than thirty (30) days prior to the date hereof;

C. duly executed signatures to a Cash Pledge Agreement, in form and substance acceptable to Bank; and

D. such other documents as Bank may reasonably request.

5. Amendments to Loan Agreement.

5.1 Section 6.12 (Post-Closing Deliverables). Section 6.12 is amended in its entirety and replaced with the following:

"**6.12 Post-Closing Deliverables**. Deliver to Bank, within forty-five (45) days after the Third Amendment Effective Date, a Perfection Certificate of New Borrower, together with the duly executed signature thereto."

5.2 Section 13.1 (Definitions). The following term and its respective definition set forth in Section 13.1 is amended in its entirety and replaced with the following:

" "**Motus GI**" is Motus GI, LLC, a Delaware limited liability company."

5.3 Section 13.1 (Definitions). The following new term and its respective definition set forth in Section 13.1 is hereby inserted alphabetically in Section 13.1:

" "**Third Amendment Effective Date**" is January 4, 2021."

5.4 Exhibit B (Compliance Certificate). The Compliance Certificate appearing as Exhibit B to the Loan Agreement is deleted in its entirety and replaced with the Compliance Certificate attached as Schedule 1 attached hereto.

5.5 Exhibit C (Loan Payment/Advance Request Form). The Loan Payment/Advance Request Form appearing as Exhibit C to the Loan Agreement is deleted in its entirety and replaced with the Loan Payment/Advance Request Form attached as Schedule 2 attached hereto.

6. Limitation of Amendments.

6.1 The amendments set forth in Section 5 above, are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Bank may now have or may have in the future under or in connection with any Loan Document.

6.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

7. Fees and Bank Expenses. New Borrower shall reimburse Bank for all legal fees and expenses incurred in connection with this Assumption Agreement and other documents to be executed in connection herewith.

8. Choice of Law, Venue and Jury Trial Waiver. Massachusetts law governs this Assumption Agreement without regard to principles of conflicts of law. New Borrower and Bank each submit to the exclusive jurisdiction of the State and Federal courts in Massachusetts, provided, however, that nothing in this Assumption Agreement shall be deemed to operate to preclude Bank from bringing suit or taking other legal action in any other jurisdiction to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of Bank. NOTWITHSTANDING THE FOREGOING, BANK SHALL HAVE THE RIGHT TO BRING ANY ACTION OR PROCEEDING AGAINST NEW BORROWER OR ITS PROPERTY IN THE COURTS OF ANY OTHER JURISDICTION WHICH BANK DEEMS NECESSARY OR APPROPRIATE IN ORDER TO REALIZE ON THE COLLATERAL OR TO OTHERWISE ENFORCE BANK'S RIGHTS AGAINST NEW BORROWER OR ITS PROPERTY.

NEW BORROWER AND BANK EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS ASSUMPTION AGREEMENT, THE LOAN AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR BOTH PARTIES TO ENTER INTO THIS ASSUMPTION AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

9. Consistent Changes. The existing Loan Documents are hereby amended wherever necessary to reflect the changes described above.

10. Ratification of Loan Documents. Borrower hereby ratifies, confirms, and reaffirms all terms and conditions of all security or other collateral granted to Bank, and confirms that the indebtedness secured thereby includes, without limitation, the Obligations.

11. No Defenses of Borrower. Borrower hereby acknowledges and agrees that Borrower has no offsets, defenses, claims, or counterclaims against Bank with respect to the Obligations, or otherwise, and that if Borrower now has, or ever did have, any offsets, defenses, claims, or counterclaims against Bank, whether known or unknown, at law or in equity, all of them are hereby expressly WAIVED and Borrower hereby RELEASES Bank from any liability thereunder.

12. Continuing Validity. Borrower understands and agrees that in modifying the existing Obligations, Bank is relying upon Borrower's representations, warranties, and agreements, as set forth in the existing Loan Documents. Except as expressly modified pursuant to this Assumption Agreement, the terms of the existing Loan Documents remain unchanged and in full force and effect. Bank's agreement to modifications to the existing Obligations pursuant to this Assumption Agreement in no way shall obligate Bank to make any future modifications to the Obligations. Nothing in this Assumption Agreement shall constitute a satisfaction of the Obligations. It is the intention of Bank and Borrower to retain as liable parties all makers of existing Loan Documents, unless the party is expressly released by Bank in writing. No maker will be released by virtue of this Assumption Agreement.

13. Countersignatures. This Assumption Agreement shall become effective only when it shall have been executed by New Borrower and Bank. This Assumption Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, are an original, and all taken together, constitute one agreement. Each party hereto may execute this Assumption Agreement by electronic means and recognizes and accepts the use of electronic signatures and records by any other party hereto in connection with the execution and storage hereof.

[The remainder of this page is intentionally left blank]

This Assumption Agreement is executed as of the date first written above.

NEW BORROWER:

MOTUS GI, LLC

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

EXISTING BORROWER:

MOTUS GI, INC.

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

HOLDINGS:

MOTUS GI HOLDINGS, INC.

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

BANK:

SILICON VALLEY BANK

By: /*s/ Sam Subilia*
Name: Sam Subilia
Title: Director

Schedule 1

EXHIBIT B

COMPLIANCE CERTIFICATE

TO: SILICON VALLEY BANK

Date: _____

FROM: MOTUS GI HOLDINGS, INC.
MOTUS GI, LLC.

The undersigned authorized officer of MOTUS GI HOLDINGS, INC. and MOTUS GI, LLC. (individually and collectively, jointly and severally, "Borrower") certifies that under the terms and conditions of the Loan and Security Agreement between Borrower and Bank (the "Agreement"):

(1) Borrower is in complete compliance for the period ending _____ with all required covenants except as noted below; (2) there are no Events of Default; (3) all representations and warranties in the Agreement are true and correct in all material respects on this date except as noted below; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date; (4) Borrower, and each of its Subsidiaries, has timely filed all required tax returns and reports, and Borrower has timely paid all foreign, federal, state and local taxes, assessments, deposits and contributions owed by Borrower except as otherwise permitted pursuant to the terms of Section 5.8 of the Agreement; and (5) no Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Bank.

Attached are the required documents supporting the certification. The undersigned certifies that these are prepared in accordance with GAAP consistently applied from one period to the next except as explained in an accompanying letter or footnotes. The undersigned acknowledges that no borrowings may be requested at any time or date of determination that Borrower is not in compliance with any of the terms of the Agreement, and that compliance is determined not just at the date this certificate is delivered. Capitalized terms used but not otherwise defined herein shall have the meanings given them in the Agreement.

Please indicate compliance status by circling Yes/No under "Complies" column.

Reporting Covenants	**Required**	**Complies**
Monthly financial statements	Monthly within 30 days	Yes No
Compliance Certificate	Monthly within 30 days	Yes No
Annual financial statement (CPA Audited)	FYE within 180 days	Yes No
Board approved projections	Within 90 days after FYE	Yes No
10-Q, 10-K and 8-K	Within 5 days after filing with SEC	Yes No

	Required	**Actual**	**Complies**
Liquidity Requirement (to be maintained at all times)	at least $10,000,000.00	$_____	Yes No

Other Matters

Have there been any amendments of or other changes to the capitalization table of Borrower and to the Operating Documents of Borrower or any of its Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate. Yes No

The following are the exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions to note.")

MOTUS GI HOLDINGS, INC.

By: _____
Name: _____
Title: _____

MOTUS GI, LLC

By: _____
Name: _____
Title: _____

BANK USE ONLY

Received by: _____
AUTHORIZED SIGNER
Date: _____

Verified: _____
AUTHORIZED SIGNER
Date: _____

Compliance Status: Yes No

Schedule 1 to Compliance Certificate

Financial Covenants of Borrower

In the event of a conflict between this Schedule and the Loan Agreement, the terms of the Loan Agreement shall govern.

Dated: _____

I. **Liquidity** (Section 6.7)

Required: At all times, Borrower shall maintain unrestricted and unencumbered cash in accounts with Bank in an amount equal to at least Ten Million Dollars ($10,000,000.00).

Actual:

A. Unrestricted and unencumbered cash in accounts with Bank $

Is Line A equal to or greater than or equal to $10,000,000.00?

_____ No, not in compliance _____ Yes, in compliance

Schedule 2

EXHIBIT C – LOAN PAYMENT/ADVANCE REQUEST FORM

DEADLINE FOR SAME DAY PROCESSING IS 1:00 PM EASTERN TIME

Fax To: Date: _____

LOAN PAYMENT: MOTUS GI HOLDINGS, INC. and MOTUS GI, LLC.

From Account #_____ To Account #_____
(Deposit Account #) (Loan Account #)

Principal $_____ and/or Interest $_____

Authorized Signature:_____ Phone Number: _____

Print Name/Title: _____

LOAN ADVANCE:

Complete *Outgoing Wire Request* section below if all or a portion of the funds from this loan advance are for an outgoing wire.

From Account #_____ To Account #_____
(Loan Account #) (Deposit Account #)

Amount of Term Loan Advance $_____

All Borrower's representations and warranties in the Loan and Security Agreement are true, correct and complete in all material respects on the date of the request for an advance; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date:

Authorized Signature:_____ Phone Number: _____

Print Name/Title: _____

OUTGOING WIRE REQUEST:

Complete only if all or a portion of funds from the loan advance above is to be wired.

Deadline for same day processing is 1:00 PM, Eastern Time

Beneficiary Name: _____ Amount of Wire: $_____
Beneficiary Bank: _____ Account Number: _____
City and State: _____
Beneficiary Bank Transit (ABA) #: _____ Beneficiary Bank Code (Swift, Sort, Chip, etc.): _____
(For International Wire Only)
Intermediary Bank: _____ Transit (ABA) #: _____
For Further Credit to: _____
Special Instruction: _____

By signing below, I (we) acknowledge and agree that my (our) funds transfer request shall be processed in accordance with and subject to the terms and conditions set forth in the agreements(s) covering funds transfer service(s), which agreements(s) were previously received and executed by me (us).

Authorized Signature: _____ 2nd Signature (if required): _____
Print Name/Title: _____ Print Name/Title: _____
Telephone #: _____ Telephone #: _____

Exhibit 21.1

Subsidiaries of Registrant

Motus GI Medical Technologies, Ltd., an Israeli corporation

Motus GI, LLC, a Delaware limited liability company

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Motus GI Holdings, Inc. on Form S-1 (No. 333-249565), Form S-3 (No. 333-230516) and Form S-8 (Nos. 333-224003, 333-230506 and 333-237476) of our report dated March 16, 2021, on our audits of the consolidated financial statements as of December 31, 2020 and 2019 and for each of the years then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 16, 2021. 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 16, 2021

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, 2020 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 16, 2021

/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, 2020 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 16, 2021

/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, 2020 (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 16, 2021

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

Dated: March 16, 2021

By: */s/ Andrew Taylor*
Andrew Taylor
Chief Financial Officer
(Principal Financial 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. A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Motus GI Holdings, Inc. and will be retained by Motus GI Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.