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, 2022

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)

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

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

Title of each class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001 per share	MOTS	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 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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

As of June 30, 2022, 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 $14.6 million based on the closing price of the registrant's Common Stock on June 30, 2022.

The number of shares outstanding of the registrant's Common Stock, par value of $0.0001 per share, as of March 27, 2023 was 4,778,873.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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

For the Year Ended December 31, 2022

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 and need for additional capital;
- our ability to execute our strategic restructuring program aimed at capital preservation, reduction in cash expenditures and reduction of our workforce;
- our ability to enter into and consummate strategic alternatives, including any acquisition, merger, reverse merger, other business combination, sale of assets, licensing and other strategic transactions;
- 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 ability to remain compliant with the requirements of The Nasdaq Capital Market for continued listing;
- our dependence on the Pure-Vu System, our sole product;
- our ability to commercialize 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 ability to obtain approval or certification from regulatory agents or other competent entities in different jurisdictions for 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;
- our ability to predict the financial impact of inflation on costs such as labor, freight and materials; 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, a medical device that has been cleared by the U.S. Food and Drug Administration (the "FDA") to help facilitate the cleansing of a poorly prepared gastrointestinal tract during colonoscopy and to help facilitate upper gastrointestinal ("GI") endoscopy procedures. The Pure-Vu System is also CE marked in the European Economic Area (EEA) for use in colonoscopy. The Pure-Vu System integrates with standard and slim colonoscopes, as well as gastroscopes, to improve visualization during colonoscopy and upper GI procedures while preserving established procedural workflow and techniques. Through irrigation and evacuation of debris, the Pure-Vu System is designed to provide better-quality exams. Challenges exist for inpatient colonoscopy and endoscopy, particularly for patients who are elderly, with comorbidities, or active bleeds, where the ability to visualize, diagnose and treat is often compromised due to debris, including fecal matter, blood, or blood clots. We believe this is especially true in high acuity patients, like GI bleeding where the existence of blood and blood clots can impair a physician's view and removing them can be critical in allowing a physician the ability to identify and treat the source of bleeding on a timely basis. We believe use of the Pure-Vu System may lead to positive outcomes and lower costs for hospitals by safely and quickly improving visualization of the colon and upper GI tract, potentially enabling effective diagnosis and treatment without delay. In multiple clinical studies to date, involving the treatment of challenging inpatient and outpatient cases, the Pure-Vu System has consistently helped achieve adequate bowel cleanliness rates greater than 95% following a reduced prep regimen. We also 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. 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 believe that during 2022 approximately 1.5 million inpatient colonoscopy procedures were performed in the U.S. and approximately 4.8 million worldwide. Upper GI bleeds occurred in the U.S. at a rate of approximately 400,000 cases per year in 2019, according to iData Research Inc. The Pure-Vu System has been assigned an ICD-10 code in the US. The system does not currently have unique codes with any private or governmental third-party payors in any other country or for any other use; however, we may pursue reimbursement activities in the future, particularly in the outpatient colonoscopy market. We received 510(k) clearance in February 2022 from the FDA for our Pure-Vu EVS System and have commenced initial commercialization of this product.

Strategic Review and Restructuring

As previously announced in January 2023, we have initiated a process to explore a range of strategic and financing alternatives focused on maximizing stockholder value and accelerating the commercialization of the Pure-Vu System. We have engaged Lake Street Capital Markets LLC ("Lake Street Capital") to advise us in this process. Potential strategic alternatives that we may consider are expected to include an acquisition, merger, reverse merger, other business combination, sale of assets, licensing and other strategic transactions.

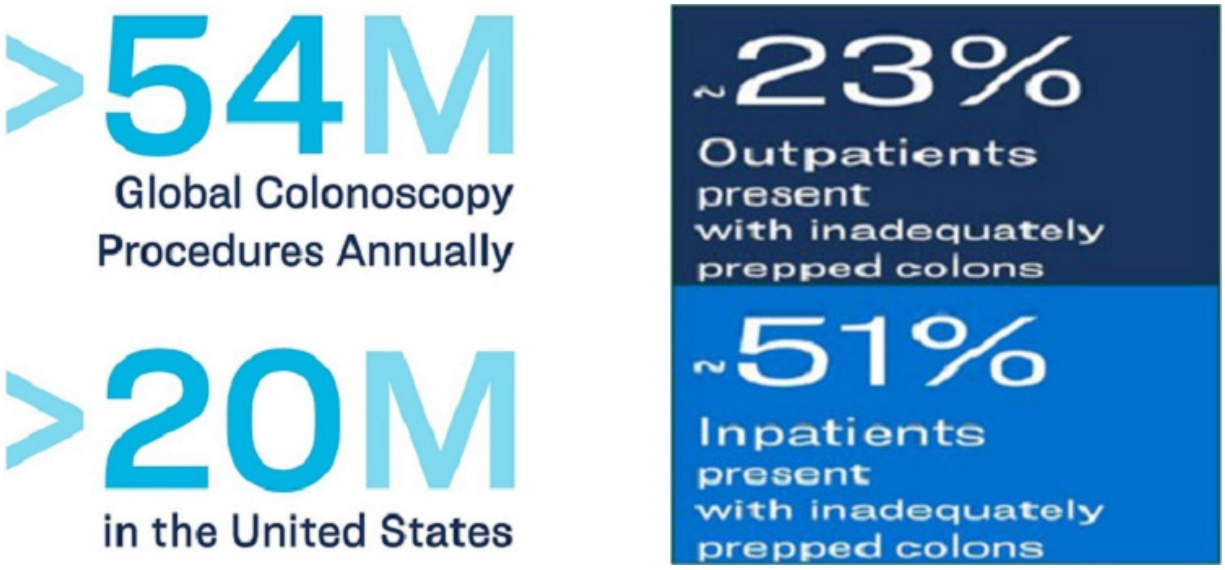
To support these objectives, we commenced a strategic restructuring program aimed at capital preservation. We have reduced our quarterly cash expenditures by approximately 35% by eliminating approximately 45% of our workforce during the first quarter of 2023. In connection with the restructuring, we expect to incur a non-recurring charge of approximately $1.0 to $2.0 million in the first quarter of 2023. In addition, the non-management members of the Board agreed to defer their Board fees until a future date.

The restructuring is intended to position us to continue to explore all strategic alternatives, continue supporting our existing customers utilizing Pure-Vu EVS for colonoscopies, as well as targeting pipeline opportunities with contracted health systems. In addition, we intend to continue to advance our Pure-Vu EVS Gastro development program, which is designed for use during an Upper GI endoscopy to improve visualization by clearing debris and may help improve procedure times and outcomes especially in high acuity situations like an upper GI bleed. We intend to seek U.S. regulatory approval for the Pure-Vu EVS Gastro device in the second half of 2023.

We intend to continue to evaluate and identify other areas of our business to enhance efficiencies and improve processes, with a goal to further lower our operating expenses and capital needs. There can be no assurance that this strategic review process will result in any changes to our current business plans or lead to any specific action or transaction. We do not intend to discuss or disclose further developments during this strategic review process unless and until the Board has approved a specific action or we otherwise determine that further disclosure is appropriate.

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 more than 54 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 2023 approximately 1.5 million inpatient colonoscopy procedures in a hospital setting will be performed in the U.S. Hospital based colonoscopies are typically performed to help diagnose and treat lower gastrointestinal (GI) bleeding, irritable bowel syndrome (IBS), inflammatory bowel disease (IBD), anemia or infection. 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, with the bulk of procedures performed to detect and prevent colorectal cancer (CRC). 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 if detected early through the use of colonoscopy screening.



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 Harewood 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).

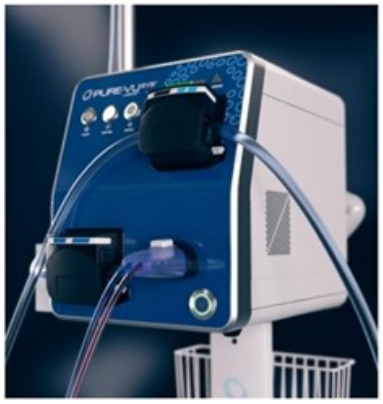
Inpatient Opportunity: improving efficiencies and shortening time to complete a successful colonoscopy

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 & 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 efforts 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 the acuity of the patient who often struggles to complete a satisfactory pre-procedural 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 shown 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 to the workstation. The workstation, through a series of peristaltic pumps activated by foot pedals, delivers an irrigation medium of air and water that creates a pulsed vortex inside the colon to break up fecal matter while simultaneously evacuating the colon content into waste receptacles already used in a standard colonoscopy procedure. The proprietary 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. The Pure-Vu System has been clinically demonstrated to be capable of cleaning poorly prepared colons in minutes. We have built and continue to extend our 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 CE Certificate of Conformity, allowing us to affix the CE Mark to the Gen 2 Pure-Vu System in March 2020. We received a supplement to the initial CE Certificate of Conformity in January 2021.

On February 14, 2022, we announced the 510(k) clearance by the FDA of our Pure-Vu EVS System. The Pure-Vu EVS offers usability advancements over the previous versions, including enhanced physician navigation and control, on-demand bedside loading, expanded cleansing capacity, and a smaller workstation footprint.

We also implemented an improved manufacturing cost structure in 2022 that we believe better positions the Company to increase margins, and establish strategic relationships in the US and other more cost sensitive global markets over time.

Pre-Clinical and Clinical Data & Safety

The Pure-Vu System has been studied in multiple clinical studies in study subjects receiving a reduced prep regime as well as a study 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 subjects and was completed in the second quarter of 2016. The second study was completed in June 2017 and involved 46 subjects. The subjects in these studies had a restricted diet for 18-24 hours and received a split dose of 20mg of over-the-counter Dulcolax® (bisocodyl). They 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 and the second study was published in the peer review journal *Endoscopy* in 2018. The clinical results from the 2017 study were presented at the UEGW in October 2017, showing similar results, as shown below. This study has been published in *Endoscopy,* one of the top peer reviewed journals in the EU.

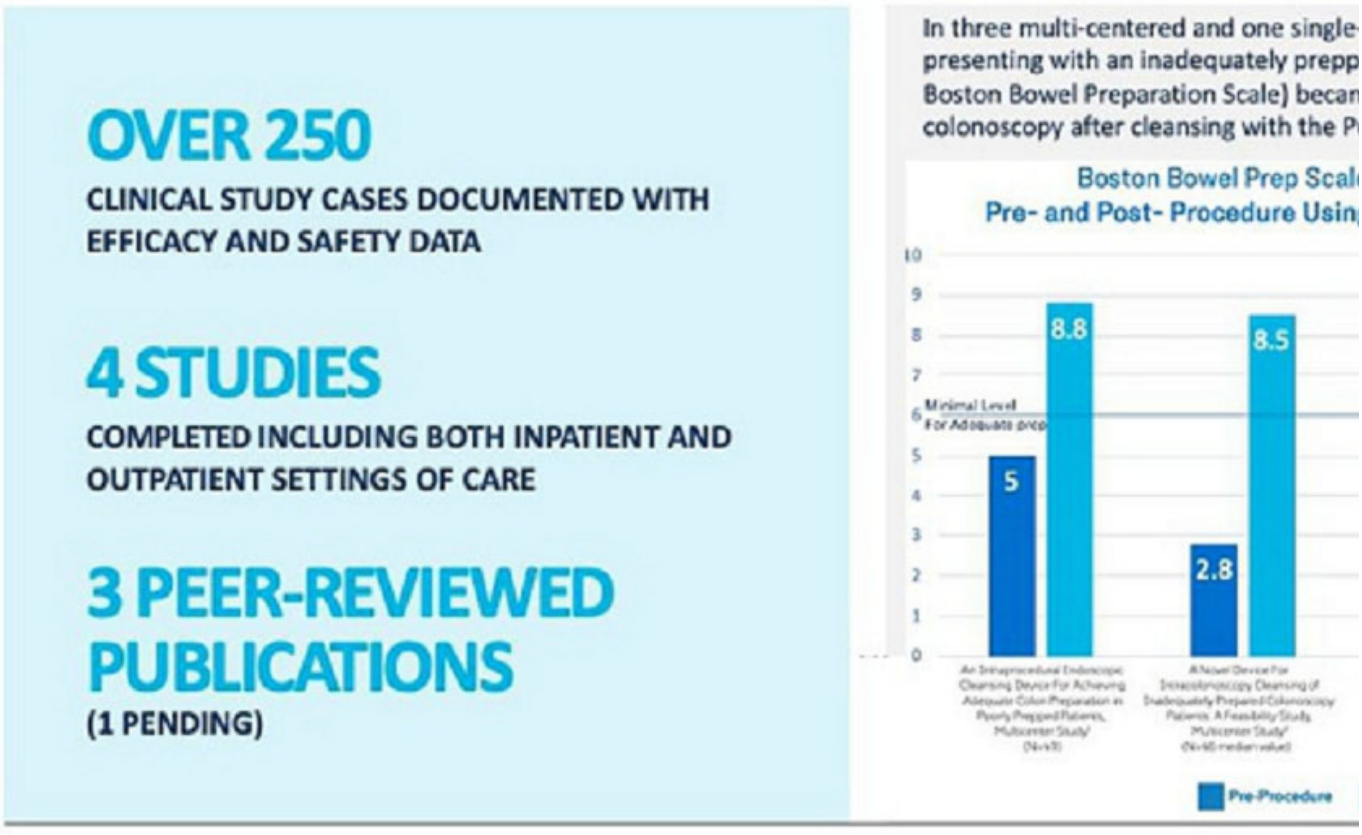
The third clinical study in the outpatient setting was presented at the American College of Gastroenterology ("ACG") Annual Meeting in October 2018. This study was performed in the United States and showed that the Pure-Vu System demonstrated safe and effective colonic cleaning in the per protocol analysis of 46 subjects receiving a reduced prep regimen. The study was initially designed to compare two different minimal bowel preparation regimens. Initially subjects 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 subjects 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 subjects 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.

REDUCE Study

The Reduce study ("Reliable Endoscopic Diagnosis Utilizing Cleansing Enhancement"), was first presented at Digestive Disease Week (DDW) conference in May of 2019 and a full manuscript, titled "A multi-center, prospective, inpatient feasibility study to evaluate the use of an intra-colonoscopy cleansing device to optimize colon preparation in hospitalized subjects: the REDUCE study", was published in the peer review journal *BMC Gastroenterology* in Q2 of 2021. The REDUCE study was 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. The study enrolled 95 hospitalized subjects 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 97% of subjects in the 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:



Current Additional Clinical Studies

In Q2 2022, we completed the EU study of subjects who have had a history of poor bowel preparation and were scheduled for either screening, diagnostic, or surveillance colonoscopy across two sites, including the Radboud University Medical Center (Netherlands) and GastroZentrum Lippe (Germany). The subjects underwent a low volume bowel preparation, with just 2x150ml picoprep. The subjects were also allowed to eat a low fiber diet for two days prior to the colonoscopy as opposed to the typical clear liquid diet the day before a colonoscopy. The subjects then received intra-procedural bowel cleansing with the Pure-Vu System. The primary endpoint for the study is improvement of the bowel preparation from baseline to post procedure as assessed by the Boston Bowel Preparation Scale (BBPS), which assesses the cleanliness of each of the three segments of the colon on a zero to three scale and requires a minimum score of two or better per segment to be considered adequately prepped. The results of the study were presented at the Digestive Disease Week meeting in May 2022 and showed a statistically significant improvement of subjects who were adequality prepped from a baseline of 31.8% to 97.7% after the use of Pure-Vu with a p-value of <0.0001.

Cost Effectiveness Analysis and Independent Studies

In 2021, we announced the publication of a sponsored Pure-Vu System® Cost Effectiveness Analysis in the Journal of Cost Effectiveness and Resource Allocation, which is titled, "*Colonoscopy in poorly prepped colons. A cost effectiveness analysis comparing standard of care to a new cleansing technology.*" This study suggests that, assuming a national average compliance rate for colonoscopy in the U.S. at 60%, as reported by the American Cancer Society in 2017, the use of Pure Vu has the potential to provide the US healthcare system lifetime savings of $833-$922 per patient depending on the insurer when compared to the standard of care. Sponsorship of analysis and development of the manuscript was provided by us.

In 2021, we also announced the presentation of results from an independent single-center study of the Pure-Vu System as an adjunct to colon cleansing in subjects with inadequate bowel preparation (IBP) in a poster presentation at the 2021 American College of Gastroenterology (ACG) Annual Scientific Meeting.

In the independent study, the Pure-Vu System was used in 40 subjects (14 inpatient procedures (35%) and 26 outpatient procedures (65%)) with IBP to complete the colonoscopy. The indication for colonoscopy was either diagnostic or colorectal cancer (CRC) screening/surveillance. Pure-Vu was used as an adjunct to IBP to allow completion of procedure in 37 subjects. In subjects with IBP, the mean BBPS score improved from 3.1 (range: 0-6) to 8.5 (range 5-9) after intra-procedural cleansing. Three subjects had active lower gastrointestinal bleeding (LGIB), and the Pure-Vu System was used without bowel preparation to promptly detect the etiology and possibly treat. When used in emergency colonoscopy without bowel preparation, procedures could be completed in all three subjects detecting and treating diverticular and post-polypectomy bleeding in one subject each and diagnosing severe right sided ischemic colitis in another. The study authors concluded the utility of the Pure-Vu System without prior bowel preparation in LGIB needs further study. Use of Pure-Vu System did not interfere with the performance of endoscopic interventions including biopsy, cold/hot snare polypectomy, or EMR. Besides minor mucosal trauma in two cases, no major complications were observed with the Pure-Vu System.

Further, at the ACG meeting in October 2022, results from an independent single center in the VA system were presented on the use of Pure-Vu EVS on 45 subjects over a 6-month period as either a rescue method for those with endoscopically visualized inadequate preparation or used initially with those subjects with high suspicion for being poorly prepped. The study showed an improvement from an average of 4.8 on the BBPS at baseline to 8.7 after the use of Pure-Vu EVS (below 6 is considered inadequate with 9 being the top of the range). The conclusion from the investigator stated, "Use of this intraprocedural cleansing device increases examination quality, extends surveillance intervals, improves resource utilization".

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 eighteen granted or allowed patents in the U.S., nineteen patents in Asia (Japan, China and Hong Kong), and ten patents in the EU, with patent protection until at least 2040. In addition, we have eleven pending patent applications in various regions of the world with a focus on the U.S., EU and Japan. We have registered trademarks for Motus GI and for the Pure-Vu System in the U.S., EU and other international jurisdictions. We also have a pending trademark application in the U.S. 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 cleaning the colon or other body cavities effectively and efficiently. 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 Motus GI. 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, Steris, 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. These include but are not limited to capsule endoscopy, virtual colonoscopy using CT scans, etc. These technologies 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, 2022, we had received grants from the IIA in the aggregate amount of $1.3 million and had a contingent obligation to the IIA up to an aggregate amount of approximately $1.4 million (assuming no increase, per the IIA Regulations, as described below). As of December 31, 2022, 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(and any derivatives of such IIA funded know-how), 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 set forth 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 the Pure-Vu EVS is manufactured by Sterling Industries in their Michigan, U.S. facility. We entered into a supply agreement with Sterling Industries in Q2 of 2021. The disposable portion of our Gen 2 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. Both Sterling Industries and Polyzen use Medacys in Shenzhen, China as key sub-supplier for the injection molded parts in the Pure Vu disposables. These manufacturing suppliers have extensive experience in medical devices and in dealing with regulatory bodies and other competent entities. These suppliers have ISO 13485 certified 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. We have been 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 other network hospital locations. On September 29, 2022, the Company announced that it has officially been recognized as a sole source provider and small business by the Veterans Health Administration (VHA). The VHA is the largest integrated health care system in the U.S., and provides care to over nine million veterans. The special designation will provide the Company with direct access to the VHA's procurement arm, thereby streamlining the purchasing and contracting process. As we continue to grow our network expansion, we continue to 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 approximately six months. Timing of hospital capital budget availability may impact this anticipated cycle. Our primary focus 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

While our time, effort and attention are primarily focused on driving adoption in the U.S. hospital market, we have identified several follow-on market expansion opportunities that are currently being evaluated, including the upper GI endoscopy and targeted outpatient markets, as described below.

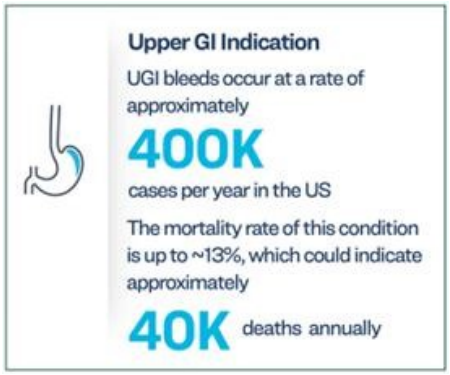
Upper GI Endoscopy Market

In 2021, we announced that we received 510(k) clearance from the FDA for a version of the Pure-Vu System that is compatible with gastroscopes used during upper gastrointestinal (GI) endoscopy procedures to remove blood, blood clots and debris in order to provide a clear field-of-view for the endoscopist. The device is designed to integrate with therapeutic gastroscopes to enable safe and rapid cleansing during the procedure, while preserving established procedural workflow and techniques.

Upper GI bleeds occurred in the U.S. at a rate of approximately 400,000 cases per year in 2019, according to iData Research Inc. Approximately 50% of these patients have blood and blood clots that impair a physician's view during the procedure, thereby making it difficult to rapidly identify the bleeding source. We believe removing adherent blood clots from the field of view is a significant need in allowing a physician the ability to identify and treat the bleed source. The mortality rate of this condition can reach up to approximately 13%, as noted in Thad Wilkins, MD, et al., American Family Physician (2012).

The Company has conducted a controlled series of Upper GI initial pilot procedures in the US market, which is intended to inform the development of a Pure-Vu EVS version of the Upper GI solution for eventual submission to FDA for marketing approval in the US. The Company successfully completed multiple pre-clinical tests in both porcine and cadaver models to evaluate Pure-Vu EVS platform for use in upper GI bleeding with multiple U.S. physicians. The results of these tests show that the Gastro version of Pure-Vu EVS can effectively break up and suction blood and blood clots, as well as frees up a gastroscope's working channel for other therapeutic tools. By eliminating the need to utilize existing irrigation and suction through the working channel of the gastroscope, physicians can use tools in tandem with Pure-Vu EVS. For example, the use of snares to break up large clots and then immediately suction out the smaller pieces using the large Pure-Vu EVS smart sense suction channel. In addition, during cases with significant bleeding, Pure-Vu EVS allows the physician to clean the area of interest and immediately apply therapy to achieve hemostasis, since the physician can have their therapeutic device prepositioned in the gastroscope's working channel and deliver it before the blood flow covers the area of interest after cleansing.

The Company plans on conducting additional pre-clinical and clinical tests for Pure-Vu EVS Gastro device in the first half of 2023. The results of these tests are expected to support submission of a 510(K) application to the U.S. Food and Drug Administration (FDA) in the second half of 2023.



High Medical Need Outpatient Market

Our targeted Outpatient market focused on those patients at risk for inadequate prep 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 targeted outpatient colonoscopies performed in the U.S. 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 for patients at risk for inadequate prep in the 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.

In 2021, the Center for Medicare and Medicaid Services ("CMS") granted the Pure-Vu System a permanent ICD-10 code for inpatient uses. This coding effort is part of a broader strategy to potentially obtain reimbursement for certain inpatient and outpatient procedures where the Pure-Vu System can help facilitate visualization of inadequately prepared colons in high medical need patients.

Employees

As of December 31, 2022, we had 43 full time employees and 6 part 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. 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, including clinical studies that assess new or modified uses for already marketed medical devices, 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 in the European Economic Area or EEA (which includes the 27 EU Member States as well as Iceland, Liechtenstein and Norway) and in 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 or certifications and comply with extensive safety and quality regulations in those countries. The time required to obtain approval or certification to market our products in 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 Economic Area (the "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.

The EU Medical Devices Regulation (Regulation 2017/745 of the European Parliament and of the Council of April 5, 2017 on medical devices), or "EU MDR", sets out the basic regulatory framework currently applicable to medical devices in the EEA. The EU MDR became applicable on May 26, 2021, repealing the prior Council Directive 93/42/EEC, or the "EU MDD", which had been regulating medical devices in the EEA for the past over 20 years. This represented a major change in the regulatory landscape of medical devices in the EEA. The EU MDR sets out certain transitional provisions that allow for medical devices covered by the repealed EU MDD (called "legacy devices") to still be marketed in the EEA for a certain period of time.

In the EEA, medical devices are currently required to comply with the General Safety and Performance Requirements (or "GSPR") in Annex I of the EU MDR (for legacy devices, this corresponds to the Essential Requirements of Annex I of the EU MDD). Compliance with GSPR is a prerequisite for us to be able to affix the CE Mark to our medical devices, without which they cannot be commercialized in the EEA. To demonstrate compliance with the GSPR and obtain the right to affix the CE Mark, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. In the EEA medical devices are classified into four different risk classes: Class I (which is further divided into (i) devices that are placed on the market in sterile condition, (ii) have a measuring function, (iii) are reusable surgical instruments, and (iv) all others), IIa, IIb and III.

Apart from low risk medical devices (Class I if they have no measuring function, are not sterile, and are not reusable surgical instruments), where the manufacturer can issue an EU Declaration of Conformity based on a self-assessment of the conformity of the devices with the GSPR, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization accredited by the competent authority of an EEA Member State to conduct conformity assessments. The Notified Body would typically audit and examine the products' technical documentation and the quality management 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 upon successful completion of the conformity assessment, we can draw up an EU Declaration of Conformity which allows us to affix the CE Mark to our products.

Under the EU MDR, confirmation of conformity with relevant GSPR under the normal conditions of intended use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit-risk-ratio, shall be based on clinical data providing sufficient clinical evidence, including where applicable post-market data. Manufacturers are required to specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant GSPR. This level of clinical evidence must be appropriate in view of the characteristics of the device and its intended purpose.

Besides its involvement in the initial conformity assessment procedure, the Notified Body is required to carry out an annual audit (surveillance audit) and is also required to randomly perform unannounced audits at least once every five years. The quality management system and technical documentation of manufacturers will be required to be recertified periodically, as CE Certificates of Conformity issued by a Notified Body remain valid only for the period indicated in them, in no case exceeding five years.

The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These include the requirement of prior authorization by the Competent Authorities of the country in which the study takes place and the requirement to obtain a positive opinion from the relevant competent Ethics Committee. The conduct of clinical studies (called "clinical investigations" under the EU MDR) is now mandatory for implantable devices and Class III medical devices (with certain exemptions).

The EU MDR also provides various requirements relating to post-market surveillance and vigilance, including the obligation for manufacturers to implement a post-market surveillance system, in a manner that is proportionate to the risk class and appropriate for the type of device. Once a device is on the EEA market, manufacturers must comply with certain vigilance requirements, such as the reporting serious incidents and field safety corrective actions (even those occurring outside the EEA) to the relevant competent authorities.

Further, the advertising and promotion of our products in the EEA is subject to the EU MDR, to the national laws of individual EEA Member States, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other 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.

The EU MDR, when compared with the EU MDD, imposes increased compliance obligations for us to access and then remain on the EEA market. Our current CE Certificate of Conformity is valid until May 27, 2024 in accordance with Article 120 of the EU MDR. This means that, if we want to keep selling our product in the EEA without interruption, we need to obtain a new CE Certificate of Conformity under the EU MDR before such expiry date. There are currently a relatively small number of Notified Bodies that have been accredited to conduct conformity assessments under the EU MDR. This may significantly delay our conformity assessment procedures in the future.

On February 16, 2023, the European Parliament adopted a legislative proposal for the amendment of the EU MDR, which is expected to modify the current transitional provisions of Article 120 of the EU MDR allowing an extension in the validity of certain CE Certificates of Conformity until 26 May 2026, 31 December 2027 and 31 December 2028 (depending on the risk classification of the devices and subject to certain conditions). The Council of the European Union still needs to formally accept the Parliament's position, after which the amendment will be published in the Official Journal of the European Union following the signature of the act. This amendment to the EU MDR may have an impact in our current CE Certificate of Conformity, by extending its validity beyond May 27, 2024.

Brexit

The UK withdrew from the EU on January 31, 2020 (the withdrawal is commonly referred to as "Brexit"). Brexit has created significant uncertainty concerning the future relationship between the UK and the EU. On December 24, 2020, the EU and UK reached an agreement in principle on the framework for their future relationship, the "EU-UK Trade and Cooperation Agreement". The Agreement primarily focuses on ensuring free trade between the EU and the UK in relation to goods, but does not specifically address medical devices. After the UK's withdrawal from the EU, Great Britain (England, Scotland and Wales) is treated by the EU as a third country. Northern Ireland continues, with regard to EU regulations, to follow the EU regulatory rules. In light of the fact that the CE marking process is set out in EU law, which no longer applies in the UK, the UK has devised a new route to market culminating in a UK Conformity Assessed (UKCA) mark to replace the CE Mark. The route to market and the UKCA marking requirements are based on the requirements of the EU MDD. Northern Ireland continues to be covered by the regulations governing CE Marks. As part of the Agreement, the EU and the UK have agreed to continue to recognize declarations of conformity based on a self-assessment in the other territory.

Since January 1, 2021, the Medical Devices (EU Exit) Regulations 2020 introduced a number of changes to how medical devices are placed on the Great Britain's market. The CE marking will continue to be recognized in Great Britain until July 2024, and certificates issued by Notified Bodies designated in the EEA will continue to be valid for the Great Britain market until July 2024. From July 2024, when the future UK Medical Device Regulations are expected to become applicable, manufacturers will have to obtain the UKCA mark to place a medical device on the Great Britain market. There are certain transition periods for existing CE and UKCA marked devices.

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 sought new technology payments from Medicare under the hospital Inpatient and Outpatient Prospective Payment Systems and were denied in 2021. We intend to seek separate reimbursement for future versions of the system 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 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 EEA 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 therapies in order to obtain or maintain reimbursement or pricing approval. Other EEA countries allow companies to fix their own prices for medical devices, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new devices. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

In recent years, a number of EEA countries have introduced so-called health technology assessments (HTA). HTA measures the added value of a new health technology, in our case a medical device, compared to existing ones. HTA's assessment include cost implications for the patient and its impact on the organization of healthcare systems in the administration of treatment. An EU Regulation on HTA entered into force in January 2022 and will be applied three years later (January 2025). It offers the possibility for EEA countries' HTA bodies to conduct Joint Clinical Assessments of new high-risk medical devices.

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 play a primary role in the recommendation and use of our current products and any future products for which we may obtain marketing approval for which payment is or may become available under any federal health care program. 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 products. 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. The term "remuneration" has been broadly interpreted 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 to provide services to the company ; 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. Failure to meet all of the requirements of a particular statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute, but the legality of the arrangement will be evaluated on a case by case basis based on the totality of the facts and circumstances.

- 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, and its 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 also imposes certain obligations, including contractual terms and technical safeguards, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

- 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, directly or indirectly, to physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse midwives, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

- Analogous state and foreign fraud and abuse laws and regulations, such as anti-kickback and false claims laws, which may apply to sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers, and state 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.

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 EEA level and in the individual EEA 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 generally prohibited in the EEA. Breach of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EEA 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 EEA Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

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, in California, the California Consumer Privacy Act ("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 continue to assess the impact of the CPRA, and other state legislation, on our business as additional information and guidance becomes available.

The Federal Trade Commission ("FTC") also sets expectations for failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the Federal Trade Commission Act ("FTC Act"). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers' personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may be result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

EEA 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 (or "GDPR") imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, especially in the case of sensitive personal data (such as health data from clinical investigations) and safety reporting. The GDPR also imposes strict rules on the transfer of personal data out of the EEA, including to the U.S., and fines and penalties for failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA countries, which can go to up to €20 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher. The obligations under the GDPR may therefore be onerous and adversely affect our business, financial condition, results of operations and prospects.

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 service providers processing personal data of subjects in the EU, we must enter into suitable agreements with these providers and receive sufficient assurances 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.

However, in March 2022, the European Commission and the U.S. announced that they have agreed in principle on a new Trans-Atlantic Data Privacy Framework, as a successor arrangement to the EU-U.S. Privacy Shield. On December, 13 2022, the European Commission adopted a draft adequacy decision for the EU-U.S. Data Privacy Framework. This draft decision follows the signature of a US Executive Order by President Biden on October, 7 2022, along with the regulations issued by the U.S. Attorney General Merrick Garland. These two instruments implemented into U.S. law the agreement in principle announced by President von der Leyen and President Biden in March 2022. The draft adequacy decision, which reflects the assessment by the European Commission of the U.S. legal framework has now been published and transmitted to the EDPB for its opinion. The draft decision concludes that the U.S. ensures an adequate level of protection for personal data transferred from the EU to U.S. companies. The two sides are now expected to finalize the details of this agreement in principle and translate it into legal texts that will form the basis of a draft adequacy decision to be proposed by the European Commission.

Furthermore, following the UK's exit from the EU, the UK became a third country to the EEA in terms of personal data transfers. The EC has adopted an Adequacy Decision concerning the level of personal data protection. However, personal data transfers from the EEA to the UK may nevertheless be at a greater risk than before because an Adequacy Decision may be suspended.

Following the Schrems II decision, the Swiss Federal Data Protection and Information Commissioner, or the FDPIC, also announced that the Swiss-U.S. Privacy Shield does not provide adequate safeguards for the purposes of personal data transfers from Switzerland to the U.S. While the FDPIC does not have authority to invalidate the Swiss-U.S. Privacy Shield regime, the FDPIC's announcement casts doubt on the viability of the Swiss-U.S. Privacy Shield as a future compliance mechanism for Swiss-U.S. data transfers.

Compliance with data transfer obligations involves documenting detailed analyses of data access and protection laws in the countries in which data importers are located, which can be costly and time-consuming. Data importers must also expend resources in analyzing their ability to comply with transfer obligations, including implementing new safeguards and controls to further protect personal data. 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, the UK, or Switzerland to 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, UK, or Switzerland is restricted, which could adversely impact our operating results.

The landscape of laws regulating personal data is constantly evolving, and compliance with these laws requires a flexible privacy framework and substantial resources, and compliance efforts will likely be an increasing and substantial cost in the future.

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.

In the EEA and as mentioned above, the EU MDR imposes increased compliance obligations for us to access and then remain on the EEA market. It introduced substantial changes to the obligations applicable to medical device manufacturers and Notified Bodies in the EEA. As a result, there are less Notified Bodies available to conduct conformity assessments under the EU MDR, which has significantly increased the time needed for companies to access the EEA market. Moreover, as the EU MDR only started to apply from May 2021, a number of guidance documents is still not available to guide manufacturers and Notified Bodies. The EU Regulation on health technology assessments (HTA) that entered into force in January 2022 and that will be applied three years later (January 2025) may also impact in the future the pricing and reimbursement of our product.

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.

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, which would be at the end of the current fiscal year, ending December 31, 2023, 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

An investment in our Common Stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all other information in this Annual Report on Form 10-K and our other reports filed with the Securities and Exchange Commission. The risks set forth below are not the only ones facing us. Additional risks and uncertainties may exist that could adversely impact our business, operations and financial conditions. If any one or more of the following risks actually materialize, our business, financial condition, reputation, operations and/or future prospects suffer. In such event, the value of our Common Stock could decline, and you could lose all or a substantial portion of the money that you pay for our Common Stock.

SUMMARY

The following summarizes key risks and uncertainties that could materially adversely affect us. You should read this summary together with the more detailed description of each risk factor contained below.

Risks relating to our strategic alternative process, including risks related to:

- the inability to identify and implement any strategic business combination or other transaction.
- the negative consequences of any strategic transaction that we may consummate.
- the operational and financial risks related to the negotiation and completion of a strategic transaction.
- if we fail to complete a strategic transaction we may need to pursue bankruptcy, dissolution or liquidation.

Risks relating to our financial position and need for capital, including risks relating to:

- the sustainability of our operations and ability to continue as a going concern.
- the recurring losses from operations since inception and possibility of never becoming profitable.
- our indebtedness to Kreos Capital VI (Expert Fund) LP and related restrictions under the Loan Agreement.
- the need for substantial additional capital to fund our operations, and if we fail to obtain such financing, we may not be able to complete the development and commercialization of any of our product candidates.
- the potential dilutive impact of issuing additional equity securities in connection with necessary capital raises.
- our ability to use net operating loss carryforward and other tax attributes may be limited.

Risks related to government regulation and third-party reimbursement, including risks related to:

- the impact of costly and complex current and future regulation.
- our ability to successfully obtain or maintain the necessary government approvals or third party certifications to market our Pure-Vu System both domestically and throughout the EEA.
- the need to obtain new 510(k) clearance or a new CE Certificate of Conformity in the event of new modifications which may require us to cease marketing or initiate recalls pending approval.
- the potential for product malfunctions causing death or serious injury, subjecting us to enforcement actions.
- the potential for recalls of our Pure-Vu System or the discovery of a serious safety issue with the product.
- our Pure-Vu System is not currently separately reimbursable through private or government third-party payors.
- the difficulty and increased costs of marketing approval and commercialization of our products due to recent and future legislation.
- the potential liability if we fail to comply with fraud and abuse laws.
- the potential liability and commercialization consequences if we engage in inappropriate promotion of our Pure-Vu System.
- the potential for civil and/or criminal sanctions related to potential non-compliance with anti-corruption laws.
- the laws and regulations governing international business operations and potential for adverse impacts on our business.

Risks related to our business operations, including risks related to:

- having only one product, and the lack of assurance that we will develop any additional products.
- being a medical technology company with a limited operating history.
- potential non-acceptance of the Pure-Vu System by physicians and patients.
- our ability to successfully commercialize our Pure-Vu System.
- our limited sales and marketing organization and related difficulties for commercializing our Pure-Vu System.
- the impact of any potential adverse side effects caused by our Pure-Vu System.
- the impact of any security breaches, computer malware, computer hacking and other security incidents.
- the breadth of data privacy laws and regulations.
- the difficulties associated with achieving commercialization.
- the difficulties related to training medical professionals on the safe and appropriate use of our products.
- competition in the marketplace.
- the potential for technological obsolescence.
- the potential reputational damage and unforeseen costs if defects were identified in our products.
- our ability to penetrate international markets.
- our dependence on third party manufacturers to manufacture our Pure-Vu System.
- the impact of Israeli regulations on outsourcing and development for our Pure-Vu System.

Risks related to our intellectual property rights, including risks related to:

- our ability to properly safeguard our intellectual property rights.
- the impact of potential intellectual property disputes.
- the impact of employment and confidentiality disputes.

General risks, including risks related to:

- the difficulties related to predicting and managing growth.
- our ability to attract and retain key personnel.
- the impact of product liability lawsuits.
- the uncertainties related to exchange rate fluctuations.
- the costs related to acquisition and investment activities.
- the outbreaks of communicable diseases, including COVID-19, which may materially affect our business, financial condition and results of operation.

Risks related to our capital stock, including risks related to:

- significant fluctuations in our quarterly operating results.
- the unpredictability of the trading market.
- a decrease in stock price related to a large sell-off.
- our ability to remain compliant with the requirements of The Nasdaq Capital Market for continued listing, including regaining compliance with the $2.5 million minimum stockholders' equity requirement.
- the potential adverse effect on the liquidity of our Common Stock if we implement a reverse stock split.
- the frequency, nature and content of equity analyst report.
- the volatility of our share price.
- royalty payments due under the terms of the Royalty Payments Rights Certificates.
- reduced disclosure requirements as an "emerging growth company."
- costs and management time devoted to operations after we are no longer an "emerging growth company."
- our ability to manage internal controls to prevent fraud or errors.
- our failure to maintain internal control over financial reporting.
- our expectations that we will not pay dividends in the foreseeable future.
- the likelihood that upon dissolution, stockholder will lose some or all portions of their investment.
- the dilutive effect of additional issuances of preferred stock.
- our choice of forum in the state of Delaware may discourage stockholder suits against us.

Risks related to our operations in Israel, including risks related to:

- the impact of Israel's political, economic and military instability on our research and development facilities and suppliers in the region.
- royalty and other payments to the Israeli government as required by certain research and development grant terms.
- the difficulties associated with enforcing a foreign court's judgment and serving process in a foreign jurisdiction.
- the impact of potential patent litigation.

Risks Related to our Strategic Alternative Process

We may not be successful in identifying and implementing any strategic business combination or other transaction.

We have engaged Lake Street to assist us in seeking a strategic transaction to benefit our shareholders. We continue to evaluate various potential strategic options for us, including a merger, reverse merger, sale or other strategic transaction. However, there can be no assurance that we will be able to identify a counterparty willing to move forward with us or, if we do, successfully consummate any particular strategic transaction. The biotech industry is a competitive industry and thus there are numerous competitors of ours for strategic transactions with a limited number of parties seeking a transaction on terms that would be beneficial to our shareholders. The process of evaluating these strategic options may be very costly, time-consuming and complex and we have incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business and may diminish or delay any future distributions to our stockholders. Any delays in identifying a potential counterparty will cause our cash balance to continue to deplete, which could make us less attractive as a strategic counterparty. Our existing outstanding indebtedness with Kreos may also impact the interest of potential third parties and may negatively impact our ability to consummate a strategic transaction. The continued review of our strategic options may also create continued uncertainty for our employees and this uncertainty may adversely affect our ability to retain key employees necessary to maintain our ongoing operations or to execute any potential strategic options, which could have a material adverse effect on our business. Further, the market capitalization of our company is below the value of our cash and cash equivalents. Potential counterparties in a strategic transaction involving our company may place minimal or no value on our remaining assets. As a result, we may not be able to execute on a strategic transaction before our cash position gets reduced, as a result of running a public company, to the point that we will need to pursue the winding down and dissolution of the company.

Any strategic transactions that we may consummate in the future could have negative consequences.

Any strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affect our business and decrease the value of our company. There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, be successfully consummated, lead to increased stockholder value, or achieve the results hoped for. Any failure of such potential transaction to achieve the anticipated results could significantly impair the ability of a shareholder to realize any benefit from any future strategic transaction.

If we are successful in completing any strategic transaction, we may be exposed to other operational and financial risks.

The negotiation and consummation of any strategic transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;

- our ability to service our outstanding indebtedness;

- exposure to unknown liabilities;

- higher than expected acquisition or integration costs;

- incurrence of substantial additional debt or dilutive issuances of equity securities to fund future operations;

● write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges;

● increased amortization expenses;

● difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;

● impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;

● inability to retain key employees of our company or any acquired business; and

● possibility of future litigation.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

If a strategic transaction is not consummated, our Board may decide to file for bankruptcy protection or pursue a dissolution and liquidation of our remaining assets. In such an event, as a result of our outstanding indebtedness, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such bankruptcy or liquidation as well as the amount of cash that will need to be reserved for our current debts, including repayment of amounts under our Loan Agreement (as defined below), and commitments and contingent liabilities and there may not be any cash or other assets to distribute to our stockholders.

There can be no assurance that a strategic transaction will be completed. If a strategic transaction is not completed, our Board may decide to file for bankruptcy protection or pursue a dissolution of the company and liquidation of all of our remaining assets. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations and service our outstanding indebtedness. The process of bankruptcy or liquidation may be lengthy and we cannot make any assurances regarding the timing of completing such a process. If our Board were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, including repayment of the indebtedness under our Loan Agreement, which debt is secured by our assets, prior to making any distributions in liquidation to our stockholders. There can be no assurance as to the amount of available cash that will be available to distribute to stockholders, if any, after paying our debts and other obligations and setting aside funds for reserves, nor as to the timing of any such distribution. Our financial commitments and contingent liabilities would include: (i) repayment of our outstanding indebtedness under our Loan Agreement; (ii) personnel costs, including severance; (iii) contractual obligations to vendors and clinical study sites; (iv) non-cancelable lease obligations; and (v) potential litigation against us.

As a result of the requirement to reserve for contingencies, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a bankruptcy or dissolution and liquidation. If a dissolution and liquidation were pursued, our Board, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a bankruptcy, liquidation, dissolution or winding up.

We may become involved in securities class action litigation that could divert management's attention and harm the company's business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as discontinuations of clinical programs. These events may also result in investigations by the SEC. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

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, 2022 were prepared under the assumption that we will continue as a going concern. The independent registered public accounting firm that audited our 2022 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, 2022 and December 31, 2021 was approximately $18.6 million and $19.0 million, respectively. As of December 31, 2022, we had an accumulated deficit of approximately $141.4 million.

Our indebtedness to Kreos Capital VI (Expert Fund) LP may limit our flexibility in operating our business and adversely affect our financial health and competitive position. Our obligations to Kreos Capital VI (Expert Fund) LP are secured by substantially all of our assets. If we default on these obligations, Kreos Capital VI (Expert Fund) LP could foreclose on our assets, which could have a materially adverse effect on our business.

In July 2021, we entered into an Agreement for the Provision of a Loan Facility with Kreos Capital VI (Expert Fund) LP (the "Loan Agreement"). All obligations under the Loan Agreement are secured by a first priority security interest on substantially all of our personal property assets, including our material intellectual property and equity interests in our subsidiaries. As a result, if we default on any of our obligations under the Loan Agreement, Kreos Capital VI (Expert Fund) LP could foreclose on its security interest and liquidate some or all of the collateral, which would harm our business, financial condition and results of operations and could require us to reduce or cease operations.

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 and we may need to file for bankruptcy protection.

The Loan Agreement restricts our ability, among other things, in each case subject to certain exceptions, to:

- sell, transfer or otherwise dispose of any of our business assets or property;
- enter into transactions resulting in significant changes to the voting control of our stock;
- consolidate or merge with other entities or acquire other entities;
- incur additional indebtedness or create encumbrances on our assets;
- pay dividends, 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 undertakings. The undertakings 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 undertakings may be affected by events beyond our control, and we may not be able to meet those undertakings.

If we breach any of the undertakings or default on any of our obligations under the Loan Agreement all of the outstanding indebtedness under the Loan Agreement could become immediately due and payable, and/or Kreos Capital VI (Expert Fund) LP could foreclose on its security interest and liquidate some or all of the collateral, which would harm our business, financial condition and results of operations and could require us to reduce or cease operations.

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, Kreos Capital VI (Expert Fund) LP 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 and cash equivalents will only fund our operations for a limited time and we will need to raise additional capital in order 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 2022 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, 2022, we had cash and cash equivalents of approximately $14.0 million.

We will need to raise additional capital or generate substantial revenue in order to support our development and commercialization efforts.

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 Kreos Capital VI (Expert Fund) LP and our Equity Distribution Agreement (as defined below) with Oppenheimer& Co. Inc. ("Oppenheimer"), 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 (which, in limited circumstances, may require the prior written consent of Oppenheimer pursuant to our Equity Distribution Agreement), debt financings (which, except for limited circumstances, would require the prior written consent of Kreos Capital VI (Expert Fund) LP 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.

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 (both domestic and foreign). It can be costly and time-consuming to obtain regulatory clearance, approval, or certification 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, as well as by the competent authorities in foreign jurisdictions, such as EEA Member States. If our sales and marketing activities fail to comply with FDA or foreign regulations or guidelines, or other applicable laws, we may be subject to regulatory inquiries, warning letters, or enforcement actions from the FDA, or other enforcement bodies and foreign competent authorities.

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

To be able to market and sell our Pure-Vu System in other countries, we must obtain regulatory approvals or certifications and comply with the regulations of those countries. These regulations, including the requirements for approvals or certifications 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 Certificate of Conformity, allowing us to affix the CE Mark and market it in the EEA. We intend to target countries with a regulatory approval process with similar requirements to the EEA. However, obtaining and maintaining foreign regulatory approvals or certifications is complex and expensive and subject to delays, and management cannot be certain that we will receive and be able to maintain regulatory approvals or certifications 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 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 management system or changes to our devices which could affect compliance with the GSPR set forth in the EU MDR, the safety and performance of the device or its conditions prescribed for use. The Notified Body will assess the changes and, if the assessment is favorable, issue a supplement to the CE Certificate of Conformity. The Notified Body may also determine that the planned changes require a new conformity assessment. For devices covered by CE Certificates of Conformity issued under the EU MDD ("legacy devices"), no significant changes in design or intended purpose are allowed after the date of application of the EU MDR (May 25, 2021). Any proposed changes to our products may oblige us to undertake future clinical and technical procedures and provide information in addition to that provided to support the initial conformity assessment.

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 EEA.

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 EEA.

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 sought new technology payments from Medicare under the hospital Inpatient and Outpatient Prospective Payment Systems and were denied in 2021. We intend to seek separate reimbursement through private or governmental third-party payors for future versions of the system, 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 modify or invalidate 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 modify or invalidate the Affordable Care Act or its implementing regulations, or portions thereof, and the uncertainty surrounding any other modification related to the Affordable Care Act or any other health care reform measure 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 modification or invalidation, in whole or in part or another health care reform measure 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. If our operations are found to be in violation of any of these laws or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that their provisions are open to a variety of evolving interpretations and enforcement discretion. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. 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 EEA. 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 EEA 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 EEA 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 a Certificate of Conformity which allows us to affix the CE Mark in the EEA, 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;
- our inability to project in the short term the hospital medical device environment considering the global pandemic and strains on hospital systems; and
- our inability to predict the financial impact of inflation on costs such as labor, freight and materials

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 or Notified Body-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, CE Certificates of Conformity by a Notified Body in the EEA and approvals from 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. With the ever-changing threat landscape, and while we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business.

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 studies, 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 to manufacture and produce the components of our Pure-Vu System, and the loss of the services of these manufacturers or an adverse change in the manufacturer's business or our relationship could have a material adverse effect on our business. Our primary reliance on these manufacturers for all or substantially all of our manufacturing needs involves several risks, including the potential inability to obtain an adequate supply of components and limited control over pricing, quality and timely delivery of the components. In addition, replacing these manufacturers may be difficult and could result in an inability or delay in obtaining the components for our Pure-Vu System. As a result, if such a disruption were to occur we may be unable to fulfill customer orders or orders for trials, and our operating results may fluctuate from period to period, particularly if a disruption occurs near the end of a fiscal period. 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 set forth 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 approval for the transfer of manufacturing of the sleeves outside of Israel. The transfer outside of Israel of manufacturing which is connected with the IIA-funded knowhow 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, 2022, we had 43 full time employees and 6 part 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 studies 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.

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 quarterly operating results may be subject to significant fluctuations.

To date, as part of our initial U.S. market launch, 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 regain compliance with the requirements for continued listing on Nasdaq, our common stock could be delisted from trading, which would adversely affect the liquidity of our common stock and our ability to raise additional capital.

The Nasdaq Capital Market's rules for listed companies requires us to meet certain financial, public float, bid price and liquidity standards on an ongoing basis in order to continue the listing of our Common Stock. In order to maintain our listing on Nasdaq, we must satisfy the continued listing requirements of Nasdaq for inclusion in the Nasdaq Capital Market, including among other things, a minimum stockholders' equity of $2.5 million and a minimum bid price for our Common Stock of $1.00 per share.

On January 4, 2023, we received a letter from the Nasdaq Stock Market notifying us that we were no longer in compliance with the minimum stockholders' equity requirement for continued listing under Nasdaq Listing Rule 5550(b)(1), which requires us to maintain stockholders' equity of at least $2,500,000. On February 21, 2023, we submitted a plan to regain compliance and on March 9, 2023, the Staff notified the Company (the "Letter") that it would be granted an extension until July 3, 2023, to demonstrate compliance with Listing Rule 5550(b)(1) to meet the continued listing requirements of The Nasdaq Capital Market, conditioned upon achievement of certain milestones included in a plan of compliance previously submitted to Nasdaq, including a plan to raise additional capital.

We intend to regain compliance with the applicable continued listing requirements of The Nasdaq Capital Market prior to the end of the compliance period set forth in the abovementioned letter. However, until Nasdaq has reached a final determination that we have regained compliance with all of the applicable continued listing requirements, there can be no assurances regarding the continued listing of our common stock on Nasdaq. In the event we fail to regain compliance within the compliance period, we would have the right to a hearing before an independent panel. The hearing request would halt any suspension or delisting action pending the conclusion of the hearing process and the expiration of any additional extension period granted by the panel following the hearing. The delisting of our common stock from Nasdaq would have a material adverse effect on our access to capital markets, and any limitation on market liquidity or reduction in the price of our common stock as a result of that delisting would adversely affect our ability to raise capital on terms acceptable to us, if at all.

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 March 2038), 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, which would be at the end of the current fiscal year, ending December 31, 2023, 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, which would be at the end of the current fiscal year, ending December 31, 2023, 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 peace agreements with Egypt and Jordan, comprehensive agreements with the Palestinian Authority, and other agreements with neighboring Arab countries regarding public normalization of relations, 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, 2022, we had received grants from the IIA in the aggregate amount of $1.3 million, and had a contingent obligation to the IIA up to an aggregate amount of approximately $1.4 million (assuming no increase, per the IIA Regulations, as described below). As of December 31, 2022, 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 approval for the transfer of manufacturing of the sleeves outside of Israel. The transfer outside of Israel of manufacturing which is connected with the IIA-funded knowhow 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). 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 2015, and the lease was for a period of five-years. Annual rent is $82 thousand per year. The lease was set to expire on December 31, 2019. In July 2019, we exercised the option to extend the lease expiration to December 31, 2022. We entered into a new tenancy contract with the facility for a period of twelve months from January 1, 2023 to December 31, 2023. Rent is approximately $192 thousand for the twelve months.

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 increased to 6,496 square feet by the second year of the lease. The term runs 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 is used for office space as well as laboratories for both quality assurance and product development. In January 2020, the Company entered into a license agreement (the "Shared Space Agreement") with Orchestra BioMed, Inc. (OBIO), 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. Pursuant to the Shared Space Agreement, the Company granted a license to OBIO for the use of portions of the office space not being used by the Company in the Company's leased facility in Fort Lauderdale, Florida (the "Premises"), and a proportionate share of common areas of such Premises, which previously covered approximately 35% of the Premises and was to expand incrementally to approximately 60 to 70% of the Premises by September 2024. In May 2022, the Company entered into an amendment to the Shared Space Agreement. Pursuant to the amendment, the area covered by the Shared Space Agreement was expanded to 95% of the premises and the aggregate license fees will generally range from approximately $212 thousand to approximately $270 thousand in any given calendar year during the term of the Shared Space Agreement until the termination of the lease in November 2024.

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 14, 2023, we had approximately 122 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. RESERVED

Not Applicable.

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

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

Overview

We have developed the Pure-Vu System, a medical device that has been cleared by the U.S. Food and Drug Administration (the "FDA") to help facilitate the cleansing of a poorly prepared gastrointestinal tract during colonoscopy and to help facilitate upper gastrointestinal ("GI") endoscopy procedures. The Pure-Vu System is also CE marked in the European Economic Area (EEA) for use in colonoscopy. The Pure-Vu System integrates with standard and slim colonoscopes, as well as gastroscopes, to improve visualization during colonoscopy and upper GI procedures while preserving established procedural workflow and techniques. Through irrigation and evacuation of debris, the Pure-Vu System is designed to provide better-quality exams. Challenges exist for inpatient colonoscopy and endoscopy, particularly for patients who are elderly, with comorbidities, or active bleeds, where the ability to visualize, diagnose and treat is often compromised due to debris, including fecal matter, blood, or blood clots. We believe this is especially true in high acuity patients, like GI bleeding where the existence of blood and blood clots can impair a physician's view and removing them can be critical in allowing a physician the ability to identify and treat the source of bleeding on a timely basis. We believe use of the Pure-Vu System may lead to positive outcomes and lower costs for hospitals by safely and quickly improving visualization of the colon and upper GI tract, potentially enabling effective diagnosis and treatment without delay. In multiple clinical studies to date, involving the treatment of challenging inpatient and outpatient cases, the Pure-Vu System has consistently helped achieve adequate bowel cleanliness rates greater than 95% following a reduced prep regimen. We also 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. 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 believe that during 2021 approximately 1.5 million inpatient colonoscopy procedures were performed in the U.S. and approximately 4.8 million worldwide. Upper GI bleeds occurred in the U.S. at a rate of approximately 400,000 cases per year in 2019, according to iData Research Inc. The Pure-Vu System has been assigned an ICD-10 code in the US. The system does not currently have unique codes with any private or governmental third-party payors in any other country or for any other use; however, we intend to pursue reimbursement activities in the future, particularly in the outpatient colonoscopy market. We received 510(k) clearance in February 2022 from the FDA for our Pure-Vu EVS System and have commenced initial commercialization of this product. We do not expect to generate significant revenue from product sales until we further expand our commercialization efforts, which is subject to significant uncertainty.

In January 2023, we committed to a restructuring initiative designed to position us to explore a range of strategic and financing alternatives focused on maximizing stockholder value and accelerating the commercialization of the Pure-Vu System. We have engaged Lake Street Capital to advise us in this process. Potential strategic alternatives that may be considered by us are expected to include an acquisition, merger, reverse merger, other business combination, sale of assets, licensing and other strategic transactions. The restructuring initiative primarily includes the reduction of our workforce. We intend to continue to evaluate and identify other areas of its business to enhance efficiencies and improve processes, with a goal to further lower its operating expenses and capital needs. We have reduced our quarterly cash expenditures by approximately 35% by eliminating approximately 45% of our workforce during the first quarter of 2023. In connection with the restructuring, we expect to incur a non-recurring charge of approximately $1.0 to $2.0 million in the first quarter of 2023.

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 $18.6 million for the year ended December 31, 2022, and we expect to continue to incur net operating losses for the foreseeable future. As of December 31, 2022, we had $14.0 million in cash and cash equivalents and an accumulated deficit of $141.4 million. We expect our current spend level to continue in connection with ongoing operating activities, including expenditures in R&D, sales and marketing, clinical affairs and manufacturing. As described above, we committed to a restructuring initiative designed to reduce our expenses and position us to explore a range of strategic and financing alternatives focused on maximizing stockholder value and accelerating the commercialization of the Pure-Vu System. In addition, in order to continue to operate as a standalone company, we would need additional financing to support our continuing operations. We also have significant debt under our Loan Agreement with Kreos which could negatively impact our ability to operate or consummate a strategic transaction.

If a strategic transaction is not completed, or if additional financing is not available, we may not be able to service our outstanding indebtedness and our payables and may have to file for bankruptcy protection or pursue a dissolution of the Company and liquidation of all of our remaining assets. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations and service our outstanding indebtedness. We cannot provide assurance as to the amount of cash that will be available to distribute to stockholders, if any, after paying our debts and other obligations and setting aside funds for reserves, nor as to the timing of any such distribution, if any.

We continue to seek to fund our operations through public or private equity or debt financings or other sources, which may include collaborations with third parties and evaluating other strategic alternative transactions including an acquisition, merger, reverse merger, other business combination, sale of assets, licensing and other transactions. 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. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital or execute a strategic transaction 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. Additionally, the effects of inflation on costs such as labor, freight, and materials as well as the ongoing volatility in the financial markets may negatively affect the financial performance and the liquidity of the business. Furthermore, the potential impact of COVID-19, which continues to evolve, on the operation of our business, related to possible travel advisories and restrictions and production delays, are highly uncertain and cannot be predicted.

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. The determination of whether inventory costs will be realizable requires estimates by management. We perform an assessment of the realizability of inventory during each reporting period, including write-downs for potentially obsolete or excess inventory are made based on management's analysis of inventory levels, historical obsolescence, future sales forecasts, and any changes in the commercial business. We write-down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Inventories that exceed estimated realization for the next twelve months from balance sheet date based on future sales forecasts are classified as long-term assets.

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 share-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 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.

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 at fair value 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 at fair value, 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, 2022 and 2021

Revenue

As of December 31, 2022, we have generated a limited amount of revenue from the sales of products. We do not expect to generate significant revenue from product sales until we further expand our commercialization efforts for the Pure-Vu EVS System, which is subject to significant uncertainty.

Revenue totaled $592.0 thousand for the year ended December 31, 2022, compared to $391.0 thousand for the year ended December 31, 2021. The increase of $201.0 thousand was primarily attributed to sales of the new EVS product launched in 2022.

Cost of Revenue

Cost of revenue for the year ended December 31, 2022 totaled $796.0 thousand, compared to $624.0 thousand for the year ended December 31, 2021. The increase of $172.0 thousand was primarily attributed to an increase of inventory impairment of $155.0 thousand and by an increase in the cost of the volume sold of our evaluation and commercial units of $17.0 thousand. Cost of revenue, net of impairments for the year ended December 31, 2022 totaled $198.0 thousand, compared to $181.0 thousand, which resulted in a gross profit of 67% and 54% for the year ended December 31, 2022 and 2021, respectively.

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, 2022 totaled $5.6 million, compared to $5.3 million for the year ended December 31, 2021. The increase of $0.3 million was primarily attributable to increases of $0.4 million in payroll and related costs, $0.5 million of clinical trial costs, partially offset by decreases of $0.2 million in share-based compensation and $0.4 million in material costs.

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 Pure-Vu System.

Sales and marketing expenses for the year ended December 31, 2022 totaled $4.4 million, compared to $3.1 million for the year ended December 31, 2021. The increase of $1.3 million was primarily attributable to increases of $1.3 million in payroll and related costs, $0.2 million in demonstrational product, $0.2 million in promotional and tradeshow, partially offset by a decrease of $0.3 million in professional services and $0.1 million in share-based compensation.

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, and compliance related fees.

General and administrative expenses for the year ended December 31, 2022 totaled $7.6 million, compared to $9.3 million for the year ended December 31, 2021. The decrease of $1.7 million was primarily attributed to decreases of $0.4 million in payroll and related costs, $1.4 million in share-based compensation, and $0.2 million in investor and public relation costs, partially offset by an increase of $0.3 million in other general and administrative costs.

Other Income and Expenses

Other expense, net for the year ended December 31, 2022 totaled $0.7 million compared to other expense, net of $1.1 million for the year ended December 31, 2021. The decrease of $0.4 million in other expense, net was primarily attributable to an increase of $0.5 million in finance expense, offset by an increase of $0.7 million from the gain on the change in estimated fair value of contingent royalty obligation and a $0.2 million decrease in loss on extinguishment of debt extinguishment.

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. As described above under "—Overview" and "—Financial Operations Overview," we have adopted a restructuring program in January 2023 intended to reduce our operating costs and other expenses and have commenced a process to evaluate strategic alternatives. If a strategic transaction is not completed, or if additional financing is not available, we may not be able to service our outstanding indebtedness and our payables and may have to file for bankruptcy protection or pursue a dissolution of the company and liquidation of all of our remaining assets. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations and service our outstanding indebtedness. We cannot provide assurance as to the amount of cash that will be available to distribute to stockholders, if any, after paying our debts and other obligations and setting aside funds for reserves, nor as to the timing of any such distribution, if any.

In March 2021, we entered into an Equity Distribution Agreement (the "Equity Distribution Agreement") with Oppenheimer& Co. Inc. ("Oppenheimer"), under which we may offer and sell from time to time common shares having an aggregate offering price of up to $25.0 million. During the year ended December 31, 2022, we sold approximately 2.2 million shares of our common stock under this agreement, resulting in net cash proceeds of $9.9 million, after deducting issuance costs of $0.4 million. From January 1, 2023 to March 14, 2023, the Company issued and sold approximately 119,104 common shares of our common stock under this agreement, resulting in net cash proceeds of approximately $118.0 thousand, after deducting issuance costs $4.0 thousand.

Rising inflation and financial market volatility may adversely impact 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, and changing priorities could also affect our ability to enter into key agreements. COVID-19 and government measures taken in response have also had an 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 certain medical services and supplies, have spiked, while demand for other goods and services have fallen. The future progression of the outbreak and its longer-term effects on our business and operations continue to evolve and are still 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 related to the outbreak in certain parts of the world. These disruptions may negatively impact our sales, results of operations, financial condition, and liquidity into 2023.

Our ability to continue as a going concern for the next twelve months from the issuance of our Annual Report on Form 10-K, depends on our ability to execute our business plan, increase revenue and reduce expenditures. As of December 31, 2022, we had cash and cash equivalents of $14.0 million and an accumulated deficit of $141.4 million. Based on our current business plan, we believe our cash and cash equivalents as of December 31, 2022 will be sufficient to meet our anticipated cash requirements into Q2 2023. We will need to raise significant additional capital to continue to fund operations. We may seek to sell common or preferred equity, convertible debt securities or seek other debt financing. In addition, we may seek to raise cash through collaborative agreements or from government grants, as well as evaluate other strategic alternative transactions. 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,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	$ (17,467)	$ (14,422)
Net cash used in investing activities	(224)	(470)
Net cash provided by financing activities	9,170	16,636
Net (decrease) increase in cash and cash equivalents	$ (8,521)	$ 1,744

Operating Activities

During the year ended December 31, 2022, operating activities used $17.5 million of cash, due to our net loss of $18.6 million, offset by non-cash expenses principally related to share-based compensation expense of $1.8 million, depreciation and amortization of $0.5 million, amortization of debt issuance costs of $0.3 million, impairment of inventory of $0.6 million, amortization of operating lease right of use asset of $0.3 million and offset by a gain on the change in estimated fair value of contingent royalty obligation of $0.5 million, changes in net working capital items principally related to the decrease in inventory of $1.3 million, and the increase in accounts payable and accrued expenses of $0.7 million.

Investing Activities

During the year ended December 31, 2022, net cash used in investing activities was $0.2 million related to the purchase of fixed assets.

Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities was $9.2 million, related to proceeds from issuance of common shares of $10.3 million, offset by repayments under term loans of $0.7 million and equity financing fees of $0.4 million.

Shelf Registration Statement

On March 16, 2021, we filed a shelf registration statement (File No. 333-254343) with the Securities and Exchange Commission (the "2021 Shelf Registration Statement"), which was declared effective on March 26, 2021, that allows us to offer, issue and sell up to a maximum aggregate offering price of $100.0 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. As of December 31, 2022, we have not sold any securities under the 2021 Shelf Registration Statement, except as described below.

The 2021 Shelf Registration Statement includes a prospectus registering the at-the-market offering program pursuant to the Equity Distribution Agreement with Oppenheimer, under which we may offer and sell from time to time common shares having an aggregate offering price of up to $25.0 million. During the year ended December 31, 2022, we sold approximately 2.2 million shares of Common Stock pursuant to the above-described Equity Distribution Agreement, resulting in net cash proceeds of $9.9 million, after deducting issuance costs of $0.4 million.

Our ability to issue securities is subject to market conditions and other factors including, in the case of our debt securities, our credit ratings. Each issuance under the shelf registration statements will require the filing of a prospectus supplement identifying the amount and terms of the securities to be issued.

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 on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide the information required by this item.

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, 2022. 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, 2022.

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 our internal control over financial reporting was effective at the reasonable assurance level as of December 31, 2022.

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.

Changes in Internal Control over Financial Reporting

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, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

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	51	Chief Executive Officer and Director
Mark Pomeranz	61	President, Chief Operating Officer and Director
Andrew Taylor	52	Chief Financial Officer
David Hochman	47	Chairman of the Board
Darren Sherman	51	Director
Shervin Korangy	48	Director
Gary J. Pruden	61	Director
Sonja Nelson	49	Director

Management

Timothy P. Moran, Chief Executive Officer and Director

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

Mark Pomeranz, President, Chief Operating Officer and Director

Mr. Pomeranz has served as Chief Operating Officer since September 24, 2018. Prior to his tenure as our Chief Operating Officer, Mr. Pomeranz served as our Chief Executive Officer from December 2016 through September 2018, and as the Chief Executive Officer of Motus GI Medical Technologies Ltd., our wholly owned subsidiary, from 2014 through September 2018. Prior to joining Motus GI Medical Technologies Ltd., from 2008 to 2014, Mr. Pomeranz was the founding CEO of Svelte Medical Systems, a start-up company that is currently commercializing a unique drug eluting stent platform. 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 majority of the operations and 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 January 2023, he has been Chairman and Chief Executive Officer of Orchestra BioMed Holdings, Inc. (Nasdaq: OBIO), the parent company of Orchestra BioMed, Inc., a biomedical innovation company focused on bringing high-impact procedure-based therapeutic innovations to life through risk-reward sharing partnerships, which he founded and of which he has served as Chairman and Chief Executive Officer since May 2018. 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. 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. 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 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 Directors of Orchestra BioMed Holdings, Inc., (NASDAQ: OBIO)., a biomedical innovation company focused on bringing high-impact procedure-based therapeutic innovations to life through risk-reward sharing partnerships. Mr. Sherman has over 27 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 ninety U.S. patents and has over one-hundred 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.

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. 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 Olympus Corporation, (OTCMKTS: OCPNY) (and serves as a member of its compensation committee), Lantheus Holdings, Inc. (NASDAQ: LNTH) (and serves as a member of its Audit committee and the chair of its Compensation committee), OSSIO Inc, 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.

Sonja Nelson, Director

Ms. Nelson has served on our board of directors since June 2021. In June 2021, Ms. Nelson began serving as the Chief Financial Officer of Ambrx Biopharma, Inc, (NYSE: AMAM) and beginning October 2022, as the company's Chief Financial and Operating Officer. Prior to that, Ms. Nelson, served as the Senior Vice President, Finance, of ImmunityBio, Inc. (NASDAQ: IBRX), from March 2021 to June 2021. Ms. Nelson served as the Chief Financial Officer of NantKwest, Inc. from June 2018 to March 2021, at which time NantKwest, Inc. merged with ImmunityBio, Inc. (NASDAQ: IBRX). Ms. Nelson previously served as the Chief Accounting Officer of NantKwest, Inc. from May 2016 to June 2018 and as the VP/Corporate Controller of NantKwest, Inc. from November 2015 to May 2016. Ms. Nelson also served as a director of Inex Bio (a subsidiary of NantKwest, Inc., now merged with ImmunityBio, Inc. (NASDAQ: IBRX)) from October 2017 to June 2021. Prior to joining NantKwest, Inc., Ms. Nelson was Vice President and Corporate Controller at AltheaDx, Inc. from July 2014 through October 2015. Previously, Ms. Nelson was Senior Director and Controller at Cadence Pharmaceuticals, Inc. (acquired by Mallinckrodt plc) from May 2012 through June 2014. Prior to that, Ms. Nelson was Director, General Accounting at Cricket Communications, Inc. (acquired by AT&T, Inc.) from September 2008 through May 2012. Ms. Nelson began her career with KPMG LLP, holds a Bachelor's degree in business administration with specialization in taxation and auditing from the University of Applied Sciences in Pforzheim, Germany, and is a Certified Public Accountant. Ms. Nelson was selected as a director due to her management experience with pharmaceutical and consumer health products, and her financial and accounting experience.

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 Ms. Nelson, Mr. Pruden and Mr. Sherman, with Ms. Nelson 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 Ms. Nelson 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 Mr. Korangy, 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 Mr. Korangy, 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, 2022, our two other most highly compensated executive officers who were serving as executive officers as of December 31, 2022, 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, 2022. 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	2022	475,000	-	79,398	79,398	49,803(3)	683,599
Chief Executive Officer	2021	475,000	265,050	250,980	202,758	47,282(3)	1,241,070
Mark Pomeranz	2022	385,000	-	43,102	43,092	44,311(3)	515,505
President and Chief Operating Officer	2021	385,000	229,025	115,700	93,470	34,837(3)	858,032
Andrew Taylor	2022	330,000	-	43,102	43,092	49,803(3)	465,997
Chief Financial Officer	2021	310,000	115,320	106,800	86,280	42,332(3)	660,732

(1) Amounts reflect the grant date fair value of option awards granted in 2022 and 2021 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 2022 and 2021 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) Amounts relate to corporate and health benefits and 401K employer match.

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 24,750 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 $75.60 per share and (ii) a restricted stock unit award, granted on February 13, 2019, for 8,250 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 25,555 shares of our Common Stock pursuant to our Equity Incentive Plan with an exercise price of $100.00 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 $90.00 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 $330,000 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 12,000 shares of our Common Stock pursuant to our Equity Incentive Plan with an exercise price of $90.0 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 – 2022

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, 2022.

	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	Exercisable	Unexercisable	Price ($)	Date	Vested	Vested ($)
Timothy P. Moran (CEO)	24,749	-	$ 75.60(1)	November 8, 2028	9,970(9)	8,375
	1,446	-	$ 86.40(2)	February 13, 2029		
	4,500	685	$ 43.20(3)	February 6, 2030		
	10,000	-	$ 23.40(4)	June 11, 2030		
	9,500	-	$ 14.80(5)	November 11, 2030		
	4,112	2,937	$ 35.60(11)	February 17, 2031		
	2,187	6,563	9.20(12)	February 10, 2032		
Mark Pomeranz (COO)	3,361	-	$ 47.60(6)	April 2, 2024	5,220(10)	4,385
	25,555	-	$ 90.00(7)	May 3, 2027		
	6,431	-	$ 86.40(2)	February 13, 2029		
	1,848	168	$ 43.20(3)	February 6, 2030		
	4,000	-	$ 23.40(4)	June 11, 2030		
	3,750	-	$ 14.80(5)	November 11,2030		
	1,893	1,356	$ 35.60(11)	February 17, 2031		
	1,187	3,562	$ 9.20(12)	February 10, 2032		
Andrew Taylor (CFO)	11,999	-	$ 90.00(8)	September 29, 2027	5,089(10)	4,275
	3,537	-	$ 86.40(2)	February 13, 2029		
	2,112	192	$ 43.20(3)	February 6, 2030		
	4,500	-	$ 23.40(4)	June 11, 2030		
	3,900	-	$ 14.80(5)	November 11, 2030		
	1,750	1,250	35.60(11)	February 17, 2031		
	1,185	3,564	$ 9.20(12)	February 10, 2032		

(1) Represents options to purchase shares of our Common Stock granted on November 8, 2018 with an exercise price of $75.60 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 $86.40 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 $43.20 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 $23.40 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 $100.00 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 $90.00 per share in September 2017.
(8) Represents options to purchase shares of our Common Stock granted on September 29, 2017, with an exercise price of $90.00 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.
(9) Represents RSUs granted on October 1, 2018, February 13, 2019, February 6, 2020, and February 17, 2021. 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. The shares underlying the RSUs granted on February 17, 2021 vest in a series of twelve (12) successive equal quarterly installments commencing on May 1, 2021 and continuing on the first day of each third month thereafter.
(10) Represents RSUs granted on February 13, 2019, February 6, 2020, and February 17, 2021. 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. The shares underlying the RSUs granted on February 17, 2021 vest in a series of twelve (12) successive equal quarterly installments commencing on May 1, 2021 and continuing on the first day of each third month thereafter.
(11) Represents options to purchase shares of our Common Stock granted on February 17, 2021 with an exercise price of $5.608 per share. The shares underlying the option vest in a series of twelve (12) successive equal quarterly installments commencing on February 1, 2021 and continuing on the first day of each third month thereafter.
(12) Represents options to purchase shares of our Common Stock granted on February 10, 2022 with an exercise price of $9.20 per share. The shares underlying the option vest in a series of twelve (12) successive equal quarterly installments commencing on May 1, 2022 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 2022.

Name	Fees earned or paid in cash ($)	Stock Awards ($)	Option Awards ($) (1)	Total ($)
David Hochman (2)	-	61,000(7)	22,685	83,685
Darren Sherman (3)	-	43,450(7)	22,685	66,135
Shervin Korangy (4)	-	39,600(7)	22,685	62,285
Gary Pruden (5)	-	51,150(7)	22,685	73,835
Sonja Nelson (6)	-	39,600(7)	22,685	62,285

(1) Amounts reflect the aggregate grant date fair value of each stock option granted in 2022 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, 2022 held by Mr. Hochman was 6,354.
(3) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2022 held by Mr. Sherman was 4,526.
(4) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2022 held by Mr. Korangy was 4,125.
(5) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2022 held by Mr. Pruden was 5,328.
(6) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2022 held by Ms. Nelson was 4,125.
(7) Represents the value of Common stock issued in lieu of cash compensation in 2022.

Non-Employee Director Compensation

Our board of directors approved a director compensation policy for our directors, effective January 1, 2022. This policy provides for the following cash compensation:

- each director is entitled to receive a quarterly fee of $7,150;
- the chairman of our board of directors will receive a quarterly fee of $6,450;
- the chair of the Audit Committee will receive a quarterly fee of $2,750;
- each chair of any other board of director committee will receive a quarterly fee of $1,650;
- each non-employee director sitting on more than two of our board of directors committees will receive an additional quarterly fee of $825;
- each non-chairperson member of the audit committee, the compensation committee and the nominating and corporate governance committee will receive annual fees of $2,062, $1,375 and $1,375, 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.

Effective January 2022, our Board approved a temporary modification to the non-employee director compensation policy to permit payment of the entire 2022 fees in a single grant of our Common Stock, in lieu of cash compensation, for the quarters ending March 31, 2022, June 30, 2022, September 30, 2022 and December 31, 2022 (the "2022 Fee Grant"). The 2022 Fee Grant was made to each non-employee director on January 5, 2022. We will also reimburse non-employee directors for reasonable expenses incurred in connection with attending board of director and committee meetings. In addition, effective January 2023, the non-management members of the Board agreed to defer their 2023 Board fees until a future date.

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, 2022.

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)	420,416(2)	$ 42.69(3)	15,165
Equity compensation plans not approved by security holders	-	$ -	-
Total	420,416	$ 42.69	15,165

(1) The amounts shown in this row include securities under the 2016 Plan.
(2) Includes 400,137 shares of Common Stock issuable upon exercise of outstanding options and 20,278 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 279,586 shares were automatically made available for issuance on the first day of 2023, which represents 6% of the number of shares outstanding on December 31, 2022; 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 14, 2023 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 4,778,873 shares of Common Stock issued and outstanding as of February 14, 2023 plus any shares issuable upon exercise of options or warrants that are exercisable on or within 60 days after February 14, 2023 held by such person or entity.

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

Name of beneficial owner	Amount and nature of beneficial ownership	Percentage of class
Officers and Directors		
Timothy P. Moran (1)	83,191	1.72%
Mark Pomeranz (2)	57,600	1.19%
David Hochman (3)	31,042	*
Darren Sherman (4)	20,620	*
Sonja Nelson (5)	20,905	*
Shervin Korangy (6)	18,634	*
Andrew Taylor (7)	37,187	*
Gary Pruden (8)	21,531	*
Directors and Officers as a Group (9 persons)	275,985	5.56%

1. Includes 58,495 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of February 14, 2023. Does not include 8,184 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of February 14, 2023. Includes 21,529 shares of our Common Stock pursuant to restricted stock unit awards which have vested as of February 14, 2023, or which will be vested within sixty days of February 14, 2023. Does not include 8,189 shares of our Common Stock issuable upon the vesting of restricted stock units that will not vest within sixty days of February 14, 2023.
2. Includes 48,858 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of February 14, 2023. Does not include 4,253 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of February 14, 2023. Includes 7,909 shares of our Common Stock pursuant to restricted stock unit awards which have vested as of February 14, 2023, or which will be vested within sixty days of February 14, 2023. Does not include 4,251 shares of our Common Stock issuable upon the vesting of restricted stock units that will not vest within sixty days of February 14, 2023.
3. Includes (i) 1,018 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) 5,500 shares of our Common Stock held by DPH 2008 Trust, a trust of which Mr. Hochman is a co-trustee and beneficiary. Includes 16,250 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of February 14, 2023. Includes (i) 45 shares of our Common Stock issuable upon the exercise of warrants, held directly by Mr. Hochman, that are exercisable within sixty days of February 14, 2023 and (ii) 189 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 14, 2023.
4. Includes 10,875 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of February 14, 2023. Includes 15 shares of our Common Stock issuable upon the exercise of warrants, held directly by Mr. Sherman, that are exercisable within sixty days of February 14, 2023.
5. Includes 3,750 shares of our Common Stock issuable upon the exercise of stock options that are exercisable withing sixty days of February 14, 2023. Does not include 1,250 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of February 14, 2022.
6. Includes 9,125 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of February 14, 2023.
7. Includes 29,820 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of February 14, 2023. Does not include 4,169 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of February 14, 2023. Does not include 4,167 shares of our Common Stock issuable upon the vesting of restricted stock units that will not vest within sixty days of February 14, 2023. Includes 7,066 shares of our Common Stock pursuant to restricted stock unit awards which have vested as of February 14, 2023, or which will be vested within sixty days of February 14, 2023.

8. Includes 8,375 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of February 14, 2023.

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, 2021 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."

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 79,056 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 March 2038). 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.

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. In May 2022, the Company entered into an amendment to the Shared Space Agreement. Pursuant to the amendment, the area covered by the Shared Space Agreement was expanded to 95% of the premises and the aggregate license fees will generally range from approximately $212 thousand to approximately $270 thousand in any given calendar year during the term of the Shared Space Agreement until the termination of the lease in November 2024.

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, Dr. Nussbaum (who ceased being a director upon his death in September 2021), Mr. Korangy, Mr. Pruden and Ms. Nelson 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	2022	2021
Audit Fees	$ 272,369	$ 246,421
Audit-Related Fees	$ -	$ -
Tax Fees	$ 27,800	$ 64,470
All Other Fees	$ -	$ -
Total Fees	$ 300,169	$ 310,891

Audit Fees

"Audit fees" consist of approximately $207,000 and $182,000 in 2022 and 2021, 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 $65,000 and $64,000 in 2022 and 2021, 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 $28,000 and $27,000, in 2022 and 2021, respectively, for services related to tax preparation and filing, and $0 and $38,000, in 2022 and 2021, 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 minimis" 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 2021 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 AS 1301, 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	Certificate of Amendment of Certificate of Incorporation of Motus GI Holdings, Inc. dated July 25, 2022	8-K	001-38389	3.1	7/26/2022	
3.5	Bylaws, as amended	8-K	001-38389	3.1	11/14/2022	
3.6	Certificate of Designations of Series A Convertible Preferred Stock	S-1	333-222441	3.4	1/5/2018	
3.7	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	10-K	001-38389	4.15	3/16/2021	
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	
4.18	Form of New Warrant	8-K	001-38389	4.1	1/21/2021	
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.	10-K	001-38389	10.20	3/29/2022	
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	10-K	001-38389	10.25	3/16/2021	
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.	10-K	001-38389	10.25	3/16/2021	
10.30	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	
10.31	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	
10.32	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	
10.33	Form of Warrant Exercise Agreement, dated January 27, 2021, by and between Motus GI Holdings, Inc. and the Holder	8-K	001-38389	10.1	1/27/2021	
10.34	Letter Agreement, dated January 27, 2021, by and between A.G.P./Alliance Global Partners and the Company	8-K	001-38389	10.2	1/27/2021	
10.35	Loan Agreement, dated July 16, 2021, by and between Kreos Capital, Motus GI Holdings, Inc., Motus GI, LLC and Motus GI Medical Technologies, LTD.	8-K	001-38389	10.1	7/21/2021	
10.36	Security Agreement, dated July 16, 2021 between Kreos Capital and Motus GI Holdings, Inc.	8-K	001-38389	10.2	7/21/2021	
10.37	Security Agreement, dated July 16, 2021 between Kreos Capital and Motus GI, LLC.	8-K	001-38389	10.3	7/21/2021	
10.38	Debenture – Fixed Charge dated July 16, 2021, between Kreos Capital and Motus GI Medical Technologies, LTD.	8-K	001-38389	10.4	7/21/2021	
10.39	Debenture – Floating Charge dated as of July 16, 2021, between Kreos Capital and Motus GI, LLC.	8-K	001-38389	10.5	7/21/2021	
10.40	US Intellectual property Security Agreement, dated July 16, 2021, between Kreos Capital and Motus GI Medical Technologies, LTD.	8-K	001-38389	10.6	7/21/2021	
10.41 #	Master Supply Agreement, dated April 1, 2021, between J. Sterling Industries LLC and Motus GI Holdings, Inc.	10-K	001-38389	10.41	3/29/2022	

21.1	List of Subsidiaries of the Company	10-K	001-38389	21.1	3/16/2021	
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	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibits 101)					

+ 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.
# Certain portions of this exhibit (indicated by "[***]") have been omitted as we have determined (1) it is not material and (2) is the type that the Company treats as private or confidential.
** 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 Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MOTUS GI HOLDINGS, INC.

Date: March 31, 2023

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

Date: March 31, 2023

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, 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 31, 2023
/s/ Andrew Taylor Andrew Taylor	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2023
/s/ David Hochman David Hochman	Chairman of the Board	March 31, 2023
/s/ Mark Pomeranz Mark Pomeranz	President, Chief Operating Officer, and Director	March 31, 2023
/s/ Darren Sherman Darren Sherman	Director	March 31, 2023
/s/ Sonja Nelson Sonja Nelson	Director	March 31, 2023
/s/ Shervin Korangy Shervin Korangy	Director	March 31, 2023
/s/ Gary Pruden Gary Pruden	Director	March 31, 2023

INDEX TO
CONSOLIDATED FINANCIAL STATEMENTS

Contents

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, 2022 and 2021, 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 financial position of the Company as of December 31, 2022 and 2021, and the 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 generated minimal revenues, experienced negative cash flows from operating activities and has incurred substantial operating losses 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 financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) 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 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 the future projected revenue 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 $1,212,000 as of December 31, 2022.

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, Pennsylvania
March 31, 2023

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

	December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 14,042	$ 22,563
Accounts receivable	59	109
Inventory, current	488	496
Prepaid expenses and other current assets	781	793
Total current assets	15,370	23,961
Fixed assets, net	1,325	1,428
Inventory, non-current	511	-
Right-of-use assets	428	687
Other non-current assets	13	13
Total assets	$ 17,647	$ 26,089
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,969	$ 2,584
Operating lease liabilities - current	245	307
Other current liabilities	53	10
Current portion of long-term debt, net of unamortized debt discount of $182 and $271, respectively	2,532	431
Total current liabilities	4,799	3,332
Contingent royalty obligation	1,212	1,760
Operating lease liabilities - non-current	178	385
Convertible note, net of unamortized debt discount of $108 and $166, respectively	3,892	3,834
Long-term debt, net of unamortized debt discount of $135 and $317, respectively	4,589	7,121
Total liabilities	14,670	16,432
Commitments and contingent liabilities (Note 9)		
Shareholders' equity		
Preferred stock $0.0001 par value; 10,000,000 shares authorized; zero shares issued and outstanding	-	-
Common stock $0.0001 par value; 115,000,000 shares authorized; 4,659,769 and 2,416,021 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	-	-
Additional paid-in capital	144,328	132,411
Accumulated deficit	(141,351)	(122,754)
Total shareholders' equity	2,977	9,657
Total liabilities and shareholders' equity	$ 17,647	$ 26,089

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,	
	2022	**2021**
Revenue	$ 592	$ 391
Operating expenses:		
Costs of revenue - sales	198	181
Costs of revenue - impairment of inventory	598	443
Research and development	5,611	5,341
Sales and marketing	4,425	3,077
General and administrative	7,611	9,273
Total costs and expenses	18,443	18,315
Operating loss	(17,851)	(17,924)
Gain (loss) on change in estimated fair value of contingent royalty obligation	548	(143)
Loss on extinguishment of debt	-	(237)
Finance expense, net	(1,252)	(717)
Other income	-	5
Foreign currency loss	(42)	(17)
Net loss	$ (18,597)	$ (19,033)
Deemed dividends from warrant issuance	-	(6,145)
Net loss attributable to common shareholders	$ (18,597)	$ (25,178)
Basic and diluted loss per common share:		
Net loss attributable to common shareholders	$ (5.74)	$ (10.74)
Weighted average number of common shares outstanding, basic and diluted	3,237,952	2,344,759

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 Capital	Accumulated deficit	Total shareholders' equity
	Shares	Amount			
Balance at December 31, 2020	1,613,591	-	115,011	(103,721)	11,290
Issuance of common shares upon public offering, net of offering costs of $74	67,043	-	1,826	-	1,826
Issuance of common stock upon exercise of warrants, net of financing fees of $366	713,362	-	11,593	-	11,593
Issuance of common stock for board of directors' compensation	9,587	-	291	-	291
Issuance of common shares upon vesting of restricted stock units	9,938	-	-	-	-
Issuance of common stock to consultants	2,500	-	53		53
Issuance of warrants associated with convertible note and long- term debt	-	-	165		165
Share-based compensation	-	-	3,472	-	3,472
Net loss	-	-	-	(19,033)	(19,033)
Balance at December 31, 2021	2,416,021	-	132,411	(122,754)	9,657
Issuance of common shares pursuant to at-the-market registered offering, net of issuance costs of $368	2,195,106	-	9,884	-	9,884
Issuance of common shares upon vesting of restricted stock units	26,230	-	-	-	-
Fractional shares settled in cash pursuant to reverse stock split	(2,046)	-	(11)	-	(11)
Issuance of common stock for board of directors' compensation	24,458	-	235	-	235
Share-based compensation	-	-	1,809	-	1,809
Net loss	-	-	-	(18,597)	(18,597)
Balance at December 31, 2022	4,659,769	$ -	$ 144,328	$ (141,351)	$ 2,977

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,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (18,597)	$ (19,033)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	510	439
Amortization of debt issuance costs	330	95
(Gain) loss on change in estimated fair value of contingent royalty obligation	(548)	143
Share-based compensation	1,809	3,472
Issuance of common stock for board of directors' compensation	235	235
Issuance of common stock for consultants	-	53
Loss on extinguishment of debt	-	237
Impairment of inventory	598	443
Impairment of fixed assets	46	-
Amortization on operating lease right of use asset	327	262
Changes in operating assets and liabilities:		
Accounts receivable	50	(74)
Inventory	(1,302)	(274)
Prepaid expenses and other current assets	12	(413)
Accounts payable and accrued expenses	(650)	303
Operating lease liability	(330)	(260)
Other current and non-current liabilities	43	(50)
Net cash used in operating activities	(17,467)	(14,422)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of fixed assets	(224)	(470)
Net cash used in investing activities	(224)	(470)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common shares	10,252	1,900
Fractional shares paid in cash pursuant to reverse stock split	(11)	-
Proceeds from exercise and purchase of warrants	-	11,959
Borrowings under convertible note and long-term debt	-	12,000
Repayment of debt	(703)	(8,220)
Payment of debt issuance costs	-	(563)
Equity financing fees	(368)	(440)
Net cash provided by financing activities	9,170	16,636
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(8,521)	1,744
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	22,563	20,819
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 14,042	$ 22,563
SUPPLEMENTAL CASH FLOW INFORMATION:		
CASH PAID FOR:		
Interest	$ 977	$ 640
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING AND INVESTING ACTIVITIES:		
Common stock issued to settle accrued expenses for board of directors' compensation	$ -	$ 56
Reclassification of inventory to fixed assets	$ 201	$ 140
Reclassification of prepaid expenses to fixed assets	$ 4	$ 75
Purchase of fixed assets in accounts payable and accrued expenses	$ 24	$ 4
Warrants issued related to convertible note and long-term debt recorded as debt discount	$ -	$ 165
Accrued end of loan payment recorded as debt discount	$ -	$ 140
Operating lease liabilities arising from obtaining right-of-use assets	$ 66	$ 184
Prepayment of lease obligation	$ -	$ 17

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

Motus GI Holdings, Inc. and Subsidiaries
Notes to the Consolidated Financial Statements
(In thousands, except share and per share amounts)

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 GI Technologies, Ltd. and Motus GI, LLC, are collectively referred to as "Motus GI" or the "Company".

The Company has developed the Pure-Vu System, a medical device that has been cleared by the U.S. Food and Drug Administration (the "FDA") to help facilitate the cleansing of a poorly prepared gastrointestinal tract during colonoscopy and to help facilitate upper gastrointestinal ("GI") endoscopy procedures. The Pure-Vu System has received a CE Mark in the EU for use in colonoscopy. The Pure-Vu System integrates with standard and slim colonoscopes, as well as gastroscopes, to improve visualization during colonoscopy and upper GI procedures while preserving established procedural workflow and techniques. Through irrigation and evacuation of debris, the Pure-Vu System is designed to provide better-quality exams. The Company received 510(k) clearance in February 2022 from the FDA for the Pure-Vu EVS System and has commenced initial commercialization of this product. The Company does not expect to generate significant revenue from product sales until it further expands its commercialization efforts, 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. Management expects the Company to continue to generate substantial operating losses and to continue to fund its operations primarily through utilization of its current financial resources, future product sales, and through the issuance of debt or equity, as well as through other strategic alternative transactions. Rising inflation and financial market volatility 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, and changing priorities could also affect the Company's ability to enter into key agreements. COVID-19 and government measures taken in response have also had an 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 certain medical services and supplies, have spiked, while demand for other goods and services have fallen. The future progression of the outbreak and its longer-term effects on the Company's business and operations continue to evolve and are still 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 related to the outbreak in certain parts of the world. These disruptions may negatively impact the Company's sales, its results of operations, financial condition, and liquidity into Q2 2023.

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 $18.6 million for the year ended December 31, 2022, and we expect to continue to incur net operating losses for the foreseeable future. As of December 31, 2022, we had $14.0 million in cash and cash equivalents and an accumulated deficit of $141.4 million. We expect our current spend level to continue in connection with ongoing operating activities, including expenditures in R&D, sales and marketing, clinical affairs and manufacturing. As described above, we committed to a restructuring initiative designed to reduce our expenses and position us to explore a range of strategic and financing alternatives focused on maximizing stockholder value and accelerating the commercialization of the Pure-Vu System. In addition, in order to continue to operate as a standalone company, we would need additional financing to support our continuing operations. We also have significant debt under our Loan Agreement with Kreos which could negatively impact our ability to operate or consummate a strategic transaction.

In January 2023, we committed to a restructuring initiative designed to position us to explore a range of strategic and financing alternatives focused on maximizing stockholder value and accelerating the commercialization of the Pure-Vu System. If a strategic transaction is not completed, or if additional financing is not available, we may not be able to service our outstanding indebtedness and our payables and may have to file for bankruptcy protection or pursue a dissolution of the Company and liquidation of all of our remaining assets. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations and service our outstanding indebtedness. We cannot provide assurance as to the amount of cash that will be available to distribute to stockholders, if any, after paying our debts and other obligations and setting aside funds for reserves, nor as to the timing of any such distribution, if any.

Such conditions 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 ("FASB").

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.

Reverse Stock Split

On July 25, 2022, the Company effected a reverse stock split of its issued and outstanding common stock, par value $0.0001 per share, at a ratio of 1-for-20. Shares of common stock underlying outstanding stock options and other equity instruments convertible into common stock were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities.

Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split.

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.

Concentrations of Credit Risk and Off-balance Sheet Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash, cash equivalents and marketable securities. The Company's cash is held in accounts with financial institutions that management believes are creditworthy. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to any significant credit risk on these funds. The Company has no financial instruments with off-balance sheet risk of loss.

Revenue recognition

Sales contracts executed for the second generation Pure-Vu System are 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, 2022, the Company recognized revenue of $592, which consisted of $540 in accordance with ASC 606 and $52 in accordance with ASC 842. During the year ended December 31, 2021, the Company recognized revenue of $391, which consisted of $303 in accordance with ASC 606 and $88 in accordance with ASC 842.

During the year ended December 31, 2022, the Company recognized revenue at a point in time of $529 and recognized revenue over time of $63. During the year ended December 31, 2021, the Company recognized revenue at a point in time of $299 and recognized revenue over time of $92.

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, 2022 and 2021, incremental commissions paid on eligible sales orders were $96 and $35, 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, 2022 and 2021, 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. Inventories that exceed estimated realization for the next twelve months from balance sheet date based on future sales forecasts are classified as long-term assets.

Leases

The Company accounts for its leases in accordance with ASC 842, Leases, or ASC 842. 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.

The Company has elected not to recognize leases with an original term of one year or less on the balance sheet. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty of renewal.

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

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.

The accounting for awards issued to non-employees is similar to the accounting for employee awards, except that:

- the Company may 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.

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. 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.

Net loss attributable to common stockholders consists of net income or loss, as adjusted for actual and deemed preferred stock dividends declared, amortized or accumulated. The Company recorded a deemed dividend of $0 and $6,145 for the issuance of warrants during the years ended December 31, 2022 and 2021, respectively. The deemed dividend is added to the net loss in determining the net loss available to common stockholders.

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, 2022 and 2021, 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, 2022 or December 31, 2021.

For the years ended December 31, 2022 and 2021, 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, 2022 and 2021, due to a full valuation allowance to offset any deferred tax asset related to net operating loss carry forwards attributable to the losses.

Fair value of financial 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, 2022 and 2021.

New Accounting Pronouncements- Recently Adopted

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50)*, *Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modification or Exchanges of Freestanding Equity-Classified Written Call Options*, which clarifies and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options due to a lack of explicit guidance in the FASB Codification. ASU 2021-04 provides guidance on modifications or exchanges of freestanding equity-classified written call options that are not within the scope of another Topic. Entities should treat a modification of the terms or conditions, or an exchange of a freestanding equity-classified written call option that remains equity-classified after modification or exchange, as an exchange of the original instrument for a new instrument. ASU 2021-04 provides further guidance on measuring the effect of such modifications or exchanges, and also provides guidance on the recognition of such modifications or exchanges on the basis of the substance of the transaction, in the same manner as if cash had been paid as consideration. ASU 2021-04 is effective for all entities for fiscal years beginning after December 15, 2021. The Company adopted this ASU on January 1, 2022, prospectively to modifications that occurred after the date of initial application. The adoption of this ASU did not result in a material impact to the consolidated financial statements and disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements*, or ASC 326. On January 1, 2023, the Company adopted ASC 326. The new standard requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The targeted transition relief standard allows filers an option to irrevocably elect the fair value option of ASC 825-10, *Financial Instruments-Overall*, applied on an instrument-by-instrument basis for eligible instruments. The adoption of ASC 326 did not have a material impact on the Company's financial position or results of operations upon adoption.

Accounting Pronouncements- Not Yet Adopted

In March 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting* which provides optional expedients and exceptions for the accounting for contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. The guidance in ASU 2020-04 is optional and may be elected over time as reference rate reform activities occur. In January 2021, the FASB issued ASU 2021-01 to clarify the scope of certain optional expedients for derivatives that are affected by the discounting transition. In December 2022, the FASB issued ASU 2022-06 to defer the sunset date of Topic 848 from December 31, 2022, to December 31, 2024, after which entities will no longer be permitted to apply the relief in Topic 848. As of December 31, 2022, the Company is currently evaluating the impact of this guidance on its consolidated financial statements.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity.* This guidance simplifies the accounting for convertible instruments primarily by eliminating the existing cash conversion and beneficial conversion models within Subtopic 470-20, which will result in fewer embedded conversion options being accounted for separately from the debt host. The guidance also amends and simplifies the calculation of earnings per share relating to convertible instruments. This guidance is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within that reporting period, using either a full or modified retrospective approach. As of December 31, 2022, the Company is currently evaluating the impact of the provisions of this guidance on its consolidated financial statements.

Note 4 – Fair Value Measurements

Liabilities measured and recorded at fair value on a recurring basis consisted of the following at December 31, 2022 and December 31, 2021:

	December 31, 2022			
	Level 1	Level 2	Level 3	Fair Value
Liabilities				
Contingent royalty obligation	$ -	$ -	$ 1,212	$ 1,212

	December 31, 2021			
	Level 1	Level 2	Level 3	Fair Value
Liabilities				
Contingent royalty obligation	$ -	$ -	$ 1,760	$ 1,760

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. Financial instruments with carrying values approximating fair value also include long-term debt and convertible notes which is based on a combined total of their face value and the amortization discount.

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, 2022 and 2021. Based on the fair value hierarchy, the Company classified contingent royalty obligation within Level 3 because the valuation inputs are based on projected revenues discounted to a present value.

Changes in the fair value of recurring fair value measurements using significant unobservable inputs (Level 3), which solely consisted of a contingent royalty obligation, during the year ended December 31, 2022 was as follows:

	Fair Value Measurements of Contingent Royalty Obligation (Level 3)
Balance at December 31, 2021	$ 1,760
Change in estimated fair value of contingent royalty obligation	548
Balance at December 31, 2022	$ 1,212

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 (23% as of December 31, 2022 and 21% as of December 31, 2021), and 5) rate of royalty payment (3% as of December 31, 2022 and December 31, 2021).

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 $126 and a 2% increase in the discount rate would decrease the liability by approximately $112.

Note 5 – Inventory

Inventory at December 31, 2022 and 2021 consisted of the following:

	December 31,	
	2022	2021
Raw materials	$ 697	$ 569
Work-in-process	155	-
Finished goods	548	292
Inventory reserve	(401)	(365)
Inventory, net	$ 999	$ 496
Inventory, current	$ 488	$ 496
Inventory, non-current	$ 511	$ -

For the years ended December 31, 2022 and 2021, an inventory impairment of $598 and $443, respectively, was recorded.

Note 6 – Fixed assets, net

Fixed assets, net, consists of the following:

	December 31,	
	2022	2021
Office equipment	$ 171	$ 171
Computers and software	321	305
Machinery	1,049	807
Lab and medical equipment	1,477	1,342
Leasehold improvements	200	193
Total	3,218	2,818
Less accumulated depreciation and amortization	(1,893)	(1,390)
Fixed assets, net	$ 1,325	$ 1,428

Depreciation and amortization expense for the years ended December 31, 2022 and 2021 was $510 and $439, respectively. The Company incurred a loss on the impairment of fixed assets in the amount of $46 and $0 for the years end December 31, 2022 and 2021, 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 expired on December 31, 2022. The Company entered into a new tenancy contract with the facility for a period of twelve months from January 1, 2023 to December 31, 2023.

The Company leases vehicles under operating leases that expire at various dates through 2025.

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.

The components of lease cost and supplemental balance sheet information for the Company's lease portfolio were as follows:

	Year Ended December 31,	
	2022	2021
Lease Cost		
Operating lease cost, net of related party license fee	$ 92	$ 139
Variable lease cost	120	119
Total lease cost	$ 212	$ 258

	As of December 31,	
	2022	2021
Assets		
Operating lease, right-of-use asset	$ 428	$ 687
Liabilities		
Current		
Operating lease liabilities	$ 245	$ 307
Non-current		
Operating lease liabilities, net of current portion	178	385
Total lease liabilities	$ 423	$ 692
Other information:		
Weighted average remaining lease term - operating leases	1.79 years	2.49 years
Weighted-average discount rate - operating leases	7.36%	7.66%

The Company records operating lease payments to lease expense using the straight-line method. The Company's lease expense was $212 and $258 for the years ended December 31, 2022 and 2021, respectively, included in general and administrative expenses, which is net of the related party license fee of $242 and $189 for the years ended December 31, 2022 and 2021, respectively (see Note 10).

Future minimum lease payments under non-cancellable operating leases as of December 31, 2022 were as follows:

Year Ended December 31,	Amount
2023	$ 266
2024	176
2025	7
Total future minimum lease payments	449
Imputed interest	(26)
Total liability	$ 423

The following table summarizes the cash paid for amounts included in the measurement of lease liabilities for the years ended December 31, 2022 and 2021:

	Years Ended December 31,	
	2022	2021
Cash paid for amounts included in measurement of lease liabilities:	$ (342)	$ (324)

Note 8 – Convertible Note, Term Debt and Long-Term Debt

On July 16, 2021 (the "Effective Date"), the Company entered into a loan facility (the "Kreos Loan Agreement") with Kreos Capital VI (Expert Fund) LP (the "Lender"). Under the Kreos Loan Agreement, the Lender will provide the Company with access to term loans in an aggregate principal amount of up to $12,000 (the "Loan") in three tranches as follows: (a) on the Effective Date, a loan in the aggregate principal amount of $4,000 (the "Convertible Note", or "Tranche A"), (b) on the Effective Date, a loan in the aggregate principal amount of $5,000 ("Tranche B"), and (c) available until December 31, 2021, a loan in the aggregate principal amount of $3,000 ("Tranche C", together with Tranche B, the "Long-term Debt"). The Kreos Loan Agreement contains customary representations and warranties, indemnification provisions in favor of the Lender, events of default and affirmative and negative covenants, including, among others, covenants that limit or restrict the Company's ability to, among other things, incur additional indebtedness, merge or consolidate, make acquisitions, pay dividends or other distributions or repurchase equity, make investments, dispose of assets and enter into certain transactions with affiliates, in each case subject to certain exceptions. Outstanding borrowings under the Loan are secured by a first priority security interest on substantially all of the personal property assets of the Company, including the Company's material intellectual property and equity interests in its subsidiaries. There are no liquidity or financial covenants.

The Convertible Note and Tranche B were funded on the Effective Date. As of December 31, 2021, the Company drew down the full $3,000 aggregate principal amount of Tranche C.

The Convertible Note requires forty-eight monthly interest only payments at 7.75% per annum commencing after the Effective Date and thereafter full payment of the then outstanding principal balance of the Convertible Note on July 1, 2025. The Kreos Loan Agreement contains features that would permit the Lender to convert all or any portion of the outstanding principal balance of the Convertible Note at any time, pursuant to which the converted part of the Convertible Note will be converted into that number of shares of common stock of the Company to be issued to the Lender at a price per share equal to the conversion price, of $28 per share. Following the conversion of any portion of the outstanding principal balance of the Convertible Note, the principal balance of the Convertible Note remaining outstanding shall continue to bear interest at 7.75% per annum. The Tranche B loan requires interest only monthly payments commencing on the Effective Date until September 30, 2022 and, thereafter, thirty-three monthly payments of principal and interest accrued thereon until June 1, 2025. The Tranche C loan requires interest only monthly payments commencing on the date of the draw down until September 30, 2022 and, thereafter, thirty-two monthly payments of principal and interest accrued thereon until June 1, 2025.

In connection with the Kreos Loan Agreement, the Company also issued to the Lender a warrant ("Warrant"), dated July 16, 2021, to purchase up to 9,547 shares of the Company's common stock, at an exercise price of $20.948 per share, payable in cash or on a cashless basis according to the formula set forth in the Warrant. The exercise price of the Warrant and the number of shares issuable upon exercise of the Warrant are subject to adjustments for stock splits, combinations, stock dividends or similar events. The Warrant is exercisable until the date that is ten years after the date of issuance. The Company concluded that the Warrant is indexed to its own stock and, accordingly is classified as equity. See note 11 for further discussion of the Warrant.

The Company treated Tranche A, Tranche B and Tranche C, and the Warrant as three separate freestanding financial instruments with the proceeds received in connection with the transaction allocated amongst the instruments based on relative fair value. The proceeds received in connection with the transaction allocated amongst the instruments based on relative fair value resulted in $165 being allocated to the Warrant and a corresponding amount recorded as a debt discount to the Convertible Note and Long-term Debt. The Company recorded an aggregate debt discount of $845 related to the Loan, inclusive of the debt discount of $165 in connection to the Warrant, which will be amortized to interest expense over the term of each respective tranche using the effective interest method. The Company also paid $540 in cash for debt issuance costs. Additionally, per the Kreos Loan Agreement, with respect to the Long-term Debt, there is an advance payment of $274 that is recorded at a debt discount. The advance payment represents the last month's payment in relation to the Long-term Debt. There is also an end of loan payment of $140 which is included on the balance sheet as a liability within the Long-term Debt and also within the total aggregate debt discount of $845.

Subsequent to the issuance of the consolidated financial statements for the year ended December 31, 2021, the Company identified that the current portion of long-term debt was incorrectly classified as non-current on the balance sheet as of December 31, 2021. Management evaluated this misstatement and concluded it was not material to the financial statements and therefore, the Company elected to correct the current portion of long-term debt as of December 31, 2021 in these consolidated financial statements for comparative purposes.

For the year ended December 31, 2022, interest expense for the Loan was as follows:

	Year Ended December 31,	
	2022	2021
Contractual interest expense	$ 1,001	$ 362
Amortization of debt issuance costs	330	91
Total interest expense	$ 1,331	$ 453

Future principal payments under the Convertible Note as of December 31, 2022 are as follows:

Years Ending December 31,	Amount
2023	$ -
2024	-
2025	4,000
Total future principal payments	4,000
Less unamortized debt issuance costs	(108)
Total balance	$ 3,892

Future principal payments under the Term Debt as of December 31, 2022 are as follows:

Years Ending December 31,	Amount
2023	$ 2,714
2024	2,983
2025	1,601
Total future principal payments	7,298
End of loan payments	140
Less unamortized debt issuance costs of current portion of long-term debt	(182)
Less unamortized debt issuance costs of non-current portion long-term debt	(135)
Total balance	$ 7,121

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 ended December 31, 2022 and 2021. 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 $1,426 and $1,419 as of December 31, 2022 and 2021, 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 Company's ongoing commercialization and generation of sales, which is subject to significant risk and uncertainty. The Company has no obligation to repay these grants if no significant sales are generated. The Company has recorded an immaterial expense for the years ended December 31, 2022 and 2021, and an immaterial liability at December 31, 2022 and 2021.

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, 2022 and 2021 (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, 2022.

** 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, 2022.

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 March 2039 jx). 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, 2022 and 2021 in the amount of $1,212 and $1,760, respectively. A gain on change in fair value of contingent royalty obligation of $548 for the year ended December 31, 2022 and a loss on change in fair value of contingent royalty obligation of $143 was recorded for the year ended December 31, 2021.

Other Commitments and Contingencies

The Company has a severance contingency for severance payments to its CEO, COO, and CFO in the aggregate of approximately $1,408, 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.

Manufacturing Component Purchase Obligations

The Company utilizes two outsourcing partners to manufacture its workstation and disposable portions of the Pure-Vu System, and to perform final assembly and testing of finished products. These outsourcing partners acquire components and build product based on demand information supplied by the Company. As of December 31, 2022, the Company expects to pay $41 under manufacturing-related supplier arrangements within the next year, substantially all of which is noncancelable.

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. (OBIO), 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. Pursuant to the Shared Space Agreement, the Company granted a license to OBIO for the use of portions of the office space not being used by the Company in the Company's leased facility in Fort Lauderdale, Florida (the "Premises"), and a proportionate share of common areas of such Premises, which previously covered approximately 35% of the Premises and was to expand incrementally to approximately 60 to 70% of the Premises by September 2024. In May 2022, the Company entered into an amendment to the Shared Space Agreement. Pursuant to the amendment, the area covered by the Shared Space Agreement was expanded to 95% of the premises and the aggregate license fees will generally range from approximately $212 to approximately $270 in any given calendar year during the term of the Shared Space Agreement until the termination of the lease in November 2024. During the year ended December 31, 2022 and 2021, the Company recorded a license fee of $242 and $189, respectively, in relation to the Shared Space Agreement. This amount is netted with rent expense in general and administrative expenses.

Note 11 – Share-based compensation and Common Stock Issuance

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, 2022 and 2021:

	Year ended December 31,	
	2022	2021
Research and development	$ 388	$ 575
Sales and marketing	238	353
General and administrative	1,183	2,544
Total	$ 1,809	$ 3,472

For the year ended December 31, 2022 and 2021, the Company recorded $1,145 and $2,270, respectively, for share-based compensation expense related to stock options.

As of December 31, 2022, unamortized share-based compensation for stock options was $964, with a weighted-average recognition period of 0.87 years.

For the year ended December 31, 2022 and 2021, the Company recorded $57 and $335, respectively, for share-based compensation expense related to warrants.

For the year ended December 31, 2022 and 2021, the Company recorded $607 and $867, respectively, for share-based compensation expense related to restricted stock units.

As of December 31, 2022, unamortized stock compensation for restricted stock units was $308, with a weighted-average recognition period of 0.81 years.

Stock option and warrant activity

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, 2022, pursuant to an annual evergreen provision, the number of shares of common stock reserved for future grants was increased by 279,586 shares. Under the 2016 Plan, effective as of January 1, 2023, the maximum number of shares of the Company's common stock authorized for issuance is 804,371. As of December 31, 2022, there were 15,165 shares of common stock available for future grant under the 2016 Plan.

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

	Options				Warrants			
	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Average Intrinsic Value	Shares Underlying Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Average Intrinsic Value
Outstanding at December 31, 2020	251,419	$ 60.00	7.96	$ -	852,820	$ 37.20	5.78	$ -
Granted	64,675	$ 32.80			326,548	$ 41.40		
Forfeited	(8,502)	$ 68.60			(45,758)	$ 100.00		
Exercised	(713,363)	$ 24.80			-	$ -		
Outstanding at December 31, 2021	307,592	$ 54.10	7.45	$ -	420,247	$ 54.76	3.40	$ -
Granted	102,997	$ 8.73			6,000	$ 10.00		
Expired	(6,597)	$ 64.24			(26,986)	$ 101.13		
Cancelled	-	$ -			(6,000)	$ 56.60		
Forfeited	(3,855)	$ 11.48			-	$ -		
Outstanding at December 31, 2022	400,137	$ 42.69	7.21	$ -	393,261	$ 50.86	2.66	$ -
Exercisable at December 31, 2022	294,152	$ 52.77			393,261	$ 50.86		

The options granted during the years ended December 31, 2022 and 2021 were valued using the Black-Scholes option pricing model using the following weighted average assumptions:

	For the year ended December 31,	
	2022	2021
Expected term, in years	5.8	5.8
Expected volatility	99.21%	106.24%
Risk-free interest rate	2.10%	0.77%
Dividend yield	-	

The grant date fair value for stock options issued during the years ended December 31, 2022 and 2021 were $8.62 and $26.4, respectively.

Restricted Stock Units

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

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2020	16,891	$ 62.00
Granted	21,300	34.20
Vested	(12,071)	48.40
Nonvested at December 31, 2021	25,120	$ 44.77
Granted	18,250	9.07
Vested	(23,092)	39.53
Nonvested at December 31, 2022	20,278	$ 18.62

As of December 31, 2021, there were 3,138 vested and unissued restricted stock units. These restricted stock units were issued as common stock during the year ended December 31, 2022.

Issuance of Warrants to Purchase Common Stock

In February 2020, the Company entered into a services agreement whereby it agreed to issue warrants to purchase 6,000 shares of common stock of the Company. The warrants fully vested over a one-year period on a monthly basis and expire three years from the date of issuance and were exercisable at weighted average exercise price equal to $56.60 per share of common stock. In March 2022, the Company granted new warrants as a replacement to the vested warrants held by the service provider, for which all the share-based compensation expense had been recognized in prior fiscal periods. The issuance of new warrants concurrently with the cancellation of the existing warrants was treated as a modification. The Company agreed to issue replacement warrants to purchase 6,000 shares of common stock of the Company exercisable at a price equal to $10 per share of common stock. The fair value of the warrants were valued on the date of grant at $0.38 using the Black-Scholes option-pricing model with the following parameters: (1) risk-free interest rate of 0.91%; (2) expected life in years of 1.62; (3) expected stock volatility of 81.97%; and (4) expected dividend yield of 0%. The replacement warrants immediately vested upon issuance and expire three years from the date of issuance. As a result, the Company recognized $26 of share-based compensation for the year ended December 31, 2022, related to the incremental fair value which is equal to the excess of the fair value of the new warrants granted over the fair value of the original award on the cancellation date.

Issuance of Common Stock

On January 5, 2022, non-employee members of the Board of Directors were granted an aggregate of 24,458 shares of fully-vested common stock with a fair value of $9.60 per share of common stock, as compensation, in lieu of $235 of cash compensation, for service as directors for 2022. The Company recorded $235 and $177 in expense for director services during the year ended December 31, 2022 and 2021, respectively.

In March 2021, we entered into an Equity Distribution Agreement (the "Equity Distribution Agreement") with Oppenheimer & Co. Inc. ("Oppenheimer"), under which we may offer and sell from time to time common shares having an aggregate offering price of up to $25.0 million. During the year ended December 31, 2022, we sold approximately 2.2 million shares of our common stock under this agreement, resulting in net cash proceeds of $9.9 million, after deducting issuance costs of $0.4 million. From January 1, 2023 to March 14, 2023, the Company issued and sold approximately 119,104 common shares of our common stock under this agreement, resulting in net cash proceeds of approximately $118.0 thousand, after deducting issuance costs $4.0 thousand.

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, 2022 and 2021.

As of December 31, 2022 and 2021, the Company had deferred tax assets of approximately $37,400 and $27,200, respectively, against which a full valuation allowance of $37,400 and $27,200, respectively had been recorded. The change in the valuation allowance for the year ended December 31, 2022 was an increase of $10,200. The increase in the valuation allowance for the year ended December 31, 2022 was mainly attributable to increases in net operating losses and non-deductible research expenses, 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, 2022 and 2021 were as follows:

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards – Federal and state	$ 14,614	$ 5,281
Net operating loss carryforwards – Israel	18,813	19,354
Share-based compensation	1,735	1,732
Capitalized research and development	2,246	218
Accrued liabilities and reserves	681	831
Total deferred tax assets	38,089	27,416
Deferred tax liabilities:		
Accelerated research and development expense	(548)	-

Right of use asset	(109)	(158)
Other	(34)	(14)
Total deferred tax liabilities	(691)	(172)
Net deferred tax assets before valuation allowance	37,398	27,244
Valuation allowance	(37,398)	(27,244)
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, 2022 and 2021 is as follows:

	For the Year Ended December 31,	
	2022	2021
U.S. federal statutory tax rate	21.0%	21.0%
State income taxes, net of federal benefit	6.6	2.0
U.S. vs. foreign tax rate differential	0.8	0.9
Non-deductible expenses	(2.7)	(1.9)
Foreign exchange adjustments	(10.7)	2.5
Change in valuation allowance	(15.0)	(24.5)
Effective tax rate	-%	-%

The Company had approximately $134,100 and $119,600 of gross net operating loss ("NOL") carryforwards (federal, state and Israel) as of December 31, 2022 and 2021, 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.

The Tax Cuts and Jobs Act of 2017 (TCJA) has modified the IRC 174 expenses related to research and development for the tax years beginning after December 31, 2021. Under the TCJA, the Company must now capitalize the expenditures related to research and development activities and amortize over five years for U.S. activities and 15 years for non-U.S. activities using a mid-year convention. Since this has been the Company's policy since 2019, the current year capitalization of research and development costs in accordance with IRC 174 was $4,900,000 for a total accumulated gross amount of $8,800,000 as of December 31, 2022.

During the year ended December 31, 2021, the Company incurred an ownership change under Internal Revenue Code Section 382, resulting in an annual NOL utilization limitation of approximately $3,700. None of the Company's NOL carryforwards or deferred tax assets were required to be reduced since the limitation did not preclude the Company from potentially utilizing all of its NOL carryforwards. Future significant ownership changes could cause a portion or all of the Company's NOL carryforwards to expire before utilization, however.

A reconciliation of the Company's NOLs for the years ended December 31, 2022 and 2021 is as follows:

	December 31,	
	2022	2021
U.S. Federal NOL's	$ 26,875	$ 18,420
U.S. State NOL's	25,464	17,009
Israel NOL's	81,794	84,148
Total NOL's	$ 134,133	$ 119,577

The Company's federal and state NOLs of $3,300 and $25,464, respectively, begin to expire after 2036 through 2042. The Company's federal NOL of $23,575, generated since 2018, and the Israel NOL of $81,794 do not expire. A check the box election for Israel was made and accepted by the IRS as of January 1, 2019. As such, approximately $38,100 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, 2022 and 2021 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.

Note 13 – Subsequent Events

In January 2023, the Company committed to a restructuring initiative designed to position the Company to explore a range of strategic and financing alternatives focused on maximizing stockholder value and accelerating the commercialization of the Pure-Vu System. The Company has engaged Lake Street Capital Markets LLC ("Lake Street Capital") to advise the Company in this process. Potential strategic alternatives that may be considered by the Company are expected to include an acquisition, merger, reverse merger, other business combination, sale of assets, licensing and other strategic transactions. The restructuring initiative primarily includes the reduction of the Company's workforce. The Company intends to continue to evaluate and identify other areas of its business to enhance efficiencies and improve processes, with a goal to further lower its operating expenses and capital needs. The Company expects to reduce its quarterly cash expenditures by approximately 35% by eliminating approximately 45% of its workforce during the first quarter of 2023. In connection with the restructuring, the Company expects to incur a non-recurring charge of approximately $1.0 to $2.0 million in the first quarter of 2023.