
**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, 2017
OR

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

For the transition period from _____ to _____

Commission file number: 001-38389

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

DELAWARE
(State or other jurisdiction of
incorporation or organization)

81-4042793
(I.R.S. Employer
Identification No.)

1301 East Broward Boulevard, 3rd Floor
Ft. Lauderdale, FL
(Address of principal executive offices)

33301
(Zip code)

786 459 1831
(Registrant's telephone number, including area code)

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

Title of Each Class
Common Stock, par value \$0.0001 per share

Name of Each Exchange on Which Registered
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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of June 30, 2017, the last business day of the registrant's most recently completed second fiscal quarter, there was no established public market for the registrant's Common Stock. The registrant's Common Stock began trading on the NASDAQ Capital Market on February 14, 2018. Accordingly, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant computed by reference to the price of the registrant's Common Stock as of the registrant's most recently completed second fiscal quarter cannot be determined.

The number of shares outstanding of the registrant's Common Stock, par value of \$0.0001 per share, as of March 1, 2018 was 15,574,752.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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

For the Year Ended December 31, 2017

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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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

ITEM 1. BUSINESS

Overview

We have developed a single-use medical device system (the “Pure-Vu system”), cleared by the United States Food and Drug Administration (the “FDA”), that is intended to connect to standard colonoscopes to help facilitate intraprocedural cleaning of a poorly prepared colon by irrigating or cleaning the colon and evacuating the irrigation fluid (water), feces and other bodily fluids and matter. The Pure-Vu system has been designed to integrate with standard colonoscopes to enable cleaning during the procedure while preserving standard procedural workflow and techniques. Our Pure-Vu system and the procedure to cleanse the colon in preparation for colonoscopy are not currently reimbursable through private or governmental third-party payors in any country, but we intend to seek reimbursement through private or governmental third-party payors in the future. 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. We will look to expand the Pure-Vu system indication to allow us to actively promote minimal prep capabilities directly to patients. We plan to initiate a clinical trial in 2018 that should facilitate approval of expanded labeling in 2019. To date, as part of our limited pilot launch, we have focused on collecting clinical data on the use of the Pure-Vu system. We do not expect to generate significant revenue from product sales unless and until we expand our commercialization efforts.

Our business was spun out from the New Generation Technology (“NGT”) incubator based in Nazareth, Israel in 2011 to focus exclusively on the development of the Pure-Vu system. We initiated preclinical testing in 2011 and started clinical testing of the first prototype version of the Pure-Vu system in Europe in late 2012. In clinical studies performed in Europe and Israel from 2012 through the second quarter of 2017, the Pure-Vu system and earlier prototype versions have demonstrated effective cleaning in over 175 patients that followed a significantly reduced pre-procedural colonoscopy preparation regimen, as compared to current prep regimens.

Market Overview

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

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

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

Our Pure-Vu Solution

To address this unmet need, we have developed our FDA-cleared Pure-Vu system, which readily integrates with existing colonoscopes to cleanse poorly prepped colons during the colonoscopy procedure. The Pure-Vu system has been cleared by the FDA to help facilitate intra-procedural cleaning of a poorly prepared colon by irrigating or cleaning the colon and evacuating the irrigation fluid (water), feces and other bodily fluids and matter. We believe that the technology may be useful in the future as a tool to help reduce user dependency on conventional pre-procedural bowel prep regimens.

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

The Pure-Vu System



In the out-patient setting, the Pure-Vu system could create the opportunity to improve patient satisfaction and enhance diagnostic quality. Additionally, in the in-patient hospital setting, the Pure-Vu system could create the opportunity to improve the time to prepare for and complete a successful colonoscopy.

Out-patient Opportunity: improving patient experience and reducing repeat procedures

The Pure-Vu system is currently cleared to help facilitate intra-procedural cleaning of a poorly prepared colon by irrigating or cleaning the colon and evacuating the irrigation fluid (water), feces and other bodily fluids and matter, e.g., blood. In this context, users are able to address visualization concerns and complete endoscopic examinations when patients are found to be poorly prepared by standard colon preparation methods. We believe that our technology may be useful in the future as a tool to help reduce user dependency on conventional pre-procedural bowel prep regimens, and we are gathering data and intend to seek FDA clearance or approval for expanded claims.

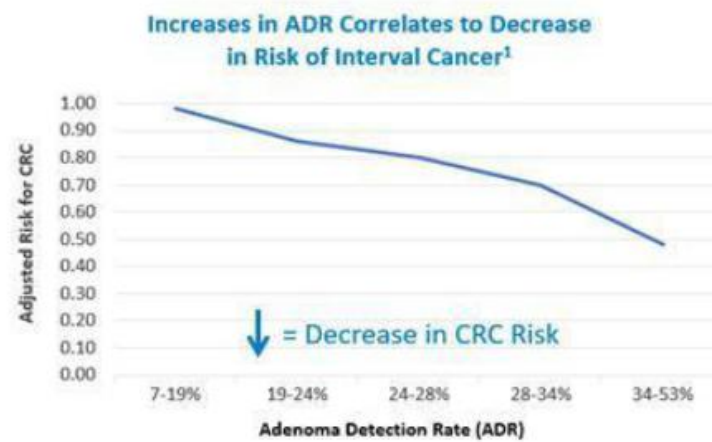
The largest commercial market opportunity presented by the Pure-Vu system in relation to these expanded claims is in the out-patient setting offering patients an alternative to the arduous experience of having to drink large volumes of purgatives that result in significant discomfort, multiple visits to the bathroom over a many-hour period and disruption of daily activities. Market research conducted by The Nova Group, which was sponsored by us, indicates that 83% of patients are willing to pay an out-of-pocket premium, depending on the cost, for this type of technology and the ability to follow a “less-prep” regimen. According to The Nova Group market research, 29% of patients indicated they were willing to consider paying an out-of-pocket cost of up to \$350, despite believing such cost to be expensive, for the ability to follow a “less-prep” regimen, while 10% believed \$350 to be an appropriate out-of-pocket price. Similarly, according to the same research, 58% of patients indicated they were willing to consider paying an out-of-pocket cost of up to \$250, despite believing such cost to be expensive, for the ability to follow a “less-prep” regimen, while 20% believed \$250 to be an appropriate out-of-pocket price. This research suggests that as the potential out-of-pocket cost of a “less-prep” regimen and examination is reduced, the percentage of patients willing to consider paying increases dramatically.

Physicians are also motivated to improve bowel preparation. Market research conducted by Healthcare Research & Analytics, which was sponsored by us, indicates, 99% of physicians understand ADR is influenced by bowel cleanliness and 68% believe ADR will be tied to reimbursement in the next three years. With increasing pressure on physician and facility reimbursement, most providers are incorporating ancillary services into their practices to supplement their revenue and increase profit. Incorporation of a “less-prep” regimen as an ancillary product into an out-patient GI practice is expected to provide an additional source of revenue and profit as well as help to differentiate the GI practice in an increasingly competitive marketplace. By offering a solution to those patients who either cannot tolerate the challenging preparation or desire a more tolerable prep, we believe the GI practice can increase their market share and improve patient satisfaction, a key quality metric being measured by payors. A “less-prep” regimen could also facilitate late afternoon and early evening procedures for those patients wishing to avoid disruption in their daily activities. Finally, with a “less-prep” regimen, the prep may no longer be as significant of a deterrent to receiving a colonoscopy, potentially increasing compliance to screening and ultimately increasing the early detection of CRC.

Based on published literature in several peer reviewed journals from 2010 to 2015 and surveys of physicians conducted in 2015, approximately 23% of patients can have an inadequate preparation, which may lead to repeat procedures earlier than the medical guidelines suggest and decrease the ADR negatively affecting the quality of the exam. If a physician has the ability to effectively cleanse the colon intra-procedurally, a “less-prep” regimen could provide the ability to turn a fair or poor preparation into an optimal preparation and achieve a high-quality colonoscopy. Further, increased cleanliness (which may be achieved through use of the Pure-Vu system), as measured by the Boston Bowel Preparation Score, or BBPS, the most commonly used method for evaluating the quality of bowel preparation, is associated with an increase of adenoma detection, which in turn predicts a decrease in CRC risk.



1: Quantification of Adequate Bowel Preparation for Screening or Surveillance Colonoscopy in Men Brian T. Clark et al. Gastroenterology 2016; 150:396-405



1: Adenoma Detection Rate and Risk of Colorectal Cancer and Death Douglas A. Corley et al. N Engl J Med. 2014 April 3; 370(14): 1298-1306

In-patient Opportunity: improving efficiencies and shortening time to complete a successful colonoscopy

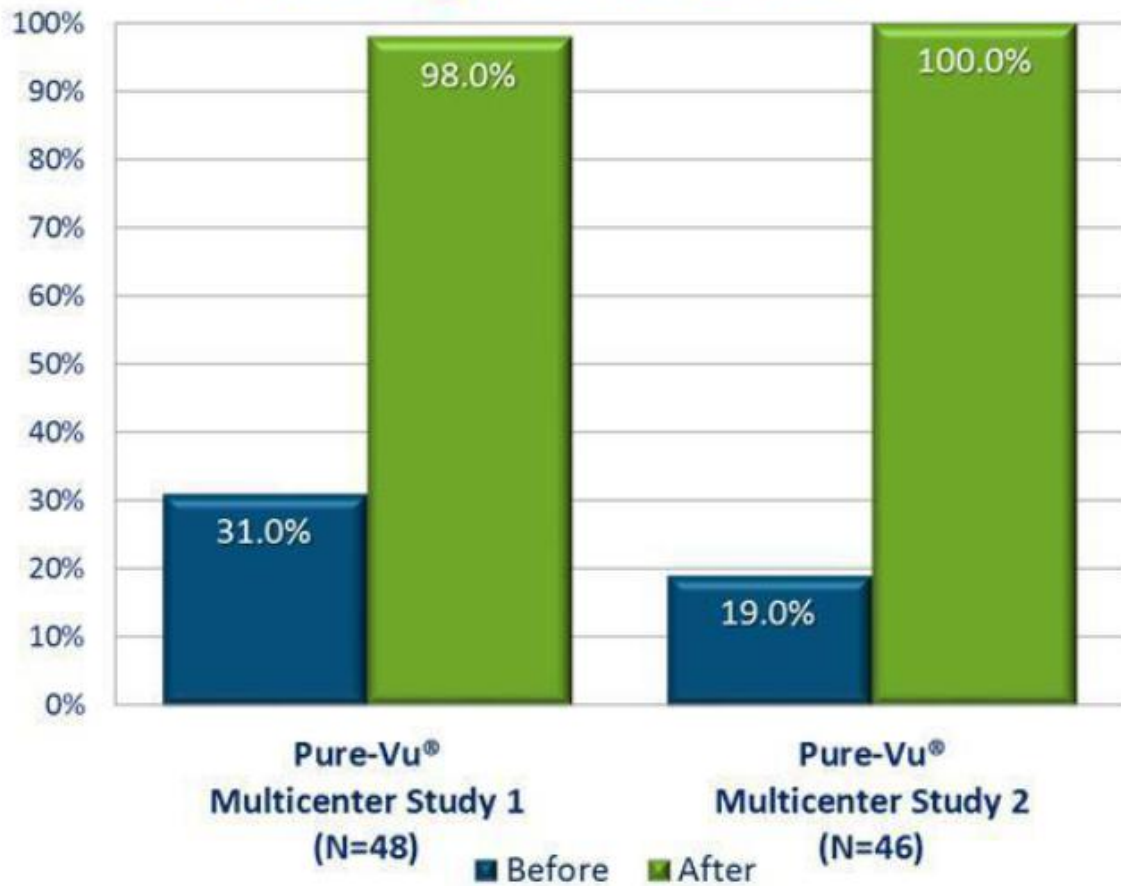
In-patient colonoscopy is usually performed to diagnose the source of various gastrointestinal conditions such as lower GI bleeding or bowel pain. For an in-patient hospital stay, the Centers for Medicare and Medicaid Services, or CMS, uses a prospective payment system, or PPS, based upon diagnostic related groups, or DRG, to pay for hospital services with the goal of encouraging providers to minimize their costs. The DRG assignment is influenced by a combination of factors such as a patient's sex, diagnosis at the time of discharge and procedures performed. Based on patient specific information, all hospital expenses for their care during an inpatient stay are packaged and assigned to one of over 500 MS-DRGs. According to Decision Driver Analytics, a reimbursement consulting agency, when a colonoscopy is performed as the primary procedure (no other procedures or complicating diagnosis), DRGs 395, 394 or 393 would apply which pay between \$3,861 (without complications or major comorbidities) and \$9,421 (with major complications and comorbidities). The cost for just one night in the hospital averages \$1,800, so reducing the length of stay can save the hospital significant expense.

An in-patient colonoscopy is more problematic than an out-patient procedure due primarily to poorer quality bowel prep which can lead to lower rates of successful completion of the procedure and a higher frequency of repeat procedures. In-patients are difficult to prep as exemplified by inadequate bowel prep rates, which have been reported in the literature as high as 45% for the in-patient setting. Managing these patients is a challenge often requiring significant healthcare provider resources to administer and monitor the prep. The poor bowel prep can be due to the patient's condition as a more fragile patient population may be unable to tolerate the significant volume of fluid required, and the clear liquid diet required, to cleanse the colon. With these patients, a high volume of purgative can also lead to electrolyte imbalances. The Pure-Vu system is cleared by the FDA for use as an aid to facilitate cleansing in patients with poor bowel preparation. The impact of the Pure-Vu system on the duration of procedures has not been established. There is a need for a system that can shorten the time to successfully complete a colonoscopy by streamlining the process with effective and safe intra-procedural cleaning thus reducing healthcare costs.

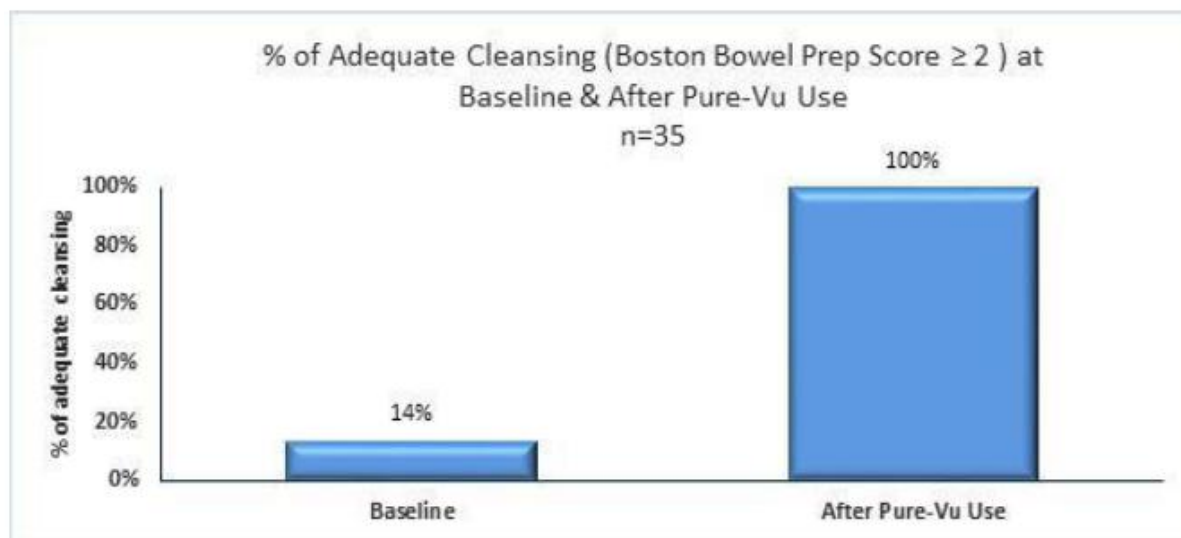
Pre-Clinical and Clinical Data & Safety

In clinical studies performed in Europe and Israel, the Pure-Vu system and earlier prototype versions have demonstrated effective cleaning in over 175 patients receiving a reduced prep regimen. The first 83 patients used three different versions of the system. The prep regimen used in these patients varied from taking a 50% dose of the standard PEG based prep to as little as taking 20mg of over-the-counter Dulcolax® (bisocodyl). More recently, the commercial version of the Pure-Vu system was used in two multi-center clinical studies. The first study involved 48 patients and was completed in the second quarter of 2016. The second study was completed in June 2017 and involved 46 patients. Patients in these studies had a restricted diet for 18-24 hours and received a split dose of 20mg of over-the-counter Dulcolax® (bisocodyl). Patients did not take any liquid purgative traditionally prescribed for bowel preparation. The clinical data showing performance of the Pure-Vu system in these studies using the BBPS, is shown below. The clinical results from the 2016 study were presented at United European Gastroenterology Week ("UEGW") in October 2016. The clinical results from the 2017 study were presented at the UEGW in October 2017, showing similar results, as shown below.

% of Subjects Adequately Prepped According to BBPS Standard



In addition, pre-clinical experience in a porcine animal model, which was used in the FDA submission, was also presented at Digestive Disease Week (“DDW”) in May 2016. In this study the animals were fasted from normal feed following the Day -2 morning meal. On the afternoon of Day -2, the animals received a standard three (3) liters of PEG-based colon preparation agent (Golytely®). This data is presented below.



We are planning to initiate post-market surveillance and clinical study programs that may involve registries, investigator sponsored studies and company sponsored studies to drive clinical and health economic data, to support product development, enhance our marketing efforts and facilitate new indications. The first of these studies was initiated in the fourth quarter of 2017 and will continue into 2018.

The Pure-Vu system is currently indicated to connect to standard colonoscopes to help facilitate intra-procedural cleaning of a poorly prepared colon by irrigating or cleaning the colon and evacuating the irrigation fluid (water), 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. We will look to expand the Pure-Vu system indication to allow us to promote minimal prep capabilities directly to patients. We plan to initiate a clinical trial in 2018 that should facilitate approval of expanded labeling in 2019.

We received CE Mark approval in Europe in February 2018. We intend to establish relationships with strategic partners for Europe, Japan, China and other key markets outside the U.S. (“OUS”) to support the regulatory process and market entry. We anticipate entering OUS markets with our second-generation Pure-Vu system during the second half of 2019. We filed for and received special 510(k) clearance from the FDA in the fourth quarter of 2017 to adjust our labeling to simplify the process of removing the Pure-Vu system from a colonoscope and to support minor enhancements to the manufacturing of the system.

Intellectual Property

Our IP position comprises a highly innovative portfolio covering technologies rooted in systems and methods for cleaning body cavities with or without the use of an endoscope. Currently we have three (3) issued U.S. patents, three (3) issued Japanese patents, one issued EU patent and 31 (11 in the U.S.) pending patent applications in various regions of the world with a focus on the U.S., EU and Japan. Our earliest patent application filing dates go back to October 2007. We have also recently received notice of allowance for Motus GI and for Pure-Vu trademarks from the USPTO. We are pursuing these marks in the EU as well.

Our issued patents cover:

- one patent for an endoscopic device insertable into a body cavity and movable in a predetermined direction and method of moving the endoscopic device in a body cavity, which expires in October 2026;
- three patents for system and methods for cleaning body cavities, which expire in the U.S. in 2031;
- and three patents for an apparatus and method for coupling between a colonoscope and add-on tubes, which expire in the U.S. in 2035.

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

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

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

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

Our Formation

In connection with our formation in September 2016, we sold an aggregate of 1,650,000 shares of our common stock, par value \$0.0001 per shares (the “Common Stock”) for an aggregate of \$82,500 (\$0.05 per share).

The Share Exchange Transaction

Effective on December 1, 2016, Motus GI Medical Technologies Ltd., an Israeli Company (“Opco”), and the holders of all issued and outstanding shares of capital stock of Opco (the “Opco 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 private placement offering of units we conducted from December 2016 to February 2017 (the “2017 Private Placement”), the Opco Stockholders sold to us, and we acquired, all of the issued and outstanding shares of capital stock of Opco (the “Share Exchange Transaction”) and Opco became our direct wholly-owned subsidiary. Pursuant to the Share Exchange Transaction (i) the Opco Stockholders received an aggregate of 4,000,000 shares of our Common Stock in exchange for all of the issued and outstanding shares of capital stock of Opco, (ii) the Convertible Notes (as defined below) and the Convertible Note Warrants (as defined below) were exchanged for our securities, as described below, and (iii) all of the issued and outstanding options to purchase or otherwise acquire shares of Opco capital stock that were outstanding and unexercised as of immediately prior to the Initial Closing were substituted for 125,730 options to acquire shares of our Common Stock pursuant to our 2016 Equity Incentive Plan at exercise prices ranging from \$2.38 to \$2.52 (see “Part III—Item 11—Executive Compensation—2016 Equity Incentive Plan”).

The Share Exchange Transaction was treated as a recapitalization of Opco for financial accounting purposes and the historical financial statements of Opco are our financial statements as a result of the Share Exchange Transaction.

2017 Private Placement and Exchange of Convertible Notes

In connection with the 2017 Private Placement we issued an aggregate of 3,080,671 units, at a purchase price of \$5.00 per unit, with each unit (a “Unit”) consisting of (i) three-quarter (3/4) of a share of our Common Stock, and (ii) one-quarter (1/4) of a share of our convertible preferred stock, par value \$0.0001 (the “Series A Convertible Preferred Stock”), for gross proceeds of approximately \$15.4 million, comprised of an aggregate of 2,310,504 shares of our Common Stock and 770,168 shares of Series A Convertible Preferred Stock to investors in the 2017 Private Placement.

In addition, from June 2015 through November 2016, pursuant to the terms of a convertible note agreement, as amended (the “CNA”), Opco issued convertible notes (the “Convertible Notes”) in an aggregate amount of approximately \$14.6 million (inclusive of accrued interest through December 22, 2016, the date of the Initial Closing) to certain investors, including related parties of us and Opco. As part of the 2017 Private Placement, at the Initial Closing, the holders of the Convertible Notes (the “Convertible Holders”) exchanged their Convertible Notes (the “Exchange of Convertible Notes”), together with accrued and unpaid interest thereon at a rate of 10% per annum, for Units of the 2017 Private Placement, at a conversion price of \$4.50 per Unit. As a result, upon consummation of the Initial Closing, the Convertible Notes were exchanged for an aggregate of 3,243,768 Units representing (i) 2,432,808 shares of our Common Stock (inclusive of shares of our Common Stock resulting from the accrued and unpaid interest of the Convertible Notes through the date of the Initial Closing) and (ii) 810,960 shares of our Series A Convertible Preferred Stock (inclusive of shares of Series A Convertible Preferred Stock resulting from the accrued and unpaid interest of the Convertible Notes through the date of the Initial Closing).

Exchange of Convertible Note Warrants

In connection with, and pursuant to the terms of, the CNA, each Convertible Holder also received a seven (7) year warrant (the “Convertible Note Warrants”) to purchase preferred A shares of Opco (the “Preferred A Shares of Opco”), nominal value NIS 0.01 per share, with an exercise price per share of \$1.00 (the “Convertible Note Warrant Exercise Price”). Each Convertible Note Warrant entitled the holder to purchase that number of shares of Preferred A Shares of Opco equal to thirty-three percent (33%) of the principal amount of the Convertible Note in connection with which it was issued. Convertible Note Warrants to purchase an aggregate 4,536,188 shares of Preferred A Shares of Opco with an exercise price of \$1.00 were issued in connection with the CNA. At the Initial Closing, the holders of the Convertible Note Warrants exchanged their Convertible Note Warrants for five (5) year warrants (the “Exchange Warrants”) to purchase an aggregate 907,237 shares of our Common Stock at an exercise price of \$5.00 per share, such amount being equal to thirty-three percent (33%) of the principal amount of the Convertible Notes divided by \$5.00.

Initial Public Offering

On February 16, 2018, we completed our initial public offering of 3,500,000 shares of our Common Stock at a public offering price of \$5.00 per share, with gross proceeds of \$17.5 million (the “IPO”). Simultaneously with the closing of our IPO, all 1,581,128 previously outstanding shares of our Series A Convertible Preferred Stock were converted, on a one-to-one basis, into an aggregate of 1,581,128 shares of our Common Stock. No shares of our Series A Convertible Preferred Stock remain outstanding as a result of such conversion. Additionally, at the closing of our IPO, we issued warrants to certain of our former Series A Convertible Preferred Stock holders, pursuant to an amendment to our registration rights agreement entered into with the investors in our 2017 Private Placement (the “Registration Rights Agreement”) and an amendment to our Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (the “Certificate of Designation”), to purchase 1,095,682 shares of our Common Stock (the “Ten Percent Warrants”). The Ten Percent Warrants are exercisable for our Common Stock at an exercise price of \$5.00. The Ten Percent Warrants are exercisable any time on or after the 180 day anniversary of the completion of our IPO, have a five year term, and provide for cashless exercise. Certain related parties received Ten Percent Warrants, see “Part III—Item 13—Certain Relationships and Related Transactions, and Director Independence—Ten Percent Warrants – Related Party Participation.” Certain related parties purchased shares of our Common Stock in our IPO, see “Part III—Item 13—Certain Relationships and Related Transactions, and Director Independence—Participation in Initial Public Offering.”

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

Competition

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

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

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

Research and Development

We incurred expenses of approximately \$4.3 million and \$3.1 million, respectively, during the years ended December 31, 2017 and 2016 for research and development activities. These expenses include cash and non-cash expenses relating to the development 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.

We have received, and may receive in the future, grants from the Government of the State of Israel through the Israel Innovation Authority of the Ministry of Economy and Industry (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 Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984 (formerly known as the Encouragement of Industrial Research and Development Law, 5744-1984), referred to as the Research Law, and related regulations.

As of December 31, 2017, we had received grants from the IIA in the aggregate amount of \$1.33 million, and had a contingent obligation to the IIA up to an aggregate amount of approximately \$1.37 million. As of December 31, 2017, 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 have been reduced in the past and may be further reduced in the future, we cannot predict whether we will be entitled to any future grants, or the amounts of any such grants.

In exchange for these grants, we are required to pay royalties to the IIA of 3% to 3.5% from our revenues on sales of products and services based on technology 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 terms of the Israeli government participation also require that products developed with IIA grants be manufactured in Israel and that the technology developed thereunder may not be transferred outside of Israel (including by way of certain licenses), unless prior approval is received from the IIA, which we intend to apply for but may not be granted. Even if such approval is granted, the transfer outside of Israel of manufacturing which is connected with the IIA-funded know-how may result in increased royalties (up to three times the aggregate amount of the IIA grants plus interest thereon), as well as in a higher royalty repayment rate. In addition, the transfer outside of Israel of IIA-funded know-how may trigger additional payments to the IIA (up to six times the aggregate amount of the IIA grants plus interest thereon). Even following the full repayment of any IIA grants, we must nevertheless continue to comply with the requirements of the Research Law. The foregoing restrictions and requirements for payment may impair our ability to sell our technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any IIA-funded product or technology outside of Israel.

If we fail to comply with any of the conditions and restrictions imposed by the Research Law, 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.

A significant amendment to the Research Law entered into effect on January 1, 2016 (the "Amendment"), under which the IIA, a statutory government corporation, was established, which replaced the OCS. Under the Amendment, the IIA is authorized to establish rules concerning the ownership and exploitation of IIA/OCS-funded know-how (including with respect to restrictions on transfer of manufacturing activities and IIA-funded know-how outside of Israel), which may differ from the restrictive laws, regulations and guidelines as currently in effect (and which shall remain in effect until such rules have been established by the IIA). Recently published rules of the IIA have generally adopted the principal provisions and restrictions specified in the Research Law prior to the Amendment. It is anticipated that additional rules will be published by the IIA and we cannot predict or estimate the changes (if any) that may be made to this legislation (including with respect to the acquisition of an IIA-funded entity or the transfer of manufacturing or ownership of IIA-funded technology outside of Israel).

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

Manufacturing and Supply

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

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

U.S. Market Entry Strategy

We have initiated a limited pilot launch in the U.S. market. Initial evaluation cases have been performed at eight centers showing cleansing capabilities similar to our clinical trial experience. This pilot phase is expected to run through 2018 with the primary objectives of expanding our clinical evidence, developing a practice integration model and creating key reference centers in both the AEC and hospital in-patient settings. We intend to work with the initial accounts to perform clinical studies to gather data for seeking expanded indications for use (such as from the FDA) and to optimize the prep for various populations including patients that have problems tolerating the prep and in-patients. For example, we expect to initiate post-market in-patient studies in the first half of 2018 to examine the ability to improve outcomes and address lower GI bleeds using the Pure-Vu system, and expect results for these trials in the fourth quarter of 2018 and second quarter of 2019, respectively. We also expect to initiate an in-patient study for the veteran population, and expect results from this trial in the second half of 2019. For out-patients, we expect to initiate trials to support reimbursement later this year with results from these trials anticipated in the second half of 2019.

We are working with a third party logistics provider specializing in medical devices to provide front and back office support to successfully fulfill customer orders. Additionally our commercial organization is putting in place the infrastructure to track account progress and help provide accurate forecasting for operations. We anticipate the sales cycle to be in the range of six to twelve months. During our limited pilot market entry, we will refine our commercialization strategy and tactics prior to our full market launch which is expected in 2019. Our full market launch will focus on launching our second generation Pure-Vu system platform (lower cost of goods, added features, and additional size for "slim" scopes), growing the top line revenues, scaling the commercial organization and expanding our clinical indications for use. We expect to develop strategic relationships to pursue OUS marketing opportunities and to initiate sales in the EU in 2019 and Japan, China and other Asian markets in 2020.

Employees

As of December 31, 2017, we had 39 full time employees. All of our employees are engaged in administration, finance, clinical, R&D, engineering, regulatory or sales and marketing functions. We believe our relations with our employees are good. We anticipate that the number of employees will grow as we scale our commercial capabilities. In addition, we utilize and will continue to utilize consultants, clinical research organizations and third parties to perform our pre-clinical studies, clinical studies, manufacturing and regulatory functions.

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

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

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

Regulatory Matters

Government Regulation

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

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

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

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

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

- Class I devices present a low risk and are not life-sustaining or life-supporting. The majority of Class I devices are subject only to “general controls” (e.g., prohibition against adulteration and misbranding, registration and listing, good manufacturing practices, labeling, and adverse event reporting. General controls are baseline requirements that apply to all classes of medical devices.)
- Class II devices present a moderate risk and are devices for which general controls alone are not sufficient to provide a reasonable assurance of safety and effectiveness. Devices in Class II are subject to both general controls and “special controls” (e.g., special labeling, compliance with performance standards, and post market surveillance. Unless exempted, Class II devices typically require FDA clearance before marketing, through the premarket notification (510(k)) process.)
- Class III devices present the highest risk. These devices generally are life-sustaining, life-supporting, or for a use that is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury. Class III devices are devices for which general controls, by themselves, are insufficient and for which there is insufficient information to determine that application of special controls would provide a reasonable assurance of safety and effectiveness. Class III devices are subject to general controls and typically require FDA approval of a premarket approval (“PMA”) application before marketing.

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

510(k) pathway

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

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

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

Premarket approval pathway

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

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

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

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

Clinical trials

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

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

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

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

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

Pervasive and continuing FDA regulation

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

- Establishment registration and device listing requirements;
- Quality System Regulation (“QSR”), which governs the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of finished devices;
- Labeling requirements, which mandate the inclusion of certain content in device labels and labeling, and generally require the label and package of medical devices to include a unique device identifier (“UDI”), and which also prohibit the promotion of products for uncleared or unapproved, i.e., “off-label,” uses;
- Medical Device Reporting (“MDR”) regulation, which requires that manufacturers and importers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and
- Reports of Corrections and Removals regulation, which requires that manufacturers and importers report to the FDA recalls (i.e., corrections or removals) if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health; manufacturers and importers must keep records of recalls that they determine to be not reportable.

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

- Untitled letters or warning letters;
- Fines, injunctions and civil penalties;
- Recall or seizure of our products;
- Operating restrictions, partial suspension or total shutdown of production;
- Refusing our request for 510(k) clearance or premarket approval of new products;
- Withdrawing 510(k) clearance or premarket approvals that are already granted; and
- Criminal prosecution.

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

International

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

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

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

Other Regulatory Matters

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

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

Third-Party Payor Coverage and Reimbursement

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

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

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

In addition, in some foreign countries, the proposed pricing for a medical device must be approved before it may be lawfully marketed. The requirements governing medical device pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be 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 products 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 product candidates in those countries would be negatively affected.

Other Healthcare Laws and Compliance Requirements

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

- The Anti-Kickback Statute (“AKS”) makes it illegal for any person, including a device manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, or order of a particular device, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it.
- The Federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between \$10,957 and \$21,916 for each separate false claim and the potential for exclusion from participation in federal healthcare programs. Conduct that violates the False Claims Act also may implicate various federal criminal statutes. The government may deem manufacturers to have “caused” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute also are deemed false or fraudulent claims for purposes of the False Claims Act. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product and any future product candidates, are subject to scrutiny under this law.
- HIPAA which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”) and its implementing regulations, also imposes certain obligations, including contractual terms and technical safeguards, with respect to maintaining the privacy, security and transmission of individually identifiable health information.
- HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions.
- The Federal Physician Payments Sunshine Act within the Affordable Care Act, and its implementing regulations, which requires that certain manufacturers of devices and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members; and
- Analogous state and foreign fraud and abuse laws and regulations, such as anti-kickback and false claims laws, which may apply to sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts. Such laws are generally broad and are enforced by various state agencies and private actions.

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

Current and future legislation

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

With the new Administration and Congress, there will likely be additional administrative or legislative changes, including modification, repeal, or replacement of all, or certain provisions of, the Affordable Care Act, which may impact reimbursement for medical devices. On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress has attempted several times to repeal and replace the Affordable Care Act, yet to date no complete repeal has occurred. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the Affordable Care Act. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. Litigation and legislation over the Affordable Care Act are likely to continue, with unpredictable and uncertain results.

Additional laws and regulations governing international operations

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

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

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

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

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 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, 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, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed \$1.07 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our Common Stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than \$1 billion in non-convertible debt during the preceding three-year period. We intend to take advantage of these reporting exemptions described above until we are no longer an "emerging growth company." Under the JOBS Act, "emerging growth companies" can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

Corporate and Available Information

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

Our principal executive offices are located at 1301 East Broward Boulevard, 3rd Floor, Ft. Lauderdale, FL 33301. Our 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 will make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any 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 we electronically file such material with, or furnish it to, the SEC. Our SEC reports can be accessed through the Investors section of our internet website. Further, a copy of this Annual Report on Form 10-K is located at the SEC's Public Reference Rooms at 100 F Street, N.E., Washington, D. C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements and other information regarding our filings at <http://www.sec.gov>.

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

ITEM 1A. RISK FACTORS

Risks Related to Our Financial Position and Need for Capital

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

Our financial statements as of December 31, 2017 were prepared under the assumption that we will continue as a going concern. The independent registered public accounting firm that audited our 2017 financial statements, in their report, included an explanatory paragraph referring to our recurring losses since inception and expressing substantial doubt in our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our ability to continue as a going concern depends on our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. We cannot assure you, however, that we will be able to achieve any of the foregoing.

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

We expect to incur substantial expenses without corresponding revenues unless and until we expand our commercialization efforts. To date, as part of our limited launch, we have generated limited revenue from our Pure-Vu system, but we do not expect to generate significant revenue from product sales unless and until we expand our commercialization efforts, which we expect will take a number of years and 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, 2017 and December 31, 2016 was approximately \$13.2 million and \$8.0 million, respectively. As of December 31, 2017, we had an accumulated deficit of approximately \$39.1 million.

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

We are currently operating at a loss and expect our operating costs will increase significantly as we incur costs associated with commercialization activities related to our Pure-Vu system. Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern in their report on our financial statements. At December 31, 2017, we had a cash and cash equivalents balance of approximately \$6.9 million. Based on our current business plan, we believe the net proceeds of approximately \$15.2 million from our IPO completed in February 2018, and additional net proceeds of approximately \$250,000 from the Partial IPO Over-Allotment Exercise completed in March 2018, together with our cash and cash equivalents balance as of December 31, 2017, will be sufficient to meet our anticipated cash requirements through approximately the second quarter of 2019.

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

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

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

- our revenue growth rate and ability to generate cash flows from operating activities;
- our sales and marketing and research and development activities;
- costs of and potential delays in product development;
- changes in regulatory oversight applicable to our products; and
- costs related to international expansion.

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

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

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

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

As a result of the Share Exchange Transaction, our ability to utilize our federal net operating loss, carryforwards and federal tax credit may be limited under Sections 382 of the Internal Revenue Code of 1986, as amended (the "Code"). The limitations apply if an "ownership change," as defined by Section 382, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect "five percent shareholders" increases by more than 50 percentage points over their lowest ownership percentage at any time during the applicable testing period (typically three years). In addition, future changes in our stock ownership, which may be outside of our control, may trigger an "ownership change" and, consequently, Section 382 limitations. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

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

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

Risks Related to Government Regulation and Third-Party Reimbursement

We are subject to complex and costly regulation.

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

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

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

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

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

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

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

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

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

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

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.

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

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

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

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

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

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

Our promotional materials and training methods for our Pure-Vu system must comply with FDA and other 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. 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 does not restrict or regulate a physician’s choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials, training or marketing efforts constitute promotion of an off-label use, it could request that we modify our training or promotional materials or marketing efforts or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties. Although we do not intend to engage in any activities that may be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged, directly or indirectly, in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could result in substantial damage awards against us and harm our reputation.

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

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

Risks Related to Our Business Operations

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

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

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

We are a medical technology company with a limited operating history. We received clearance from the FDA, and CE Mark approval in Europe, for our Pure-Vu system and have recently initiated a limited pilot launch that will run through 2018. We plan to then move into a full market launch during 2019. We expect that sales of our Pure-Vu system will account for substantially all of our revenue for the foreseeable future. However, we have limited experience in selling our products and we may be unable to successfully commercialize our Pure-Vu system for a number of reasons, including:

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

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

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

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

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

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

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

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

- demonstration of clinical safety and efficacy;
- relative convenience, burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe the Pure-Vu system and of the target patient population to try new procedures;
- efficacy of our Pure-Vu system compared to competing procedures;
- the introduction of any new products and procedures that may in the future become available for colonoscopy preparation may be approved;
- pricing and cost-effectiveness;
- the inclusion or omission of our Pure-Vu system in applicable treatment guidelines;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in FDA-approved labeling;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture our Pure-Vu system, as well as the other related device components for high volume commercial purposes. We do have capability to produce limited units for use in our clinical trials, if required. As a result, we are obligated to rely on contract manufacturers for the commercial supply of our product. We currently rely on two manufacturers, 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 Research Law, and related regulations.

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

If we fail to comply with any of the conditions and restrictions imposed by the Research Law, 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, 2017, we had 39 full time employees. As our marketing and commercialization plans and strategies develop, we will need to expand the size of our employee and consultant base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize the Pure-Vu system and any other future product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage our future growth.

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

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

We depend on key members of our management team. The loss of the services of Mark Pomeranz, our Chief Executive 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. In connection with the Share Exchange Transaction, we entered into an employment agreement with our Chief Executive Officer, but this agreement is terminable by Mr. Pomeranz on short or no notice at any time without penalty. We also entered into an employment agreement with our Chief Financial Officer, and this agreement is also terminable by Mr. Taylor on short or no notice at any time without 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 significant portion of our operating expenses, including personnel and facilities related expenses, are incurred in NIS. As a result, we are exposed to the risks that the NIS may appreciate relative to the U.S. dollar, or, if the NIS instead devalues relative to the U.S. dollar, that the inflation rate in Israel may exceed such rate of devaluation of the NIS, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected. Given our general lack of currency hedging arrangements to protect us from fluctuations in the exchange rates of the NIS and other foreign currencies in relation to the U.S. dollar (and/or from inflation of such foreign currencies), we may be exposed to material adverse effects from such movements. We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the NIS against the U.S. dollar.

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

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

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

Risks Related to our Capital Stock

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

Our officers, directors, entities controlled by our officers and directors, and principal stockholders who beneficially own more than 5% of our Common Stock, in the aggregate, beneficially own shares representing approximately 55.95% of our outstanding capital stock as of March 1, 2018. As a result, such entities and individuals have the ability, acting together, to control the election of our directors and the outcome of corporate actions requiring stockholder approval, such as: (i) a merger or a sale of our company, (ii) a sale of all or substantially all of our assets, and (iii) amendments to our certificate of incorporation and bylaws. This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other stockholders and be disadvantageous to our stockholders with interests different from those entities and individuals. These individuals also have significant control over our business, policies and affairs as officers and directors of our company.

Our quarterly operating results may be subject to significant fluctuations.

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

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

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

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

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

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

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

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

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

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

- actual or anticipated fluctuations in our quarterly or annual operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares; additions or departures of key management or other personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;

- announcement or expectation of additional debt or equity financing efforts;
- sales of our Common Stock by us, our insiders or our other stockholders; and
- general economic, market or political conditions in the United States or elsewhere.

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

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

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

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

Pursuant to the terms of the Royalty Payment Rights Certificates (as defined in "Part II—Item 5—Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities—Recent Sales of Unregistered Securities—2017 Private Placement") which were issued in connection with the conversion of all of our outstanding shares of Series A Convertible Preferred Stock upon the consummation of our IPO, we may be required to make certain royalty payments. After we generate sales of the current and potential future versions of the Pure-Vu system, including disposables, parts, and services, in excess of \$20 million since our inception, then we will be required to pay to the holders of our Royalty Payment Rights Certificates a royalty equal to (i) three percent (3%) of our net sales, if any, in any calendar year, not in excess of \$30 million per year. Additionally, after we receive any proceeds from the licensing of the current and potential future versions of the Pure-Vu system in excess of \$3.5 million since our inception, then we will be required to pay to the holders of the Royalty Payment Rights Certificates a royalty equal to 5% of our licensing proceeds, if any, in any calendar year, not in excess of \$30 million per year. The royalties will be payable up to the later of (i) the latest expiration date for our current patents (which is currently October 2026), or (ii) the latest expiration date of any pending patents as of the date of the Initial Closing that may be issued in the future.

Additionally, pursuant to the terms of the Placement Agent Royalty Payment Rights Certificates (as defined in "Part II—Item 5—Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities—Recent Sales of Unregistered Securities—2017 Private Placement") 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, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed \$1.07 billion, (ii) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our Common Stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than \$1 billion in non-convertible debt during the preceding three year period.

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

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

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

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

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

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

Proper systems of internal controls over financial accounting and disclosure controls and procedures are critical to the operation of a public company. As we have a limited operating history, we only have 5 employees, and 3 contractors in our finance and accounting functions, which may result in a lack of segregation of duties and are at the very early stages of establishing, and we may be unable to effectively establish such systems, especially in light of the fact that we expect to operate as a publicly reporting company. This would leave us without the ability to reliably assimilate and compile financial information about our company and significantly impair our ability to prevent error and detect fraud, all of which would have a negative impact on our company from many perspectives.

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

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

We may be 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 for the first fiscal year beginning after the effective date of our registration statement on Form S-1 (Registration Number 333-222441, declared effective in February 2018). This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting, as well as a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting. We are in the very early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of December 31, 2017, we had received grants from the IIA in the aggregate amount of \$1.33 million, and had a contingent obligation to the IIA up to an aggregate amount of approximately \$1.37 million. As of December 31, 2017, 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 have been reduced in the past and may be further reduced in the future, we cannot predict whether we will be entitled to any future grants, or the amounts of any such grants.

In exchange for these grants, we are required to pay royalties to the IIA of 3% to 3.5% from our revenues on sales of products and services based on technology 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 terms of the Israeli government participation also require that products developed with IIA grants be manufactured in Israel and that the technology developed thereunder may not be transferred outside of Israel (including by way of certain licenses), unless prior approval is received from the IIA, which we intend to apply for but may not be granted. Even if such approval is granted, the transfer outside of Israel of manufacturing which is connected with the IIA-funded know-how may result in increased royalties (up to three times the aggregate amount of the IIA grants plus interest thereon), as well as in a higher royalty repayment rate. In addition, the transfer outside of Israel of IIA-funded know-how may trigger additional payments to the IIA (up to six times the aggregate amount of the IIA grants plus interest thereon). Even following the full repayment of any IIA grants, we must nevertheless continue to comply with the requirements of the Research Law. The foregoing restrictions and requirements for payment may impair our ability to sell our technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any IIA-funded product or technology outside of Israel.

If we fail to comply with any of the conditions and restrictions imposed by the Research Law, 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.

A significant amendment to the Research Law entered into effect on January 1, 2016 (the "Amendment"), under which the IIA, a statutory government corporation, was established, which replaced the OCS. Under the Amendment, the IIA is authorized to establish rules concerning the ownership and exploitation of IIA/OCS-funded know-how (including with respect to restrictions on transfer of manufacturing activities and IIA-funded know-how outside of Israel), which may differ from the restrictive laws, regulations and guidelines as currently in effect (and which shall remain in effect until such rules have been established by the IIA). Recently published rules of the IIA have generally adopted the principal provisions and restrictions specified in the Research Law prior to the Amendment. It is anticipated that additional rules will be published by the IIA and we cannot predict or estimate the changes (if any) that may be made to this legislation (including with respect to the acquisition of an IIA-funded entity or the transfer of manufacturing or ownership of IIA-funded technology outside of Israel).

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.

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We currently rent 7,732 square feet of space in Tirat Carmel, Israel. This facility is used for office space as well as laboratories for product development. We entered the lease on January 1, 2015, and the lease is for a period of five-years. Annual rent is \$82,000 per year.

On April 13, 2017, we entered into a lease for a facility in Fort Lauderdale, Florida, which we began occupying in October 2017. The facility currently consists of 4,554 square feet, which will increase to 6,390 square feet by the second year of the lease. The term will run for seven years and two months from October 2017. Annual base rent is initially \$156,555 per year, subject to annual increases of 2.75%. This facility will be used for office space as well as laboratories for both quality assurance and product development.

We believe our facilities are adequate for our foreseeable needs.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Our Common Stock trades on the NASDAQ Capital Market under the symbol "MOTS". Trading of our Common Stock commenced on February 14, 2018 in connection with our IPO. Prior to that time, there was no established public trading market for our Common Stock. As a result, we have not set forth quarterly information with respect to the high and low prices for our Common Stock for the two most recent fiscal years.

Holder of Record

As of March 1, 2018, we had approximately 320 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.

Dividend Policy

We have never declared or paid cash dividends on our Common Stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends to holders of our Common Stock in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects, then applicable contractual restrictions and any other factors deemed relevant by our board of directors.

Recent Sales of Unregistered Securities

During the period covered by this Form 10-K, or such period as described below, we made sales of the following unregistered securities:

2017 Private Placement

From December 2016 through February 2017, we sold an aggregate of 4,743,311 shares of our Common Stock and 1,581,128 shares of Series A Convertible Preferred Stock at a price of \$5.00 per Unit, inclusive of 2,432,808 shares of our Common Stock and 810,960 shares of Series A Convertible Preferred Stock issued pursuant to the Exchange of Convertible Notes, to 229 accredited investors (the "2017 Private Placement").

In connection with the 2017 Private Placement, we issued (i) the Placement Agent Warrants (the "Placement Agent Warrants") to the placement agent (the "Placement Agent") for our 2017 Private Placement to purchase 403,632 shares of our Common Stock with an exercise price of \$5.00 per share and (ii) the Placement Agent Royalty Payment Rights Certificates (the "Placement Agent Royalty Payment Rights Certificates") 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 our Common Stock, which conversion occurred simultaneously with the closing of our IPO in February 2018.

Service Provider Stock and Warrants

In May 2017, we issued a service provider (a) 90,000 shares of our Common Stock, subject to a lock-up agreement, and (b) five (5) year warrants to purchase 30,000 shares of our Common Stock with an exercise price of \$8.00 per share, as partial payment for services pursuant to a consulting agreement between the service provider and us.

During August, September, and October 2017, we issued a service provider an aggregate of 4,167 shares, pursuant to the terms of the agreement with such service provider.

Issuance Pursuant to Exercise of Stock Option

In May 2017, we issued 754 shares of our Common Stock pursuant to the exercise of a stock option.

Stock Options

During the period covered by this Form 10-K, we have granted stock options under our 2016 Equity Incentive Plan to purchase an aggregate of 2,020,769 shares of our Common Stock with a weighted average exercise price of \$4.51.

Unrestricted Stock Awards

We have granted unrestricted stock awards under our 2016 Equity Incentive Plan for an aggregate of 5,000 shares of our Common Stock.

Securities Act Exemptions

We deemed the offers, sales and issuances of the securities described above under “Part II—Item 5—Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities—Recent Sales of Unregistered Securities” to be exempt from registration under the Securities Act of 1933, as amended (the “Securities Act”), in reliance on Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, relative to transactions by an issuer not involving a public offering. All purchasers of securities in transactions exempt from registration pursuant to Regulation D represented to us that they were accredited investors and were acquiring the shares for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

We deemed the grants of stock options and issuances of our Common Stock upon exercise of such options, and the share awards, described above under “Part II—Item 5—Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities—Recent Sales of Unregistered Securities” to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder and Rule 701 of the Securities Act as offers and sales of securities under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701. Each of the recipients of securities in any transaction exempt from registration either received or had adequate access, through employment, business or other relationships, to information about us.

All certificates representing the securities issued in the transactions described in “Part II—Item 5—Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities—Recent Sales of Unregistered Securities” included appropriate legends setting forth that the securities had not been offered or sold pursuant to a registration statement and describing the applicable restrictions on transfer of the securities. There were no underwriters employed in connection with any of the transactions set forth in “Part II—Item 5—Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities—Recent Sales of Unregistered Securities”. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Use of Proceeds from Registered Securities

On February 13, 2018, our registration statement on Form S-1 (Registration No. 333-222441) was declared effective by the SEC for our IPO pursuant to which we sold an aggregate of 3,500,000 shares of our Common Stock at a price to the public of \$5.00 per share, for an aggregate offering of approximately \$17.5 million. Piper Jaffray & Co. acted as the sole book-running manager and Oppenheimer & Co. acted as lead manager for the offering. On February 16, 2018, we closed the sale of 3,500,000 shares, resulting in net proceeds to us of \$15.2 million after deducting underwriting discounts and commissions and other offering expenses. On March 12, 2018 we closed the sale of an additional 56,000 shares pursuant to the Partial IPO Over-Allotment Exercise, resulting in net proceeds to us of approximately \$250,000 after deducting underwriting discounts and commissions. No payments were made by us to directors, officers or persons owning ten percent or more of our Common Stock or to their associates, or to our affiliates. There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on February 15, 2018 pursuant to Rule 424(b).

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

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

Overview

We have developed a single-use medical device system (the "Pure-Vu system"), cleared by the United States Food and Drug Administration (the "FDA"), that is intended to connect to standard colonoscopes to help facilitate intraprocedural cleaning of a poorly prepared colon by irrigating or cleaning the colon and evacuating the irrigation fluid (water), feces and other bodily fluids and matter. The Pure-Vu system has been designed to integrate with standard colonoscopes to enable cleaning during the procedure while preserving standard procedural workflow and techniques. Our Pure-Vu system and the procedure to cleanse the colon in preparation for colonoscopy are not currently reimbursable through private or governmental third-party payors in any country, but we intend to seek reimbursement through private or governmental third-party payors in the future. 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. We will look to expand the Pure-Vu system indication to allow us to actively promote minimal prep capabilities directly to patients. We plan to initiate a clinical trial in 2018 that should facilitate approval of expanded labeling in 2019. To date, as part of our limited pilot launch, we have focused on collecting clinical data on the use of the Pure-Vu system. We do not expect to generate significant revenue from product sales unless and until we expand our commercialization efforts.

Our business was spun out from the New Generation Technology ("NGT") incubator based in Nazareth, Israel in 2011 to focus exclusively on the development of the Pure-Vu system. We initiated preclinical testing in 2011 and started clinical testing of the first prototype version of the Pure-Vu system in Europe in late 2012. In clinical studies performed in Europe and Israel from 2012 through the second quarter of 2017, the Pure-Vu system and earlier prototype versions have demonstrated effective cleaning in over 175 patients that followed a significantly reduced pre-procedural colonoscopy preparation regimen, as compared to current prep regimens.

Financial Operations Overview

We are a development stage company and have not generated any significant revenues from the sale of products. We have never been profitable and our accumulated deficit as of December 31, 2017 was approximately \$39.1 million. Our net loss for the years ended December 31, 2017 and 2016 was approximately \$13.2 million and \$8.0 million, respectively. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase significantly in connection with our ongoing activities to commercialize and market the Pure-Vu system. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need additional financing to support our continuing operations. We will seek to fund our operations through public or private equity or debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

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

- conduct a limited pilot launch through 2018 to refine how the Pure-Vu system integrates into the workflow of both the out-patient and in-patient settings;
- contract with third parties to scale up the manufacture of the workstation and the disposable portion of Pure-Vu system;
- develop a second generation system to improve user interface, optimize ease of use and reduce the cost structure;
- raise sufficient funds in the capital market to effectuate our business plan, including commercialization activities related to our Pure-Vu system and our research and development activities, including clinical and regulatory development and the continued development and enhancement of our Pure-Vu system; and
- operate as a public company.

Critical Accounting Policies and Estimates

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

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

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

Revenue

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

Research and Development

We incurred expenses of approximately \$4.3 million and \$3.1 million, respectively, during the years ended December 31, 2017 and 2016 for research and development activities. These expenses include cash and non-cash expenses relating to the advancement of our development and clinical programs for the Pure-Vu system. We have research and development capabilities in electrical and mechanical engineering with laboratories in our facility in Israel for development and prototyping, and electronics design and testing. We also use consultants and third-party design houses to complement our internal capabilities.

Sales and Marketing

We incurred expenses of approximately \$2.4 million and \$1.0 million, respectively, during the years ended December 31, 2017 and 2016 for sales and marketing activities. These expenses include cash and non-cash expenses relating to the development of our sales and marketing infrastructure for the Pure-Vu system. We have hired limited sales and marketing personnel in the U.S. as part of our pilot launch to develop our policies and procedures, as well as to spearhead the pilot phase of the company's market penetration.

General and Administrative Expenses

We incurred expenses of approximately \$6.3 million and \$1.9 million, respectively, during the years ended December 31, 2017 and 2016 for general and administrative activities. General and administrative expenses consist primarily of payroll and professional services. Other general and administrative expenses include accounting and legal services and expenses associated with obtaining and maintaining patents. We anticipate that our general and administrative expenses will increase significantly during 2018 and in the future as we increase our headcount to support our continued development and commercialization activities related to our Pure-Vu system. We also anticipate increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations and communication costs associated with being a public company. Additionally, commencing in 2017, we began to compensate our outside directors.

Stock-Based Compensation

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

We recognize compensation costs resulting from the issuance of stock-based awards to employees, members of our Board of directors and consultants. The fair value of each option grant was estimated as of the date of grant using the Black-Scholes option-pricing model. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. Due to our limited operating history and limited volume of sales of our common stock, we estimated our volatility in consideration of a number of factors, including the volatility of comparable public companies. The expected term of options granted to employees under our stock plans is based on the average of the contractual term (generally 10 years) and the vesting period (generally 36 months). The expected term of options granted under the 2016 Plan, all of which qualify as "plain vanilla" per SEC Staff Accounting Bulletin 107, is based on the average of the 5.81 years. For non-employee options, the expected term is the contractual term and stock options granted to non-employee consultants are revalued at the end of each reporting period until vested and changes in their fair value are recorded as adjustments to expense over the related vesting period. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the expected term of the option. We have never paid dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future. Accordingly, we have assumed no dividend yield for purposes of estimating the fair value of our share-based compensation.

The following assumptions were used to estimate the fair value of stock options granted using the Black-Scholes option pricing model:

Fair value of common stock	\$	4.50 - \$5.00
Expected volatility		60%
Dividend Yield		0%
Risk-free interest		1.92% - 2.36%
Expected life of up to (years)		5.81

Emerging Growth Company Status

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

Results of Operations

Comparison of Year Ended December 31, 2017 and 2016

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

Research and Development

Research and development expenses for the year ended December 31, 2017 totaled approximately \$4.3 million, an increase of \$1.2 million over the \$3.1 million recorded for the year ended December 31, 2016. The increase in fiscal 2017 compared to fiscal 2016 was primarily attributable to increases of \$1.1 million in salaries and wages, \$0.6 million in materials, \$0.5 million in clinical and related, \$0.5 million in stock-based compensation, and \$0.03 million in other costs, partially offset by a decrease in subcontractor costs of \$1.1 million.

Sales and Marketing

Sales and marketing expenses for the year ended December 31, 2017 totaled approximately \$2.4 million, an increase of \$1.4 million over the \$1.0 million recorded for the year ended December 31, 2016. The increase in fiscal 2017 compared to fiscal 2016 was primarily attributable to increases of \$0.7 million in salaries and wages, \$0.2 million in marketing and training product units, \$0.2 million in subcontractor costs, \$0.1 million in travel costs, \$0.1 million in other costs, and \$0.1 million in stock-based compensation.

General and Administrative

General and administrative expenses for the year ended December 31, 2017 totaled approximately \$6.3 million, an increase of \$4.4 million over the \$1.9 million recorded for the year ended December 31, 2016. The increase in fiscal 2017 compared to fiscal 2016 was primarily attributable to increases of \$1.9 million in legal and professional fees, \$1.3 million in stock-based compensation, \$0.6 million in salaries and wages, \$0.5 million in public relations and investor communications fees, and \$0.2 million in other expenses.

Liquidity and Capital Resources

Since inception, we have experienced negative cash flows from operations. We have financed our operations primarily through sales of equity-related securities. At December 31, 2017, our accumulated deficit since inception was approximately \$39.1 million.

At December 31, 2017, we had total current assets of approximately \$8.3 million and current liabilities of approximately \$2.0 million resulting in working capital of \$6.3 million. Net cash used in operating activities for the year ended December 31, 2017 was approximately \$10.4 million, which includes a net loss of approximately \$13.2 million, offset by non-cash expenses of approximately \$2.6 million principally related to the increase in stock-based compensation expense of \$2.2 million and revaluation of contingent royalty obligation of \$0.3 million, approximately \$1.0 million of cash provided from a change in net working capital items principally related to the increase in accounts payable and accrued expenses, and approximately \$0.5 million of cash used from a change in net working capital items principally related to the increase in prepaid expenses, other current and long-term assets.

Cash used in investing activities for the year ended December 31, 2017 totaled approximately \$0.7 for the purchase of fixed assets.

Cash provided by financing activities for the year ended December 31, 2017 totaled approximately \$6.4 million. In January and February of 2017 we sold 1,098,849 shares of our common stock and 366,283 shares of our Series A Convertible Preferred Stock in the 2017 Private Placement which resulted in net proceeds to us totaling approximately \$6.5 million. In December 2017, we paid deferred financing fees of \$0.4 million in relation to our IPO.

At December 31, 2017, we had cash and cash equivalents of approximately \$6.9 million. On February 16, 2018, we closed our IPO in which we sold 3,500,000 shares of our Common Stock at a public offering price of \$5.00 per share. In connection with the closing of the IPO, we received net proceeds of approximately \$15.2 million after deducting underwriting discounts and commissions of approximately \$1.4 million and other offering expenses of approximately \$0.9 million. On March 12, 2018, we received net proceeds of approximately \$250,000 after deducting underwriting discounts and commissions of approximately \$22,000 in relation to the sale of an additional 56,000 shares of our Common Stock at a price of \$5.00 per share, pursuant to the Partial IPO Over-Allotment Exercise completed in March 2018. Based on our current business plan, we believe the net proceeds from the IPO and the Partial IPO Over-Allotment described above, together with our cash and cash equivalents balance as of December 31, 2017, will be sufficient to meet our anticipated cash requirements through approximately the second quarter of 2019.

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

The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our clinical development programs. 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 some or all of our planned clinical trials.

Contractual Obligations and Commitments

We may enter into contracts in the normal course of business with suppliers and other vendors for operating purposes. These contracts generally provide for termination on notice, and therefore we believe that our non-cancelable obligations under these agreements are not material. As of December 31, 2017, we had no material contractual obligations or commitments that will affect our future liquidity other than our leases for office space described below.

On January 1, 2015, we entered into a five year lease for a facility with 7,732 square feet of space in Tirat Carmel, Israel. Annual rent is \$82,000 per year.

On April 13, 2017, we entered into a lease for a facility in Fort Lauderdale, Florida, which we began occupying in October 2017. The facility currently consists of 4,554 square feet, which will increase to 6,390 square feet by the second year of the lease. The term will run for seven years and two months from October 2017. Annual base rent is initially \$156,555 per year, subject to annual increases of 2.75%.

Off-Balance Sheet Arrangements

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See pages F-1 through F-25 following the signature page of this Form 10-K.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2017. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2017, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management’s Annual Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management’s assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for “emerging growth companies”.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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

Name	Age	Position(s)
Mark Pomeranz	56	Chief Executive Officer and Director
Andrew Taylor	47	Chief Financial Officer
David Hochman	42	Chairman of the Board
Darren Sherman	46	Director
Gary Jacobs	60	Director
Samuel Nussbaum	69	Director
Shervin Korangy	43	Director
Gary J. Pruden	56	Director

Management

Mark Pomeranz, Chief Executive Officer and Director

Mr. Pomeranz has been Chief Executive Officer of Opco since 2014 and has served as our CEO since December 2016. Prior to joining Opco, from 2007 to 2014, Mr. Pomeranz was the founding CEO of Svelte Medical Systems, a start-up company that is currently commercializing a unique drug eluting stent platform in the EU. From 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 Corporation 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 Opco and his business and leadership experience in the medical technology sector; his broad scientific background is also seen as an asset to us.

Andrew Taylor, Chief Financial Officer

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

Directors

Mark Pomeranz, Chief Executive Officer and Director

See description under Management.

David P. Hochman, Chairman of the Board

Mr. Hochman has been Chairman of the Board of Opco since 2011 and has served on our board of directors as Chairman since December 2016. Since June 2006, Mr. Hochman has been Managing Partner of Orchestra Medical Ventures, LLC, an investment firm that employs a strategy to create, build and invest in medical technology companies intended to generate substantial clinical value and investor returns. He is also President of Accelerated Technologies, Inc., a medical device accelerator company managed by Orchestra. He has over twenty years of venture capital and investment banking experience. He is Chairman of Caliber Therapeutics and a director of BackBeat Medical, Inc. (where he is also President), and FreeHold Surgical, Inc., all of which are Orchestra portfolio companies. Mr. Hochman currently serves as a board member of Corbus Pharmaceuticals Holdings, Inc. (NASDAQ: CRBP), a clinical stage biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat rare, life-threatening inflammatory-fibrotic diseases with clear unmet medical needs. Mr. Hochman currently serves as a director of Adgero Biopharmaceuticals Holdings, Inc. Prior to joining Orchestra, Mr. Hochman was Chief Executive Officer of Spencer Trask Edison Partners, LLC, an investment partnership focused on early stage healthcare companies. He was also Managing Director of Spencer Trask Ventures, Inc. during which time he led financing transactions for over twenty early-stage companies. 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 for \$750 million. 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 (NASDAQ: OPK) in 2013 for over \$600 million. He currently serves on the board of two non-profit organizations: the Citizens Committee for New York City and the Mollie Parnis Livingston Foundation, for which he also serves as President. 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 Opco, 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 Opco since 2015 and has served on our board of directors since December 2016. Since 2009, Mr. Sherman has been a Managing Partner of Orchestra Medical Ventures, LLC, an investment firm that employs a strategy to create, build and invest in medical technology companies intended to generate substantial clinical value and investor returns. He has also served as Chief Technology Officer of Accelerated Technologies, Inc., a medical device accelerator company managed by Orchestra, since 2008. Mr. Sherman has over 20 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. He is the CEO and a Director of Caliber Therapeutics, Inc., CEO and a Director of FreeHold Surgical, Inc., and a Director of BackBeat Medical, Inc., all of which are Orchestra portfolio companies. Prior to joining Orchestra, from February 2002 until March 2008, Mr. Sherman held 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. He had responsibility for all neurovascular R&D and global strategic marketing responsibilities for the stroke franchise, including budgets, a portfolio of products and strategic planning. Mr. Sherman made contributions to the design and commercialization of a series of products including the Enterprise Vascular Reconstruction Device and the Orbit Embolic Coil. From January 1997 until February 2002, Mr. Sherman was involved in the formation and development of Revivant Corp (acquired by Zoll Medical Corporation) while working at Fogarty Engineering. At Revivant, he 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, and Baxter Healthcare. Mr. Sherman has authored more than sixty-five U.S. patents and has over eighty 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 Opco and his leadership experience at other companies, including medical technology companies.

Gary Jacobs, Director

Mr. Jacobs has been a director of Opco since 2011 and has served on our board of directors since December 2016. Mr. Jacobs is the Founder and Managing Director at Jacobs Investment Company, LLC, and served as Chief Executive Officer of DermTech, Inc. He has served as Chairman of DermTech International since 2006, NGT New Generation Technologies Ltd., Galilee Tech Management Ltd., Remedor Biomed Ltd., Sebana Medical Ltd. and ParaSonic Ltd. He has been a Director of Fallbrook Technologies, Inc. since March 31, 2004. He serves as a Director of Bio2 Technologies, Inc., and Nutrinia Ltd. Mr. Jacobs served as a software engineer and senior education specialist of QUALCOMM, Inc. and as a software programmer at Linkabit Incorporated. He owns and operates a professional minor league baseball team, the Lake Elsinore Storm, affiliated with the San Diego Padres. In addition, Mr. Jacobs serves as Chair of the Dean's Advisory Council for Social Sciences at the University of California, San Diego and as Chairman of the Board of Trustees of High Tech High in San Diego. He serves as Vice Chairman and Chair-Elect of the Jewish Community Center Association Continental Board. Mr. Jacobs received his B.A. in Management Science from the University of California, San Diego in 1979. Mr. Jacobs was selected as a director due to his history as a director of Opco, his extensive experience serving on the board of directors of other companies, including medical technology companies, and his financial experience.

Samuel R. Nussbaum, M.D., Director

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

Shervin J. Korangy, Director

Mr. Korangy has served on our board of directors since March 2017. Mr. Korangy also serves as the Chief Financial Officer and Head of Strategy of Beaver-Visitec International ("BVI"), a leading global developer, manufacturer and marketer of specialized surgical devices for the ophthalmic marketplace. From 2012 to 2017, Mr. Korangy served in various country General Manager roles for the Alcon division of 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 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 member of the audit committee) of The Hain Celestial Group (NASDAQ: HAIN), a leading organic and natural products company, and a senior advisor to Sight Sciences LLC, a medical device growth stage business. Mr. Korangy 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 distributor 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 management experience with medical device, pharmaceutical and consumer health products, and his financial and accounting experience.

Gary J. Pruden, Director

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

Family Relationships

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

Code of Business Conduct and Ethics

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

Committees of the Board of Directors

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

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

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

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

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

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

Section 16(a) Beneficial Ownership Reporting Compliance

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

Our officers, directors and ten percent stockholders did not become subject to the reporting requirements of Section 16(a) until February 14, 2018 and, therefore, there were no reports required during the fiscal year ended December 31, 2017.

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, 2017, our two other most highly compensated executive officers who were serving as executive officers as of December 31, 2017, 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, 2017. The persons listed in the following table are referred to herein as the “named executive officers”.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$) (1)	All Other Compensation (\$)	Total (\$)
Mark Pomeranz	2017	350,000	87,500	639	1,122,788	30,712	1,591,639
<i>Chief Executive Officer</i>	2016	350,000	70,000	-	-	57,382	477,382
Andrew Taylor (3)	2017	110,625	27,000	-	601,050	9,492	748,167
<i>Chief Financial Officer</i>	2016	-	-	-	-	-	-
James Martin (5)	2017	93,154	-	639	289,934	7,182	390,909
<i>Former Chief Financial Officer</i>	2016	31,818	-	-	-	690	32,508

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

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

(3) James Martin began serving as our Chief Financial Officer on November 6, 2016, and ceased serving as our Chief Financial Officer effective June 9, 2017.

Narrative Disclosure to Summary Compensation Table

Employment Agreements with Our Named Executive Officers

In connection with the Share Exchange Transaction, we entered into an employment agreement with Mr. Pomeranz, which became effective on December 22, 2016 for a period of three years, which contains non-disclosure and invention assignment provisions. Under the terms of Mr. Pomeranz’s employment agreement, he holds the position of Chief Executive Officer, and is a member of the board of directors, and receives a base salary of \$350,000 annually, subject to adjustments in the discretion of the board of directors; and he received a signing bonus of \$70,000 upon the closing of the Share Exchange Transaction. In addition, Mr. Pomeranz is also eligible to receive an annual bonus, which is targeted at up to 25% of his base salary but which may be adjusted by our board of directors based on his individual performance and our performance as a whole. In connection with the final closing of the 2017 Private Placement, in May 2017 Mr. Pomeranz received a grant of options to purchase up to 511,113 shares of our Common Stock pursuant to our Equity Incentive Plan with an exercise price of \$5.00 per share, of which fifty-three percent (53%) were fully vested when issued, forty percent (40%) will vest in a series of twelve (12) successive equal quarterly installments upon the completion of each successive calendar quarter of active service over the three (3) year period measured from the date of grant, as was determined by the Compensation Committee of the board of directors, and seven percent (7%) will not become fully vested until three years from the date of his employment agreement. This option was repriced to \$4.50 per share in September 2017. In addition, pursuant to the terms of his employment agreement, Mr. Pomeranz is 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 by us 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 termination by us 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) payment as severance twelve months of his base salary; (iv) reimbursement of business expenses; and (v) 25% of any unvested options will vest upon termination.

On August 16, 2017, we entered into an employment agreement with Mr. Taylor, which became effective on August 16, 2017 (the "Commencement Date") for a period of two years, which contains non-disclosure and invention assignment provisions. Under the terms of Mr. Taylor's employment agreement, he holds the position of Chief Financial Officer and receives a base salary of \$295,000 annually, subject to adjustments in the discretion of the board of directors; and he will be eligible to receive a signing bonus of \$15,000 upon the date that is six (6) months following the Commencement Date. Mr. Taylor is also eligible to receive a relocation bonus of up to \$35,000 if Mr. Taylor elects to relocate to Florida. In addition, Mr. Taylor is also eligible to receive a first year bonus payable following the one year anniversary of the Commencement Date, which is targeted at \$30,000, and a second year bonus payable following the two year anniversary of the Commencement Date, which is targeted at \$35,000, both of which may be adjusted by our board of directors based on his individual performance and our performance as a whole. In connection with his employment agreement, in September 2017 Mr. Taylor received a grant of options to purchase up to 240,000 shares of our Common Stock pursuant to our Equity Incentive Plan with an exercise price of \$4.50 per share, which vests in a series of twelve (12) successive equal quarterly installments upon the completion of each successive calendar quarter of active service over the three (3) year period measured from the date of grant, as determined by the Compensation Committee of the board of directors. In addition, pursuant to the terms of his employment agreement, Mr. Taylor is 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 by us for cause or by Mr. Taylor without good reason, Mr. Taylor 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; (iii) any vested amount or benefit. In the event of termination by us without cause or by Mr. Taylor for good reason, Mr. Taylor 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; (iv) payment as severance six months of his base salary if Mr. Taylor has been actively employed in good standing by us for at least 91 days, or if Mr. Taylor has been actively employed in good standing with us for at least eighteen months, payment as severance nine months of his base salary; (v) payment of our portion of the cost of COBRA coverage for twelve months; and, (vi) accelerated vesting of any options that otherwise would have vested on the last day of the calendar quarter during which the termination date occurred.

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

Outstanding Equity Awards at Fiscal Year-End Table – 2017

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, 2017.

Name	Number of securities underlying unexercised options (#)		Option Exercise Price (\$)	Option Expiration Date
	Exercisable	Unexercisable		
Mark Pomeranz (CEO)	41,076(1)	26,162	2.38	March 26, 2024
	304,964(2)	206,149(2)	4.50(2)	May 3, 2027
Andrew Taylor (CFO)	20,000(3)	220,000(3)	4.50	September 28, 2027
James Martin (Former CFO) (4)	-	-	-	-

(1) Represents options to purchase shares of our Common Stock granted on March 26, 2014, under the Motus G.I. Medical Technologies LTD Employee Share Option Plan that were outstanding as of the Share Exchange Transaction, which were assumed by the 2016 Equity Incentive Plan (the “2016 Plan”) and continue in effect in accordance with their terms, on an adjusted basis to reflect the Share Exchange Transaction (see “Part III—Item 11—Executive Compensation—2016 Equity Incentive Plan—Description of the 2016 Equity Incentive Plan—Administration” below). 61% of the option was vested as of December 31, 2017, with the remaining 39% of the option vesting in full in November 2018.

(2) Represents options to purchase shares of our Common Stock granted on May 4, 2017, with an exercise price of \$5.00 per share. Fifty-three percent (53%) of the option vested immediately upon grant, forty percent (40%) of the option vests in a series of twelve (12) successive equal quarterly installments commencing on May 4, 2017 and continuing on the first day of each third month thereafter, and the remaining seven percent (7%) of the option vests on December 22, 2019. This option was repriced to \$4.50 per share in September 2017.

(3) Represents options to purchase shares of our Common Stock granted on September 29, 2017, with an exercise price of \$4.50 per share. The shares underlying the option vest in a series of twelve (12) successive equal quarterly installments commencing on December 1, 2017 and continuing on the first day of each third month thereafter.

(4) Mr. Martin ceased serving as our Chief Financial Officer effective June 9, 2017. Pursuant to the terms of the option to purchase shares of our Common Stock granted on May 4, 2017, and the 2016 Equity Incentive Plan, Mr. Martin’s options terminated and were canceled as of September 7, 2017, the date which was 90 days after Mr. Martin’s continuous service ended. Mr. Martin had no vested or unvested equity awards outstanding as of December 31, 2017.

2016 Equity Incentive Plan

General

On December 14, 2016, our board of directors adopted the 2016 Plan having substantially the terms described herein.

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

Description of the 2016 Equity Incentive Plan

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

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

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

Shares Subject to the 2016 Plan. As of January 1, 2018, the aggregate number of shares of our Common Stock that are available for issuance in connection with options and awards granted under the 2016 Plan and Assumed Options is 2,641,250. Incentive stock options may, but need not be, granted with respect to all of the shares available for issuance under the 2016 Plan. If any award granted under the 2016 Plan payable in shares of our Common Stock is forfeited, cancelled, returned for failure to satisfy vesting requirements, is otherwise forfeited, otherwise terminates without payment being made, or if shares of our Common Stock are surrendered in full or partial payment of the exercise price or withheld to cover withholding taxes on options or other awards, the number of shares of our Common Stock as to which such option or award was forfeited, or which were surrendered or withheld, will be available for future grants under the 2016 Plan.

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

Terms and Conditions of Options. Options granted under the 2016 Plan may be either “incentive stock options” that are intended to meet the requirements of Section 422 of the Code or “nonqualified stock options” that do not meet the requirements of Section 422 of the Code. The Compensation Committee will determine the exercise price of options granted under the 2016 Plan. The exercise price of stock options may not be less than the fair market value per share of our Common Stock on the date of grant (or 110% of fair market value in the case of incentive stock options granted to a ten-percent stockholder).

If on the date of grant our Common Stock is listed on a stock exchange or national market system, the fair market value will generally be the closing sale price on the date of grant. If our Common Stock is not traded on a stock exchange or national market system on the date of grant, the fair market value will generally be the average of the closing bid and asked prices for our Common Stock on the date of grant. If no such prices are available, the fair market value shall be determined in good faith by the Compensation Committee based on the reasonable application of a reasonable valuation method. Notwithstanding the foregoing, if the date for which fair market value is determined is the date on which the final prospectus relating to an initial public offering of the Company is filed, the fair market value for such date will be the "Price to the Public" (or equivalent) set forth on the cover page for the final prospectus.

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

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

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

Stock Appreciation Rights. The Compensation Committee is authorized to grant stock appreciation rights ("SARs") independent of or in connection with an option. The Compensation Committee is also authorized to determine the other terms applicable to SARs. The base price of a SAR will be determined by the Compensation Committee, but will not be less than 100% of the fair market value of a share of our Common Stock on the date of grant. The maximum term of any SAR granted under the 2016 Plan will be ten years from the date of grant. Generally, each SAR will entitle a participant upon exercise to an amount equal to:

- the excess of the fair market value on the exercise date of one share of our Common Stock over the base price, *multiplied by*
- the number of shares of our Common Stock as to which the SAR is exercised.

Payment may be made in shares of our Common Stock, in cash, or partly in shares of our Common Stock and partly in cash, all as determined by the Compensation Committee.

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

Performance Shares and Performance Units. The Compensation Committee is authorized to award performance shares and/or performance units under the 2016 Plan. Performance shares and performance units are awards, denominated in either shares or U.S. dollars, which are earned during a specified performance period subject to the attainment of performance criteria, as established by the Compensation Committee. The Compensation Committee has the authority to determine the restrictions and conditions applicable to each award of performance shares and performance units.

Incentive Bonus Awards. The Compensation Committee is authorized to award incentive bonus awards payable in cash or shares of our Common Stock, as set forth in an award agreement. The Compensation Committee has the authority to determine the terms and conditions applicable to each incentive bonus award.

Other Stock-Based and Cash-Based Awards. The Compensation Committee is authorized to award other types of equity-based or cash-based awards under the 2016 Plan, including the grant or offer for sale of shares of our Common Stock that do not have vesting requirements and the right to receive one or more cash payments subject to satisfaction of such conditions as the Compensation Committee may impose.

Section 162(m) Compliance. Section 162(m) of the Code, as amended by the 2017 Tax Act, generally limits the deductibility of compensation paid by a publicly-held company to a “covered employee” for a taxable year to \$1 million. “Covered employees” include our Chief Executive Officer, Chief Financial Officer and our next three highest compensated named executive officers. Effective for taxable years beginning prior to January 1, 2018, an exception to this deduction limit applied to “performance-based compensation”, such as stock options and other equity awards, that satisfies certain criteria. The exception for “performance-based compensation” continues to apply to certain written binding contracts which were in effect on November 2, 2017 and that are not modified in any material respect on or after that date.

Unless materially modified, stock options and other equity awards made under the Plan prior to January 1, 2018 should be exempt from the Section 162(m) deductibility limit because they were granted before the completion of our IPO. However, in light of the elimination of the exception to the Section 162(m) deduction limit for performance-based compensation, we will not be able to deduct amounts with respect to stock options and other equity awards made under the Plan on or after January 1, 2018 in excess of the Section 162(m) limit.

The Plan includes certain terms that were intended to allow awards to be made that would meet the Section 162(m) exception for performance-based compensation. In light of the elimination of the exception for performance-based compensation by the 2017 Tax Act effective for taxable years beginning on and after January 1, 2018, those provisions are no longer relevant. However, a Plan limitation intended to satisfy the Section 162(m) exception for performance-based compensation will continue to apply. Under that limitation, the maximum number of shares of our Common Stock with respect to which any one participant may be granted stock options or stock appreciation rights under the Plan during any calendar year is 1,500,000 shares.

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

Amendment, Termination. The Compensation Committee has the authority to amend the terms of awards in any manner not inconsistent with the 2016 Plan, provided that no amendment shall adversely affect the rights of a participant with respect to an outstanding award without the participant's consent. In addition, our board of directors has the authority, at any time, to amend, suspend, or terminate the 2016 Plan, provided that (i) no such amendment, suspension or termination materially and adversely affects the rights of any participant under any outstanding award without the consent of such participant and (ii) to the extent necessary to comply with any applicable law, regulation, or stock exchange rule, the 2016 Plan requires us to obtain stockholder consent. Stockholder approval is required for any plan amendment that increases the number of shares of our Common Stock available for issuance under the 2016 Plan or changes the persons or classes of persons eligible to receive awards.

Tax Withholding

As and when appropriate, we shall have the right to require each optionee purchasing shares of our Common Stock and each grantee receiving an award of shares of our Common Stock under the 2016 Plan to pay any federal, state or local taxes required by law to be withheld.

Option Grants and Stock Awards

The grant of options and other awards under the 2016 Plan is discretionary and we cannot determine now the specific number or type of options or awards to be granted in the future to any particular person or group.

Israeli Aspects of the 2016 Plan

The 2016 Israeli Sub-Plan (the "Sub-Plan") provides for the grant of awards pursuant to the Israeli Income Tax Ordinance (New Version), 1960, as amended (the "Israeli Tax Ordinance"): awards granted pursuant to (i) Section 102 of the Israeli Tax Ordinance ("Section 102 Awards") and (ii) Section 3(i) of the Israeli Tax Ordinance ("Section 3(i) Awards"). The 2016 Plan and the Sub-Plan provide, subject to applicable law, that Section 102 Awards may be granted only to Israeli employees, officers and directors (excluding Controlling Shareholders as defined by the Israeli Tax Ordinance¹) and Section 3(i) Awards (which does not provide for similar tax benefits) may be granted to Israeli non-employees including consultants, service providers and Controlling Shareholders (as defined by the Israeli Tax Ordinance), in each case, of our company or any subsidiary. The 2016 Plan and the Sub-Plan were submitted for the approval of the Israeli Tax Authority (the "ITA"), as required by applicable law.

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

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

Director Compensation

The following table sets forth information concerning the compensation paid to certain of our non-employee directors during 2017.

Name	Fees earned or paid in cash (\$)	Option awards (\$)(1)	Total (\$)
David Hochman	34,000	126,000(2)(7)	160,000
Darren Sherman	16,000	72,000(3)(7)	88,000
Gary Jacobs	14,500	66,600(4)(7)	81,100
Samuel Nussbaum	13,000	36,000(5)(7)	49,000
Shervin Korangy	18,000	46,800(6)(7)	64,800
Gary Pruden	2,167	-	2,167

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

(2) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2017 held by Mr. Hochman was 175,000.

(3) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2017 held by Mr. Sherman was 100,000.

(4) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2017 held by Mr. Jacobs was 92,500.

(5) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2017 held by Mr. Nussbaum was 50,000.

(6) The aggregate number of shares of Common Stock underlying stock options outstanding as of December 31, 2017 held by Mr. Korangy was 65,000.

(7) This stock option was granted in May 2017 with an exercise price of \$5.00 per share, which stock option was repriced to have an exercise price of \$4.50 per share in September 2017.

Non-Employee Director Compensation and Advisory Board Compensation

Our board of directors approved a director compensation policy for our directors, effective beginning July 1, 2017. This policy provides for the following cash compensation:

- each director is entitled to receive a quarterly fee from us of \$6,500;
- the chairman of the Board will receive a quarterly fee from us of \$9,000;
- the chair of the Audit Committee will receive a quarterly fee from us of \$2,500;
- each chair of any other board of director committee will receive a quarterly fee from us of \$1,500; and
- each non-employee director sitting on more than two Board committees will receive an additional quarterly fee of \$750.

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

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

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information with respect to our compensation plans under which equity compensation was authorized as of December 31, 2017.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column a) (c)(2)
Equity compensation plans approved by security holders(1)	1,803,096	\$ 4.40	202,122
Equity compensation plans not approved by security holders	—	\$ —	—
Total	1,803,096	\$ 4.40	202,122

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

(2) In accordance with the “evergreen” provision in our 2016 Plan, an additional 629,594 shares were automatically made available for issuance on the first day of 2018, which represents 6% of the number of shares outstanding on December 31, 2017; these shares are excluded from this calculation.

Security Ownership of Certain Beneficial Owners and Management

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

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

Beneficial ownership is determined based on the rules and regulations of the SEC. A person has beneficial ownership of shares if such individual has the power to vote and/or dispose of shares. This power may be sole or shared and direct or indirect. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of our Common Stock that are subject to options or warrants held by that person and exercisable as of, or within 60 days of, March 1, 2018 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 15,574,752 shares of Common Stock issued and outstanding as of March 1, 2018 plus any shares issuable upon exercise of options or warrants that are exercisable on or within 60 days after March 1, 2018 held by such person or entity.

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

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Officers and Directors		
Mark Pomeranz (1)	371,218	2.33%
David Hochman (2)(4)(5)(6)(7)	2,660,584	16.89%
Darren Sherman (3)(4)(5)(6)(7)	2,590,584	16.45%
Gary Jacobs (8)(9)	801,862	5.13%
Samuel Nussbaum (10)	10,000	*
Shervin Korangy (11)	20,000	*
Andrew Taylor (12)	42,000	*
Gary Pruden	50,000	*
Directors and Officers as a Group (8 persons)	3,963,664	24.43%
5% Stockholders		
Ascent Biomedical Ventures II, L.P. (13)	1,748,215	11.11%
ABV, LLC (13)(14)	2,386,889	15.15%
Orchestra Medical Ventures II, L.P. (4)	1,218,630	7.77%
Orchestra MOTUS Co-Investment Partners, LLC (5)	1,229,104	7.86%
Orchestra Medical Ventures II GP, LLC (4)(6)	1,301,982	8.30%
Jacobs Investment Company LLC (9)	792,762	5.07%
Perceptive Life Sciences Master Fund Ltd. (15)	2,866,541	18.33%
Perceptive Advisors LLC (15)	2,866,541	18.33%

* Less than 1%

1. Includes 363,077 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of March 1, 2018. Does not include 215,274 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 1, 2018.
2. Does not include (i) 175,000 shares of our Common Stock issuable upon the exercise of stock options and (ii) 300 shares of Common Stock issuable upon exercise of Ten Percent Warrants, that are not exercisable within sixty days of March 1, 2018.
3. Does not include (i) 100,000 shares of our Common Stock issuable upon the exercise of stock options and (ii) 300 shares of Common Stock issuable upon exercise of Ten Percent Warrants, that are not exercisable within sixty days of March 1, 2018.
4. Includes 108,838 shares of Common Stock issuable upon exercise of Exchange Warrants, held by Orchestra Medical Ventures II, L.P. Does not include 106,980 shares of Common Stock issuable upon exercise of Ten Percent Warrants that are not exercisable within sixty days of March 1, 2018. The managing members of Orchestra Medical Ventures II GP, LLC, David Hochman and Darren Sherman, exercise sole dispositive and voting power over the shares owned by Orchestra Medical Ventures II, L.P.
5. Includes 69,136 shares of Common Stock issuable upon exercise of Exchange Warrants, held by Orchestra MOTUS Co-Investment Partners, LLC. Does not include 115,997 shares of Common Stock issuable upon exercise of Ten Percent Warrants that are not exercisable within sixty days of March 1, 2018. The managing partners of Orchestra Medical Ventures, LLC, David Hochman and Darren Sherman, exercise sole dispositive and voting power over the shares owned by Orchestra MOTUS Co-Investment Partners, LLC.
6. Includes (i) 83,352 shares of Common Stock held by Orchestra Medical Ventures II Reserve, L.P. The managing members of Orchestra Medical Ventures II GP, LLC, David Hochman and Darren Sherman, exercise sole dispositive and voting power over the shares owned by Orchestra Medical Ventures II Reserve, L.P.
7. Includes 51,498 shares of Common Stock held by Accelerated Technologies, Inc. David Hochman and Darren Sherman share dispositive and voting power over the shares owned by Accelerated Technologies, Inc.
8. Does not include 92,500 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 1, 2018.
9. Includes 68,906 shares of Common Stock issuable upon exercise of Exchange Warrants, held by Jacobs Investment Company LLC. Does not include 72,386 shares of Common Stock issuable upon exercise of Ten Percent Warrants that are not exercisable within sixty days of March 1, 2018. The managing member of Jacobs Investment Company LLC, Gary Jacobs, exercises sole dispositive and voting power over the shares owned by Jacobs Investment Company LLC.
10. Does not include 50,000 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 1, 2018.
11. Does not include 65,000 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 1, 2018.
12. Includes 40,000 shares of our Common Stock issuable upon the exercise of stock options that are exercisable within sixty days of March 1, 2018. Does not include 200,000 shares of our Common Stock issuable upon the exercise of stock options that are not exercisable within sixty days of March 1, 2018.

13. Includes 156,734 shares of Common Stock issuable upon exercise of Exchange Warrants, held by Ascent Biomedical Ventures II, L.P. Does not include 159,149 shares of Common Stock issuable upon exercise of Ten Percent Warrants that are not exercisable within sixty days of March 1, 2018. The managing members of ABV, LLC, Geoffrey W. Smith and Steve Hochberg, exercise sole dispositive and voting power over the shares owned by Ascent Biomedical Ventures II, L.P. The principal address for the entities affiliated with ABV, LLC is 60 East 42nd Street, New York, NY 10165.
14. Includes 27,433 shares of Common Stock issuable upon exercise of Exchange Warrants, held by Ascent Biomedical Ventures Synecor, L.P. Does not include 61,125 shares of Common Stock issuable upon exercise of Ten Percent Warrants that are not exercisable within sixty days of March 1, 2018, held by Ascent Biomedical Ventures Synecor, L.P. The managing members of ABV, LLC, Geoffrey W. Smith and Steve Hochberg, exercise sole dispositive and voting power over the shares owned by Ascent Biomedical Ventures Synecor, L.P. The principal address for the entities affiliated with ABV, LLC is 60 East 42nd Street, New York, NY 10165. Ascent Biomedical Ventures II, L.P. and Ascent Biomedical Ventures Synecor, L.P. are collectively referred to herein as the "Ascent Entities."
15. Includes 66,000 shares of Common Stock issuable upon exercise of Exchange Warrants, held by Perceptive Life Sciences Master Fund Ltd. Does not include 180,055 shares of Common Stock issuable upon exercise of Ten Percent Warrants that are not exercisable within sixty days of March 1, 2018. The managing member of Perceptive Advisors LLC, Mr. Joseph Edelman, exercises sole dispositive and voting power over the shares owned by Perceptive Life Sciences Master Fund Ltd. The principal address for the entities affiliated with Perceptive Advisors LLC is 51 Astor Place, 10th floor New York, NY 10003.

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, 2017, 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 the section entitled “Executive Compensation.”

2017 Private Placement - Related Party Participation

In January 2017, Perceptive Life Sciences Master Fund Ltd., a beneficial owner of 5% or more of our Common Stock, purchased 20,960 Units sold in the 2017 Private Placement at a price of \$5.00 per Unit, for an aggregate purchase price of \$104,800, resulting in the issuance of (i) 15,720 shares of our Common Stock and (ii) 5,240 shares of our Series A Convertible Preferred Stock.

In February 2017, David Hochman, Chairman of the Board, purchased 3,000 Units sold in the 2017 Private Placement at a price of \$5.00 per Unit, for an aggregate purchase price of \$15,000, resulting in the issuance of (i) 2,250 shares of our Common Stock and (ii) 750 shares of our Series A Convertible Preferred Stock.

In February 2017, Darren Sherman, Chairman of the Board, purchased 3,000 Units sold in the 2017 Private Placement at a price of \$5.00 per Unit, for an aggregate purchase price of \$15,000, resulting in the issuance of (i) 2,250 shares of our Common Stock and (ii) 750 shares of our Series A Convertible Preferred Stock.

See “Part I—Item 1—Business—2017 Private Placement” for a description of the 2017 Private Placement. See “Part I—Item 1—Business—Initial Public Offering” for a description of the conversion of all Series A Convertible Preferred Stock, on a one-to-one basis, into shares of our Common Stock in February 2018.

Sales and Marketing Services Arrangement with FreeHold Surgical, Inc.

In August, 2017, we began paying a monthly fee to FreeHold Surgical, Inc., or FreeHold, an entity in which Darren Sherman, one of our Directors, serves as a Director and President. Pursuant to the fee arrangement, we pay FreeHold a monthly amount of approximately \$25,000 as all-in compensation for sales and marketing services performed for us, on a part time basis, by two Freehold sales representatives.

Ten Percent Warrants - Related Party Participation

Upon the completion of our IPO in February 2018, we issued warrants to certain of our former Series A Convertible Preferred Stock holders, pursuant to an amendment to our Registration Rights Agreement and an amendment to our Certificate of Designation k, to purchase an aggregate of 1,095,682 shares of our Common Stock (the “Ten Percent Warrants”), including (i) Ten Percent Warrants to purchase 300 shares of our Common Stock to David Hochman, the Chairman of our Board, (ii) Ten Percent Warrants to purchase 300 shares of our Common Stock to Darren Sherman, one of our directors, (iii) Ten Percent Warrants to purchase an aggregate of 220,274 shares of our Common Stock to the Ascent Entities, beneficial owners of more than five percent of our Common Stock, (iv) Ten Percent Warrants to purchase 106,980 shares of our Common Stock to Orchestra Medical Ventures II, L.P., a beneficial owner of more than five percent of our Common Stock, (v) Ten Percent Warrants to purchase 115,997 shares of our Common Stock to Orchestra MOTUS Co-Investment Partners, LLC, a beneficial owner of more than five percent of our Common Stock, (vi) Ten Percent Warrants to purchase 72,386 shares of our Common Stock to Jacobs Investment Company, an investment firm in which Gary Jacobs, one of our Directors, serves as Founder and Managing Director, and (vii) Ten Percent Warrants to purchase 180,055 shares of our Common Stock to Perceptive Life Sciences Master Fund Ltd., a beneficial owner of more than five percent of our Common Stock. The Ten Percent Warrants are exercisable for shares of our Common Stock at an exercise price equal to \$5.00. The Ten Percent Warrants are exercisable any time on or after August 15, 2018, the 180 day anniversary of the completion of our IPO, have a five year term, and provide for cashless exercise. No fractional shares will be issued upon the exercise of the Ten Percent Warrants.

Royalty Payment Rights Certificates - Related Party Participation

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

<u>The Company Commercializes Product Directly</u>	<u>The Rights to Commercialize the Product is Sublicensed by the Company to a third-party</u>
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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 the Company has first generated, in the aggregate, since its 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 Certificate of Designations.

** 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 \$3.5 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 Certificate of Designations.

The royalty will be payable up to the later of (i) the latest expiration date for the Company's current patents (which is currently October 2026), or (ii) the latest expiration date of any pending patents as of the date of the Initial Closing that may be issued in the future. Following the expiration of all such patents, the Holders of the Royalty Payment Rights Certificates will no longer be entitled to any further royalties for any period following the latest to occur of such patent expiration.

Participation in Initial Public Offering

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

Directed Share Program

At our request, the underwriters sold at the IPO price 175,000 shares of Common Stock, or five percent (5%) of the shares offered in our IPO, to our employees and other persons associated with us, including Gary Jacobs, one of our Directors, who purchased 5,000 shares of our Common Stock at the IPO price. The directed share program was arranged through Piper Jaffray & Co.

Indemnification Agreements

In 2017, we entered into indemnification agreements with all of our directors and named executive officers. These agreements require us to indemnify these individuals to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to us, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified. We also intend to enter into indemnification agreements with our future directors and executive officers.

Policies and Procedures for Related Party Transactions

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

Director Independence

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

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Principal Accountant Fees and Services

The following table summarizes the fees paid for professional services rendered by Brightman Almagor Zohar & Co., a member firm of Deloitte Touche Tohmatsu Limited, our independent registered public accounting firm, for each of the last two fiscal years:

Fee Category	2017	2016
	(In thousands)	
Audit Fees	\$ 120,000	\$ 30,000
Audit-Related Fees	\$ -	\$ -
Tax Fees	\$ 11,200	\$ 5,000
All Other Fees	\$ -	\$ -
Total Fees	<u>\$ 131,200</u>	<u>\$ 35,000</u>

Audit Fees

Represents fees, including out of pocket expenses, for professional services provided in connection with the audit of our annual audited financial statements and of our internal control over financial reporting, the review of our quarterly financial statements, accounting consultations or advice on accounting matters necessary for the rendering of an opinion on our financial statements, services provided in connection with the offerings of our Common Stock and audit services provided in connection with other statutory or regulatory filings.

Tax Fees

Tax fees were principally for services related to tax compliance and reporting and analysis services.

Procedures for Approval of Fees

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

The Audit Committee has considered whether the provision of Audit-Related Fees, Tax Fees, and all other fees as described above is compatible with maintaining Brightman Almagor Zohar & Co.’s independence and has determined that such services for fiscal year 2017 were compatible. All such services were approved by the Audit Committee pursuant to Rule 2-01 of Regulation S-X under the Exchange Act to the extent that rule was applicable.

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

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

(1) Consolidated Financial Statements

The financial statements and related notes, together with the report of Brightman Almagor Zohar & Co., a member firm of Deloitte Touche Tohmatsu Limited appear at pages F-1 through F-25 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 INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
2.1 +	Share Exchange Agreement, dated December 1, 2016	S-1	333-222441	2.1	1/5/2018	
3.1	Certificate of Incorporation	S-1	333-222441	3.1	1/5/2018	
3.2	Certificate of Amendment to the Certificate of Incorporation	S-1	333-222441	3.2	1/5/2018	
3.3	Bylaws	S-1	333-222441	3.3	1/5/2018	
3.4	Certificate of Designations of Series A Convertible Preferred Stock	S-1	333-222441	3.4	1/5/2018	
3.5	Certificate of Amendment of Certificate of Designations of Series A Convertible Preferred Stock, to be effective upon the consummation of this offering	S-1	333-222441	3.5	1/5/2018	

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 Consultant Warrant	S-1	333-222441	4.6	1/5/2018
4.7	Form of Placement Agent Royalty Payment Rights Certificate	S-1	333-222441	4.7	1/5/2018
4.8	Form of Amendment to Registration Rights Agreement	S-1	333-222441	4.8	1/5/2018
4.9	Form of Ten Percent Warrant	S-1	333-222441	4.9	1/5/2018
4.10	Form of Royalty Payment Rights Certificate	S-1/A	333-222441	4.10	1/31/2018
10.1	Placement Agency Agreement, dated December 1, 2016, between the Company and Aegis Capital Corp.	S-1	333-222441	10.1	1/5/2018
10.2	Form of Subscription Agreement	S-1	333-222441	10.2	1/5/2018
10.3	Form of Voting Agreement, dated December 1, 2016, by and among the Company and the stockholders named therein	S-1	333-222441	10.3	1/5/2018
10.4 †	2016 Equity Incentive Plan and 2016 Israel Sub-Plan	S-1	333-222441	10.4	1/5/2018
10.5 †	Form of Incentive Stock Option Agreement	S-1	333-222441	10.5	1/5/2018

10.6 †	Form of Non-Qualified Stock Option Agreement	S-1	333-222441	10.6	1/5/2018
10.7 †	Form of Restricted Stock Agreement	S-1	333-222441	10.7	1/5/2018
10.8 †	Form of Assumed Options to Israeli Employees and Directors Agreement	S-1	333-222441	10.8	1/5/2018
10.9	Form of Assumed Options to Israeli Non-Employees and Controlling Shareholders Agreement	S-1	333-222441	10.9	1/5/2018
10.10 †	Form of Israeli Option Grant to Israeli Employees and Directors Agreement	S-1	333-222441	10.10	1/5/2018
10.11	Form of Israeli Option Grant to Israeli Non-Employees and Controlling Shareholders Agreement	S-1	333-222441	10.11	1/5/2018
10.12 †	Employment Agreement, dated December 22, 2016, between the Company and Mark Pomeranz	S-1	333-222441	10.12	1/5/2018
10.13	Lease, dated April 13, 2017, between Company and Victoriana Building, LLC	S-1	333-222441	10.13	1/5/2018
10.14	Form of Subscription Agreement for Convertible Notes Offering	S-1	333-222441	10.14	1/5/2018
10.15	Finders Agreement, dated October 14, 2016, between the Company and Aegis Capital Corporation	S-1	333-222441	10.15	1/5/2018
10.16	Finders Agreement, dated December 22, 2016, between the Company and Aegis Capital Corporation	S-1	333-222441	10.16	1/5/2018
10.17 †	Form of Indemnification Agreement	S-1	333-222441	10.17	1/5/2018

10.18 †	Employment Agreement, dated August 16, 2017, between the Company and Andrew Taylor	S-1	333-222441	10.18	1/5/2018	
10.19 #	Supply Agreement, dated September 1, 2017, between Motus GI Technologies Ltd. and Polyzen, Inc.	S-1/A	333-222441	10.19	2/7/2018	
21.1	List of Subsidiaries of the Company	S-1	333-222441	21.1	1/5/2018	
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
+	As permitted by Item 601(b)(2) of Regulation S-K, certain schedules to this agreement have not been filed herewith. The company will furnish supplementally a copy of any omitted schedule to the SEC upon request.					
†	Indicates management contract or compensatory plan.					
#	Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been submitted separately to the SEC.					

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

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

MOTUS GI HOLDINGS, INC.

Date: March 28, 2018

By: /s/ Mark Pomeranz

Mark Pomeranz
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 28, 2018

By: /s/ Andrew Taylor

Andrew Taylor
Chief Financial Officer
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities on March 28, 2018.

Signature	Title	Date
<u>/s/ Mark Pomeranz</u> Mark Pomeranz	President, Chief Executive Officer and Director (Principal Executive Officer)	March 28, 2018
<u>/s/ Andrew Taylor</u> Andrew Taylor	Chief Financial Officer (Principal Financial and Accounting Officer)	March 28, 2018
<u>/s/ David Hochman</u> David Hochman	Chairman of the Board	March 28, 2018
<u>/s/ Darren Sherman</u> Darren Sherman	Director	March 28, 2018
<u>/s/ Gary Jacobs</u> Gary Jacobs	Director	March 28, 2018
<u>/s/ Samuel Nussbaum</u> Samuel Nussbaum	Director	March 28, 2018
<u>/s/ Shervin Korangy</u> Shervin Korangy	Director	March 28, 2018
<u>/s/ Gary Pruden</u> Gary Pruden	Director	March 28, 2018

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CONSOLIDATED FINANCIAL STATEMENTS**

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Motus GI Holdings, Inc. and subsidiaries (the "Company") as of December 31, 2017 and 2016 and the related consolidated statements comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company's minimal revenues and substantial operating losses raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 1 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Basis for Opinion

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

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

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

/s/ Brightman Almagor Zohar & Co.

Certified Public Accountants

Member of Deloitte Touche Tohmatsu Limited

Tel Aviv, Israel

March 28, 2018

We have served as the Company's auditor since 2009.

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

	December 31,	
	2017	2016
ASSETS		
Current assets		
Cash and cash equivalents	\$ 6,939	\$ 11,644
Short-Term Deposits	76	-
Inventory	6	81
Prepaid expenses and other	663	263
Deferred financing fees	602	-
Total current assets	8,286	11,988
Fixed assets, net	783	141
Long-term deposits	99	62
Total assets	\$ 9,168	\$ 12,191
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 882	\$ 107
Other current liabilities	1,101	645
Total current liabilities	1,983	752
Contingent royalty obligation	1,662	1,410
Commitments and contingent liabilities		
Shareholders' equity		
Common Stock \$0.0001 par value; 50,000,000 authorized; 10,493,233 and 9,294,463 issued and outstanding as of December 31, 2017 and 2016, respectively	1	1
Preferred Series A stock \$0.0001 par value; 2,000,000 authorized; 1,581,128 and 1,214,845 issued and outstanding as of December 31, 2017 and 2016, respectively	-	-
Preferred stock \$0.0001 par value; 8,000,000 authorized; zero issued and outstanding as of December 31, 2017 and 2016, respectively	-	-
Additional paid-in capital	44,643	35,949
Accumulated deficit	(39,121)	(25,921)
Total shareholders' equity	5,523	10,029
Total liabilities and shareholders' equity	\$ 9,168	\$ 12,191

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

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

	Years Ended December 31	
	2017	2016
Revenue	\$ 7	\$ -
Cost of revenue	3	-
Gross loss	4	-
Operating expenses:		
Research and development, net	4,266	3,079
Sales and marketing	2,415	1,034
General and administrative	6,287	1,894
Total operating expenses	12,968	6,007
Operating loss	(12,964)	(6,007)
Finance expense, net	236	1,966
Loss before income taxes	(13,200)	(7,973)
Income tax expense	-	50
Net loss	\$ (13,200)	\$ (8,023)
Net loss per common share, basic and diluted	\$ (1.28)	\$ (7.00)
Weighted average number of common shares outstanding, basic and diluted	10,332,554	1,146,028

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

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

	Preferred Stock - Motus LTD. (pre-merger)		Preferred Series A Stock		Common Stock		Additional paid- in capital	Accumulated deficit	Total shareholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at January 1, 2016	2,971,224	\$ -	-	\$ -	940,028	\$ -	\$ 14,175	\$ (17,898)	\$ (3,723)
Conversion of convertible notes	3,243,768	-	-	-	-	-	16,253	-	16,253
Exercise of warrants	-	-	-	-	88,748	-	-	-	-
Effect of reverse recapitalization transaction	(6,214,992)	-	1,214,845	-	8,265,687	1	5,467	-	5,468
Share-based compensation	-	-	-	-	-	-	54	-	54
Net loss	-	-	-	-	-	-	-	(8,023)	(8,023)
Balance at December 31 , 2016	-	-	1,214,845	-	9,294,463	1	35,949	(25,921)	10,029
Issuance of shares	-	-	366,283	-	1,098,849	-	6,474	-	6,474
Share-based compensation	-	-	-	-	99,167	-	2,220	-	2,220
Exercise of options	-	-	-	-	754	-	-	-	-
Net loss	-	-	-	-	-	-	-	(13,200)	(13,200)
Balance at December 31 , 2017	-	\$ -	1,581,128	\$ -	10,493,233	\$ 1	\$ 44,643	\$ (39,121)	\$ 5,523

(*) Number of shares prior to the reverse capitalization has been retroactively adjusted based on the equivalent number of shares received by the accounting acquirer in the transaction.

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

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

	For the year ended December 31,	
	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (13,200)	\$ (8,023)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	65	46
Revaluation of contingent royalty obligation	252	-
Interest and revaluation of convertible notes	-	1,907
Share based compensation	2,220	54
Changes in operating assets and liabilities:		
Inventory	75	(81)
Prepaid expenses	(400)	(83)
Short-term deposits	(76)	-
Trade accounts payable	210	(355)
Other current liabilities	456	409
Net cash used in operating activities	<u>(10,398)</u>	<u>(6,126)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of fixed assets	(707)	(30)
(Repayment) Proceeds from long term deposits	(44)	31
Proceeds (Repayment) in restricted cash	7	(7)
Net cash used in investing activities	<u>(744)</u>	<u>(6)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of shares, net of financing cost of \$850,670	6,474	-
Cash acquired in connection with the reverse recapitalization, net	-	6,878
Proceeds from issuance of convertible notes	-	9,606
Deferred financing fees	(37)	-
Net cash provided by financing activities	<u>6,437</u>	<u>16,484</u>
NET (DECREASE) INCREASE IN CASH	(4,705)	10,352
CASH AT BEGINNING OF PERIOD	11,644	1,292
CASH AT END OF PERIOD	<u>\$ 6,939</u>	<u>\$ 11,644</u>
SUPPLEMENTAL CASH FLOW INFORMATION:		
CASH PAID FOR:		
Interest	\$ -	\$ -
Income taxes	\$ -	\$ -
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING ACTIVITIES:		
Convertible notes exchanged for common and preferred stock	\$ -	\$ 16,253
Exercise of options	\$ *	\$ -

* Represents amounts less than \$1,000

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

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

NOTE 1 - GENERAL

A. Organization and Business

Organization

Motus GI Holdings, Inc. (the “Company”) was incorporated in Delaware, U.S.A. in September 2016. The Company was established for the purpose of raising capital for the recapitalization of Motus GI Medical Technologies, Ltd. (“Motus, Ltd.”), a company incorporated in Israel and its then wholly owned subsidiary Motus GI, Inc (“Motus, Inc.”), a company incorporated in Delaware, U.S.A.

On December 22, 2016, the Company acquired (the “Recapitalization Transaction”) 100% of the outstanding shares of Motus, Ltd. pursuant to a capital stock exchange agreement dated December 1, 2016, between the Company and the shareholders of Motus, Ltd. (the “Exchange Agreement”). In exchange for the outstanding shares of Motus, Ltd., the Company issued to the shareholders of Motus, Ltd. a total of 4,000,000 shares of the Company’s common stock representing approximately 69% of the total shares then issued and outstanding after giving effect to the Recapitalization Transaction. As a result of the Recapitalization Transaction, Motus, Ltd. became a wholly owned subsidiary of the Company. As the shareholders of Motus, Ltd. received the largest ownership interest in the Company, Motus, Ltd. was determined to be the “accounting acquirer” in the reverse recapitalization. As a result, the historical financial statements of the Company were replaced with the historical financial statements of Motus, Ltd.

On December 31, 2016, the Company executed a stock purchase agreement to acquire Motus, Inc. from Motus, Ltd resulting in Motus, Inc. becoming a wholly owned subsidiary of the Company.

The Company and its subsidiaries, Motus, Ltd. and Motus, Inc., are collectively referred to as the “Company”.

Business

The Company has developed a single-use medical device system, the Pure-Vu system, cleared by the United States Food and Drug Administration, which is intended to connect to standard colonoscopes to help facilitate intraprocedural cleaning of a poorly prepared colon by irrigating or cleaning the colon and evacuating the irrigation fluid (water), feces and other bodily fluids and matter, e.g. blood. The Pure-Vu system has been designed to integrate with standard colonoscopes to enable cleaning during the procedure while preserving standard procedural workflow and techniques. The Pure-Vu system and the procedure to cleanse the colon in preparation for colonoscopy are not currently reimbursable through private or governmental third-party payors in any country, but the Company does intend to seek reimbursement through private or governmental third-party payors in the future. To date, as part of the Company’s limited pilot launch, the Company has focused on collecting clinical data on the use of the Pure-Vu system.

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

B. Going concern

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

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

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

The significant accounting policies used in the preparation of the financial statements are as follows:

Basis of presentation

The financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America.

Use of estimates

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

Functional currency and foreign currency translation

The functional currency of the Company is the U.S dollar ("dollar") since the dollar is the currency of the primary economic environment in which the Company has operated and expects to continue to operate in the foreseeable future.

Transactions and balances denominated in dollars are presented at their original amounts. Transactions and balances denominated in foreign currencies have been re-measured to dollars in accordance with the provisions of ASC 830-10, "Foreign Currency Translation".

All transaction gains and losses from re-measurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the statement of operations as financial income or expenses, as appropriate.

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

Consolidation

The consolidated financial statements 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.

Cash and cash equivalents

The Company considers all highly liquid short-term investments purchased with an original maturity date of three months or less to be cash equivalents. The Company had approximately \$6,939 and \$11,644, on deposit in bank operating accounts at December 31, 2017 and 2016, 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, 2017 and 2016, the allowance for doubtful accounts was \$0.

Fair value of financial instruments

The carrying values of cash and cash equivalents, restricted cash, short-term deposits, accounts receivable, prepaid expenses, other receivables, deferred financing fees, accounts payable, and other current liabilities approximate their fair value due to the short-term maturity of these instruments.

The Company measures the fair value of certain of its financial instruments such as the Contingent royalty obligation on a recurring basis. The method of determining the fair value of other long-term liabilities is discussed in Note 10.

A fair value hierarchy is used to rank the quality and reliability of the information used to determine fair values. Financial assets and liabilities carried at fair value will be classified and disclosed in one of the following three categories:

Level 1 - Quoted prices (unadjusted) in active markets for identical assets and liabilities.

Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as unadjusted quoted prices for similar assets and liabilities, unadjusted quoted prices in the markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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

Inventory

Inventories are stated at lower of cost or net realizable value using the weighted average cost method and are evaluated at least annually for impairment. Inventories at December 31, 2017 and 2016 consisted of finished goods. Write-downs for potentially obsolete or excess inventory are made based on management's analysis of inventory levels, historical obsolescence and future sales forecasts. For the year ended December 31, 2017, an impairment charge of \$72 was recorded based on management determination to use the inventory for clinical trials, training and demonstration purposes.

Deferred Financing Fees

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

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 estimate useful lives of the related assets, as follows:

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

Stock-based compensation

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

ASC 718-10 requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in the Company's statement of operations.

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

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

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The Company recognizes compensation expenses for the value of non-employee awards, which have graded vesting, based on the straight-line method over the requisite service period of each award.

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

Basic and diluted net loss per share

Basic loss per share is computed by dividing the net loss by the weighted average number of ordinary shares outstanding during the year.

Diluted loss per share is computed by dividing the net loss by the weighted average number of ordinary shares outstanding during the year, plus the number of ordinary 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.

Research and development costs, net

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

Patent costs

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

Liabilities due to termination of employment agreements

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

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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, 2017 and 2016, the Company had a full valuation allowance against deferred tax assets.

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

Reclassification

Certain prior year amounts have been reclassified to conform to the current year presentation.

Transaction Costs

Transaction costs incurred in the Merger were charged directly to equity to the extent of cash and net other current assets acquired.

Recent accounting standards

In May 2014, the FASB issued ASC 606, "Revenue From Contracts With Customers" a new revenue recognition standard that will supersede current revenue recognition guidance. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard is effective for the Company on January 1, 2018, and the Company intends on applying the standard retrospectively to each prior reporting period presented as of the date of adoption. As the Company has generated minimal revenues to date, the adoption of this standard is not expected to have a material impact on the Company's financial position or results of operations.

In February 2016, the FASB issued ASU 2016-02 "Leases" to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. For operating leases, the ASU requires a lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, on its balance sheet. The ASU retains the current accounting for lessors and does not make significant changes to the recognition, measurement, and presentation of expenses and cash flows by a lessee.

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The ASU is effective for the Company in the first quarter of 2019, with early adoption permitted. The Company continues to evaluate the effect of the adoption of this ASU and expects the adoption will result in an increase in the assets and liabilities on the consolidated balance sheets for operating leases and will likely have an insignificant impact on the consolidated statements of comprehensive loss.

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

In November 2016, the FASB issued ASU 2016-18 “Restricted Cash” to provide guidance on the presentation of restricted cash in the statement of cash flows. Currently, the statement of cash flows explained the change in cash and cash equivalents for the period. The ASU requires that the statement of cash flows explain the change in cash, cash equivalents and restricted cash for the period. The ASU will be adopted by the Company on January 1, 2018, on a prospective basis. The Company does not expect the adoption to have a material effect on the statements of cash flows as the Company’s restricted cash is not expected to be material.

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

NOTE 3 - PREPAID EXPENSES AND OTHER

In 2017, the Company contracted with vendors to produce components and inventory for the Company’s clinical studies, training, and future sales. As of December 31, 2017 and 2016, the Company advanced payments totaling \$408 and \$222 respectively, with two of these suppliers which was recorded as vendor deposits against future purchases. As of December 31, 2017, and 2016, \$663 and \$263 were recorded as prepaid expenses and other, respectively.

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NOTE 4 - FIXED ASSETS, NET

As of December 31, 2017 and 2016, fixed assets, net consisted of the following:

	<u>Office equipment</u>	<u>Computer and software</u>	<u>Leasehold improvements</u>	<u>Machinery</u>	<u>Laboratory & Medical equipment</u>	<u>Total</u>
<u>Cost:</u>						
Balance - January 1, 2017	45	112	83	-	91	331
Additions	89	80	22	328	188	707
Balance - December 31, 2017	<u>134</u>	<u>192</u>	<u>105</u>	<u>328</u>	<u>279</u>	<u>1,038</u>
<u>Accumulated depreciation:</u>						
Balance - January 1, 2017	7	105	21	-	57	190
Additions	5	18	8	-	34	65
Balance - December 31, 2017	<u>12</u>	<u>123</u>	<u>29</u>	<u>-</u>	<u>91</u>	<u>255</u>
<u>Net book value:</u>						
December 31, 2017	<u>122</u>	<u>69</u>	<u>76</u>	<u>328</u>	<u>188</u>	<u>783</u>
December 31, 2016	<u>38</u>	<u>7</u>	<u>62</u>	<u>-</u>	<u>34</u>	<u>141</u>

NOTE 5 - OTHER CURRENT LIABILITIES

As of December 31, 2017 and 2016, other current liabilities consisted of the following

	<u>As of December 31,</u>	
	<u>2017</u>	<u>2016</u>
Wage-related liabilities	536	421
Deferred financing fees	250	-
Accrued expenses	315	224
	<u>1,101</u>	<u>645</u>

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NOTE 6 - COMMITMENTS AND CONTINGENCIES

Royalties to the IIA

The Company has received grants from the Government of the State of Israel through the Israel Innovation Authority of the Ministry of Economy and Industry (the "IIA") (formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry (the "OCS")) for the financing of a portion of its research and development expenditures pursuant to the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984 (formerly known as the Encouragement of Industrial Research and Development Law, 5744-1984), referred to as the Research Law, and related regulations. As of December 31, 2017, we had received funding from the IIA in the aggregate amount of \$1,330 and had a contingent obligation to the IIA in the amount of approximately \$1,370, which is generally repaid in the form of royalties ranging from 3% to 3.5% of revenues on sales of products and services based on technology developed using IIA grants, up to an aggregate of 100% (which may be increased under certain circumstances) of the U.S. dollar-linked value of the grant, plus interest at the rate of 12-month LIBOR

Repayment of the grants is contingent upon the successful completion of the Company's R&D programs and generating sales. The Company has no obligation to repay these grants, if the R&D program fails, is unsuccessful or aborted or if no sales are generated. The Company had not yet generated significant sales revenue as of December 31, 2017; therefore, no liability was recorded in these consolidated financial statements.

Lease Agreements

On April 13, 2017, the Company entered into a lease for a facility in Fort Lauderdale, Florida, which the Company began occupying in October 2017. The facility currently consists of 4.6 square feet, which will increase to 6.5 square feet by the second year of the lease. The term runs for seven years and two months from October 2017. Annual base rent is initially \$159 per year, subject to annual increases of 2.75%, which is recognized on a straight-line basis.

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

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

Many of these leases provide for payment by us, as the lessee, of taxes, insurance premiums, costs of maintenance and other costs. At December 31, 2017, the Company had the following future minimum lease commitments:

<u>Twelve Months Ended December 31,</u>	<u>Amount</u>
2018	\$ 366
2019	332
2020	235
2021	176
2022	179
Thereafter	341
Total	<u>\$ 1,629</u>

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Contingent Royalty Obligation

During 2016, the Company entered into a Contingent Royalty Obligation (as defined in Note 8) which was recorded as a liability in the amount of \$1,662 and \$1,410 as of December 31, 2017 and 2016, respectively.

Other Commitments

The Company has a severance liability to its CEO and CFO of approximately \$600 in the event that they are terminated or leave due to good cause, as outlined in their employee agreements. Management estimates that the likelihood of payment is remote; therefore, no liability was reflected in these consolidated financial statements.

NOTE 7 - RELATED PARTY TRANSACTIONS

Other than transactions and balances related to cash and share-based compensation to officers and directors, the Company did not have any transactions and balances with related parties and executive officers during 2017 and 2016 except for the following:

Sales and Marketing Services Arrangement with FreeHold Surgical, Inc.

In August, 2017, the Company began paying a monthly fee to FreeHold Surgical, Inc (“FreeHold”), an entity in which one of our Directors serves as a Director and President. Pursuant to the fee arrangement, the Company pays FreeHold a monthly amount of approximately \$25 as all-in compensation for sales and marketing services performed for the Company, on a part time basis, by two Freehold sales representatives. As of December 31, 2017, and 2016, the Company had \$50 and \$0 recorded as trade accounts payable to FreeHold.

NOTE 8 - SHARE CAPITAL

Formation Shares

During October and November 2016, the Company issued 1,650,000 common shares pursuant to the formation of the Company.

Share Exchange

As detailed in Note 1, during the Recapitalization Transaction in December 2016 the Company issued 4,000,000 common shares in exchange for 100% of the issued and outstanding and preferred shares of Motus Ltd.

Registration Rights

In connection with the 2017 Private Placement (as defined below), the Company entered into a registration rights agreement (the “Registration Rights Agreement”) with the 2017 Private Placement investors, (the “Investors”). On November 9, 2017, the Company entered into an amendment to the Registration Rights Agreement (the “Registration Rights Amendment”) to waive Investors’ rights to receive penalties under the Registration Rights Agreement if the Company is successful in consummating an IPO by June 30, 2018. On February 16, 2018, the Company closed its IPO. Accordingly, all penalties or other amounts due to the Investors under the Registration Rights Agreement have been forever waived and discharged, and the Company may be required to file a registration statement in accordance with the Registration Rights Agreement, as amended, within 225 days after the IPO date (see Note 14).

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Private Placement

On December 22, 2016, prior to the consummation of the Recapitalization Transaction, the Company consummated a private placement transaction (the “2017 Private Placement”) as part of the Recapitalization Transaction. The 2017 Private Placement consisted of units (“Units”) each consisting of three-quarter of a share of common stock, par value \$0.0001 and one-quarter a share of Series A Convertible Preferred Stock, par value \$0.0001.

On December 22, 2016, the Company completed the first closing of the Private Placement (the “Initial Closing”). The Company raised approximately \$8,077 for 1,615,540 Units.

On January 30, 2017, the Company completed the second closing of the private placement. The Company raised approximately \$2,937 for 587,460 Units.

On February 24, 2017, the Company completed the third and final closing of the private placement. The Company raised approximately \$4,388 for 877,671 Units.

Exchange of Convertible Notes

From June 2015 through November 2016, pursuant to the terms of a convertible note agreement, as amended (the “CNA”), Motus Ltd. issued convertible notes (the “Convertible Notes”) in an aggregate amount of approximately \$14,597 (inclusive of accrued interest through December 22, 2016, the date of the Initial Closing) to certain investors, including related parties of the Company and Motus Ltd. As part of the 2017 Private Placement, at the Initial Closing, the holders of the Convertible Notes (the “Convertible Holders”) exchanged their Convertible Notes (the “Exchange of Convertible Notes”), together with accrued and unpaid interest thereon at a rate of 10% per annum, for Units of the 2017 Private Placement, at a conversion price of \$4.50 per Unit. As a result, upon consummation of the Initial Closing, the Convertible Notes were exchanged for an aggregate of 3,243,768 Units representing (i) 2,432,808 shares of the Company’s common stock (inclusive of shares of the Company’s common stock resulting from the accrued and unpaid interest of the Convertible Notes through the date of the Initial Closing) and (ii) 810,960 shares of the Company’s Series A Convertible Preferred Stock (inclusive of shares of the Company’s Series A Convertible Preferred Stock resulting from the accrued and unpaid interest of the Convertible Notes through the date of the Initial Closing).

Convertible Notes Warrants

In connection with, and pursuant to the terms of the CNA, at the Initial Closing the Company issued warrants to purchase an aggregate of 907,237 shares of the Company’s common stock (the “CNA Warrants”) to replace the warrants previously issued to the Convertible Holders. The five-year CNA Warrants are exercisable for the Company’s common stock at an exercise price of \$5.00 per share.

Royalty Payment Rights on Series A Convertible Preferred Stock

On December 20, 2016, the Company filed its 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. As set forth in the in the Certificate of Designation, the Royalty Payment Rights initially entitled the holders in aggregate, to a royalty in an amount of:

- 3% of net sales subject to a maximum in any calendar year equal to the total dollar amount of Units closed on in the 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.

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On February 16, 2018, each share of Series A Convertible Preferred Stock converted into one share of common stock pursuant to the Mandatory Conversion. As provided for in the Certificate of Designation, if a holder had elected to convert all of their Series A Convertible Preferred Stock into shares of the Company's common stock prior to the Mandatory Conversion, the holder would have forfeited any and all rights to future royalty payments, if any. If a holder had elected to convert any portion of their Series A Convertible Preferred Stock to common stock at any time prior to the Mandatory Conversion, such holder would have forfeited any rights to future royalty payments, if any, with respect to such converted shares. No such conversion elections were received by the Company prior to the Mandatory Conversion.

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, 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, 2017 and 2016 (see Note 10 – Contingent Royalty Obligation). 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.

On November 9, 2017, the Company entered into an agreement to amend the Certificate of Designation to modify the Royalty Payment Rights if the Company is successful in consummating an IPO by June 30, 2018. Pursuant to the amended terms, if and when the Company generates sales of the Pure-Vu system, including disposables, parts, and services, or if the Company receives any proceeds from the licensing of the Pure-Vu system, then the Company will pay to the holders of the Series A Convertible Preferred Stock a royalty (the "Royalty Amount") equal to, in the aggregate, in royalty payments in any calendar year for all products:

- 3% of net sales* for commercialized product directly;
- 5% of any licensing proceeds** for rights to commercialize the product if sublicensed by the Company to a third-party.

* Notwithstanding the foregoing, with respect to Net Sales based Royalty Amounts, (a) no Net Sales based Royalty Amount shall begin to accrue or become payable until the Company has first generated, in the aggregate, since its inception, Net Sales equal to \$20,000 (the "Initial Net Sales Milestone"), and royalties shall only be computed on, and due with respect to, Net Sales generated in excess of the Initial Net Sales Milestone, and (b) the total Net Sales based Royalty Amount due and payable in any calendar year shall be subject to a cap per calendar year of \$30,000. Net Sales is defined in the Certificate of Designations.

** 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 cap per calendar year of \$30,000. Licensing Proceeds is defined in the Certificate of Designations.

The royalty will be payable up to the later of (i) the latest expiration date for the Company's current patents (which is currently October 2026), or (ii) the latest expiration date of any pending patents as of the date of the Initial Closing that may be issued in the future. Following the expiration of all such patents, the holders of the Royalty Payment Rights 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.

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NOTE 9 - SHARE-BASED COMPENSATION

Employee stock grant

On May 4, 2017, the Company's Board of Directors approved unrestricted stock awards for the issuance of 5,000 shares of its common stock to employees of the Company, under the 2016 Equity Incentive Plan. As of December 31, 2017, the Company recorded an expense in the amount of \$23 with respect to this grant as general and administrative expense.

Employee stock option grants

The Company has one option plan that was approved in 2009. This plan was adjusted in 2016 following the reverse recapitalization transaction on December 22, 2016.

On January 1, 2018, 629,594 additional shares of the Company's common stock were replenished to the Company's reserve for future issuance under its 2016 Equity Incentive Plan.

On May 4, 2017, the Company's Board of Directors approved the issuance of 1,595,769 options to directors and employees. The options that were granted have an exercise price of \$4.50 and vest in accordance with the terms of the option agreements.

As part of the 1,595,769 options granted on May 4, 2017, the Company's CEO received options to purchase 511,113 shares of the Company's common stock. Fifty-three percent (53%) of the options were fully vested immediately upon grant, forty percent (40%) of the options will vest in a series of twelve (12) successive equal quarterly installments upon the CEO's completion of each successive calendar quarter of active service over the three (3) year period measured from the date of grant, and seven percent (7%) of the options will vest on December 22, 2019, provided that the CEO remains an employee of the Company through each applicable vesting date. Additionally, the Company's former CFO as of the grant date, received options to purchase 154,227 shares of the Company's common stock. A portion of the options vested on the grant date and the remaining options were to vest over a period of 3 years. Following the former CFO's resignation, the non-vested options were forfeited in accordance with the terms of the option agreement as the CFO was no longer employed by the Company.

As part of the 1,595,769 options granted on May 4, 2017, Directors of the Company received options to purchase 482,500 shares of the Company's common stock. The options will vest on the first and second anniversary of the grant date contingent upon continued services as director of the Company.

On August 16, 2017, the Company hired a new CFO. Pursuant to the terms of the employment agreement, the CFO was granted options to purchase 240,000 common shares of the Company. The options will vest over a three-year period on a quarterly basis and the exercise price will be equal to the fair market value on the grant date of \$4.50 per share as determined by the Board of Directors.

On September 29, 2017, the Company's Board of Directors approved the issuance of 7,000 options to two employees. The additional options that were granted have an exercise price of \$4.50 and vest quarterly over a three-year period.

On September 29, 2017, the Board of Directors approved the repricing of the May 4, 2017 options awarded from an exercise price of \$5.00 to \$4.50 per share. This repricing was accounted for as a modification of a share-based payment award and increased the fair value of each option award from \$2.34 per share to \$2.45 per share. The incremental compensation expense recognized as a result of the modification during the period ended December 31, 2017 was approximately \$203.

On November 9, 2017, the Company's Board of Directors approved the issuance of 47,000 options to eight employees. The options that were granted have an exercise price of \$5.00 and vest quarterly over a three-year period.

On November 9, 2017, the Company's Board of Directors approved the accelerated vesting of 29,863 options issued prior to January 1, 2016 from milestone-based vesting to instead vest in full on November 8, 2018. This accelerated vesting was accounted for as a modification of a share-based payment award and increased the fair value of each option award from \$0 up to \$3.34 per share. The incremental compensation expense recognized as a result of the modification during the period ended December 31, 2017 was approximately \$14.

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The following table summarizes stock option activity related to employees during the years ended December 31, 2017 and 2016:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at January 1, 2016	119,293	\$ 2.42	9	\$
Granted	-	-	-	
Exercised	-	-	-	
Forfeited/canceled	(8,582)	2.38	-	
Outstanding at December 31, 2016	110,711	\$ 2.42	8	\$ 175
Granted	1,889,769	4.51	10.00	
Exercised	(1,438)	5.00	-	
Forfeited/canceled	(341,967)	4.32	-	
Outstanding at December 31, 2017	1,657,075	\$ 4.42	9.27	\$ 335

At December 31, 2017, unamortized stock compensation for employee stock options was \$2,131, with a weighted-average recognition period of 1.97 years.

At December 31, 2017 and 2016, outstanding employee options to purchase 478,372 and 67,908 shares of common stock were exercisable, respectively.

The following table summarizes total non-cash employee stock-based compensation for stock option grants by operating statement classification:

	Year ended December 31,	
	2017	2016
General administrative	\$ 1,238	\$ 20
Sales and marketing	139	-
Research and development	182	-
Total	\$ 1,559	\$ 20

Stock, options and warrants to service providers

The Company accounts for options to purchase common stock issued to non-employees using the guidance of ASC 505-50, "Equity-Based Payments to Non-Employees", whereby the fair value of such options is determined at the earlier of the date at which the non-employee's performance is completed or a performance commitment is reached.

In January 2017, the Company signed an agreement by which it granted a service provider an option to purchase 100,000 shares of the Company's common stock as compensation for past services, and therefore, the option was fully vested as of the signing date of the agreement. The option may be exercised during a period of 5 years from issuance at an exercise price of \$5.00 per share.

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In March 2017, the Company signed a consulting service agreement by which it granted the service provider 90,000 shares of the Company's common stock as compensation for past services provided. As such, the share award was fully vested as of the signing date of the agreement. The shares are subject to a lock-up agreement that will end, (i) with respect to 22,500 of the shares upon the nine month anniversary of the signing of the consulting agreement, (ii) with respect to 22,500 of the shares upon the 6 month anniversary the SEC declares the S-1 registration agreement effective (the "Effective Date"), and (iii) with respect to the remaining 45,000 upon the year anniversary of the Effective Date. The measurement date was reached on the signing date of the agreement. As of December 31, 2017, the Company recorded an expense in the amount of \$434 with respect to this grant as general and administrative expense.

Additionally, within the framework of the agreement, the Company granted the service provider a warrant to purchase 30,000 shares of the Company's common stock at an exercise price of \$8.00 per share, as compensation for services to be provided. The warrant will vest and become exercisable as follows: (i) 7,500 warrant shares will become exercisable on December 27, 2017, (ii) 7,500 warrant shares will become exercisable on August 14, 2018, and (iii) 15,000 warrant shares will become exercisable on the twelve month anniversary of the Registration Statement Effectiveness Date. The warrants are exercisable for a period of 5 years from the signing date of the agreement.

On May 4, 2017, the Company granted options to purchase 31,000 common shares of the Company to two services providers as consideration for consulting services. 250 of the options underlying the common shares vested on the grant date and the remaining options will vest in a series of twelve equal, quarterly installments contingent upon providing continued service as of each quarter over a three-year period from the grant date. The exercise price of the options is \$4.50 and will expire 10 years from the grant date.

In August, September and October 2017, the Company granted 4,167 shares of common stock in connection with a consulting agreement. As of December 31, 2017, the Company recorded an expense in the amount of \$19 with respect to this grant as general and administrative expense.

In connection with the 2017 Private Placement, the Company issued 403,632 warrants to purchase 403,632 shares of the Company's common stock to the placement agent at an exercise price of \$5. These warrants are exercisable for a period of 5 years from the grant date and provide for a cashless exercise.

Motus GI Holdings, Inc.
Notes to the Consolidated Financial Statements
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The following table summarizes stock option activity related to non-employees during the years ended December 31, 2017 and 2016:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Outstanding at January 1, 2016	15,019	\$ 2.42	9.34	
Granted	-	-	-	
Exercised	-	-	-	
Forfeited/canceled	-	-	-	
Outstanding at December 31, 2016	15,019	\$ 2.42	6.94	\$ 29
Granted	131,000	4.50	10.00	
Exercised	-	-	-	
Forfeited/canceled	-	-	-	
Outstanding at December 31, 2017	146,019	\$ 4.42	9.27	\$ 86

At December 31, 2017, unamortized stock compensation for non-employee stock options was \$53, with a weighted-average recognition period of 2.34 years.

At December 31, 2017 and 2016, outstanding non-employee options to purchase 118,218 and 11,392 shares of common stock were exercisable, respectively.

The following table summarizes total non-cash stock-based compensation for stock option grants to service providers by operating statement classification:

	Year ended December 31,	
	2017	2016
General administrative	\$ 185	\$ 4
Sales and marketing	-	6
Research and development	-	24
Total	\$ 185	\$ 34

Stock option pricing model

The fair value of the stock options and warrants granted to employees and service providers during the period was estimated at the date of grant using the Black-Scholes options pricing model with the following assumptions. Given the absence of an active market for the Company's stock at the time of grant, the fair value of common stock at the time of grant of each share award was based upon several factors, including consideration of input from management.

Fair value of common stock	\$4.50 - \$5.00
Expected volatility	60%
Dividend Yield	0%
Risk-free interest	1.92% - 2.36%
Expected life of up to (years)	5.81

NOTE 10 - CONTINGENT ROYALTY OBLIGATION

On December 20, 2016, the Company filed its Certificate of Designation which sets forth the Contingent Royalty Obligation, as defined in (Note 8, "Royalty Payment Rights on Series A Convertible Preferred Stock"), which was recorded as a liability at fair value as "other-long-term liabilities" in the consolidated balance sheets at December 31, 2017 and 2016 in the amount of 1,662 and 1,410, respectively. The Company records changes in the fair value of the Contingent Royalty Obligation in the consolidated statements of comprehensive loss as "financing" income or expense. For the years ending December 31, 2017 and 2016, the Company recorded financing expense in the amount of \$252 and \$0 in connection with the Contingent Royalty Obligation.

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The Company measured the fair value according to the discounted cash flow method. The following assumptions (level 3 measurements) were used:

	Year ended December 31,	
	2017	2016
Discount rate	20%	20%
Rate of royalty payment	3%	3%

The following table summarizes the contingent royalty obligation during the years ended December 31, 2017 and 2016:

	Contingent Royalty Obligation
As of December 22, 2016	\$ 1,410
Revaluation of liabilities	-
As of December 31, 2016	1,410
Revaluation of liabilities	252
As of December 31, 2017	\$ 1,662

In accordance with ASC-820-10-50-2(g), the Company performed a sensitivity analysis of the liability, which was classified as a level 3 financial instrument. The Company recalculated the fair value of the liability by applying a +/- 2% change to the input variable in the discounted cash flow model; the discount rate. A 2% decrease in the discount rate would increase the liability by approximately \$159; a 2% increase in the discount rate would decrease the liability by approximately \$182.

NOTE 11 - FINANCE EXPENSES, NET

The following table summarizes finance expenses for the years ended December 31, 2017 and 2016,

	Year ended December 31,	
	2017	2016
Bank fees and interest	6	86
Change in fair value of Contingent Royalty Obligation	252	-
Change in fair value and interest on convertible notes	-	1,907
Exchange rate differences	(22)	(27)
Total finance expenses, net	236	1,966

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, 2017 and 2016.

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At December 31, 2017 and 2016, the Company had deferred tax assets of \$7,900 and \$4,800, respectively, against which a full valuation allowance of \$7,900 and \$4,800, respectively, had been recorded. The change in the valuation allowance for the year ended December 31, 2017 was an increase of \$3,100. The increase in the valuation allowance for the year ended December 31, 2017 was mainly attributable to increases in net operating losses and accrued liabilities, which resulted in an increase in the deferred tax assets with a corresponding valuation allowance. Significant components of the Company's deferred tax assets at December 31, 2017 and 2016 were as follows:

	<u>December 31,</u>	
	<u>2017</u>	<u>2016</u>
Deferred taxes assets:		
Net operating loss carryforwards – U.S.	\$ 291	\$ 160
Net operating loss carryforwards – Israel	6,295	4,113
Accrued liabilities	1,269	525
Gross deferred tax assets	7,855	4,798
Valuation allowance	(7,855)	(4,798)
Gross deferred tax assets after valuation allowance	<u>\$ -</u>	<u>\$ -</u>

A reconciliation of the federal statutory tax rate and the effective tax rates for the years ended December 31, 2017 and 2016 is as follows:

	<u>For the Year Ended December 31,</u>	
	<u>2017</u>	<u>2016</u>
U.S. federal statutory tax rate	34.0%	34.0%
State income taxes, net of federal benefit	1.1	-
U.S. vs. foreign tax law change	(8.8)	(11.0)
Impact of tax law change	(3.0)	-
Other	(0.1)	(0.7)
Change in valuation allowance	(23.2)	(22.9)
Effective tax rate	<u>-%</u>	<u>(0.6)%</u>

The Company had approximately \$29,500 and \$18,700 of gross net operating loss (“NOL”) carryforwards (federal, state and Israel) as of December 31, 2017 and 2016, respectively. Sections 382 and 383 of the Internal Revenue Code, and similar state regulations, contain provisions that may limit the U.S. and State NOL carryforwards available to be used to offset income in any given year upon the occurrence of certain events, including changes in the ownership interests of significant stockholders. In the event of a cumulative change in ownership in excess of 50% over a three-year period, the amount of the NOL carryforwards that the Company may utilize in any one year may be limited.

A reconciliation of the Company's U.S. and State NOLs for the years ended December 31, 2017 and 2016 is as follows:

	<u>December 31,</u>	
	<u>2017</u>	<u>2016</u>
U.S. Federal NOL's	\$ 1,074	\$ 411
U.S. State NOL's	1,074	411
Israel NOL's	27,371	17,885
Total NOL's	<u>\$ 29,519</u>	<u>\$ 18,707</u>

Motus GI Holdings, Inc.
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The Company's federal and state NOL's of \$1,100 each begin to expire after 2036 through 2037. The Company's Israel NOL of \$27,400 does not expire.

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

NOTE 13 - SUBSEQUENT EVENTS

The Company has analyzed its operations subsequent to December 31, 2017 through March 28, 2018, the issuance date of the financial statements, and noted the following subsequent events:

On January 1, 2018, 629,594 additional shares of the Company's common stock were replenished to the Company's reserve for future issuance under its 2016 Equity Incentive Plan (see Note 9).

On February 16, 2018, the Company closed its IPO in which it sold 3,500,000 shares of the Company's common stock at a public offering price of \$5.00 per share. In connection with the closing of the IPO, (1) the Company received net proceeds of \$15,200 after deducting underwriting discounts and commissions of \$1,400 and other offering expenses of approximately \$900, (2) the amendment to the Registration Rights Agreement described above in Note 8, "Registration rights" became effective, (3) the amendment to the Certificate of Designation described above in Note 8, "Royalty Payment Rights on Series A Convertible Preferred Stock" became effective, (4) all outstanding shares of Series A Convertible Preferred Stock converted, on a one-to-one basis, into shares of the Company's common stock, (5) the Company issued the Royalty Payment Rights Certificates as described in Note 8, "Royalty Payment Rights on Series A Convertible Preferred Stock", and (6) the Company issued warrants to certain of the former Series A Convertible Preferred Stock holders, pursuant to the amendment to the Registration Rights Agreement and the amendment to the Certificate of Designation, to purchase an aggregate of 1,095,682 shares of the Company's common stock (the "Ten Percent Warrants"). The Ten Percent Warrants are exercisable any time on or after the 180 day anniversary of the completion of the IPO, have a five year term, and provide for cashless exercise. No fractional shares will be issued upon the exercise of the Ten Percent Warrants. In addition, the Company granted the representative of the several underwriters in the IPO (the "Representative") a 30-day option (the "Over-Allotment Option") to purchase up to an aggregate 525,000 additional shares of the Company's common stock at an exercise price of \$5.00 per share.

On February 21, 2018, a consultant exercised 896 options on a cashless basis which resulted in the issuance of 394 shares of the Company's common stock.

On February 27, 2018, the Company announced that it received CE mark approval for the Pure-Vu System, which enables continued work with expert clinical thought leaders in Europe and lays the foundation for future commercial expansion into Europe.

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

On March 27, 2018, the Company's Board of Directors approved the issuance of 44,000 options to six employees which vest over a three-year period on a quarterly basis and 50,000 options to one board member which vests over a two-year period on an annual basis to purchase shares of the Company's common stock at \$4.58, the closing share price of the Company's common stock on the Nasdaq Capital Market on March 27, 2018.

On March 27, 2018, the Company's Board of Directors approved the issuance of 15,000 shares of the Company's common stock to a third party for services to be provided. The stock vests immediately and is subject to a lock-up through February 14, 2019.

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Mark Pomeranz, certify that:

1. I have reviewed this annual report on Form 10-K for the period ended December 31, 2017 of Motus GI Holdings, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2018

/s/ Mark Pomeranz

Mark Pomeranz
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Andrew Taylor, certify that:

1. I have reviewed this annual report on Form 10-K for the period ended December 31, 2017 of Motus GI Holdings, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 28, 2018

/s/ Andrew Taylor

Andrew Taylor
Chief Financial Officer
(Principal Financial Officer)

**Certification Pursuant to
18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002**

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Annual Report on Form 10-K of Motus GI Holdings, Inc. for the year ended December 31, 2017 (the "Annual Report"), each of the undersigned hereby certifies in his capacity as an officer of Motus GI Holdings, Inc. (the "Company") that to such officer's knowledge:

(1) The Annual Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 28, 2018

By: /s/ Mark Pomeranz

Mark Pomeranz
Chief Executive Officer
(Principal Executive Officer)

Dated: March 28, 2018

By: /s/ Andrew Taylor

Andrew Taylor
Chief Executive Officer
(Principal Executive Officer)
