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

FORM 20-F

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2016

OR

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

OR

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

Commission file number: **001-37381**

Medigus Ltd.

(Exact name of Registrant as specified in its charter)

Israel

(Jurisdiction of incorporation or organization)

Omer Industrial Park No. 7A, P.O. Box 3030, 8496500, Israel

(Address of principal executive offices)

Oded Yatzkan
7A Industrial Park, P.O. Box 3030
Omer, 8496500, Israel
Tel: +972 72 260-2211
Fax: +972 72 260-2231
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of class	Name of each exchange on which registered
American Depositary Shares, each representing fifty (50) Ordinary Shares[1]	Nasdaq Capital Market
Ordinary shares, par value NIS 0.10 per share[2]	Nasdaq Capital Market

(1) Evidenced by American Depositary Receipts.
(2) Not for trading, but only in connection with the registration of the American Depositary Shares.

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

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: **None**

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2016: 44,142,884 **ordinary shares, par value NIS 0.10 per share**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act:

Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934:

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 whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large Accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

Indicate by check mark the basis of accounting the registrant has used to prepare the financial statements included in this filing:

☐ U.S. GAAP

☒ International Financial Reporting Standards as issued by the International Accounting Standards Board

☐ Other

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act):

Yes ☐ No ☒

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INTRODUCTION

Certain Definitions

In this annual report, unless the context otherwise requires:

- references to "Medigus," the "Company," "us," "we" and "our" refer to Medigus Ltd. (the "Registrant"), an Israeli company, and its consolidated subsidiary.
- references to "ordinary shares," "our shares" and similar expressions refer to the Registrant's Ordinary Shares, NIS 0.10 nominal (par) value per share.
- references to "ADS" refer to American Depositary Shares.
- references to "dollars," "U.S. dollars" and "$" refer to United States Dollars.
- references to "NIS" refer to New Israeli Shekels, the Israeli currency.
- references to the "Companies Law" refer to Israel's Companies Law, 5759-1999, as amended.
- references to the "SEC" refer to the United States Securities and Exchange Commission.
- references to MUSE™ refer to the trade name of an endoscopy system developed by the Company which is intended as a minimally invasive treatment for Gastroesophageal Reflux Disease, or GERD. It should be noted that this term may refer to both versions of the system, according to the applicable context. MUSE™ II is second version of the MUSE™ system. The system was previously called "SRS."
- references to "endoscopy" refer to a medical procedure which is used to diagnose or treat various diseases using an endoscope (a flexible tube which contains lighting features, imaging features and a system used to direct the endoscope within bodily systems).

All share data information in this annual report on Form 20-F reflects a 1-for-10 reverse share split of our ordinary shares effected on November 6, 2015, and a change in the ratio of ordinary shares per ADS from five ordinary shares per ADS to 50 ordinary shares per ADS effected on March 15, 2017. The change in the ordinary shares ratio for the ADSs had the same effect as a 1-for-10 reverse stock split of the ADSs.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain information included or incorporated by reference in this annual report on Form 20-F may be deemed to be "forward-looking statements". Forward-looking statements are often characterized by the use of forward-looking terminology such as "may," "will," "expect," "anticipate," "estimate," "continue," "believe," "should," "intend," "project" or other similar words, but are not the only way these statements are identified.

These forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies, statements that contain projections of results of operations or of financial condition, statements relating to the research, development and use of our products, and all statements (other than statements of historical facts) that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future.

Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. We have based these forward-looking statements on assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.

Important factors that could cause actual results, developments and business decisions to differ materially from those anticipated in these forward-looking statements include, among other things:

- the overall global economic environment;
- insufficient coverage or reimbursement from medical insurers;
- the impact of competition and new technologies;
- general market, political, reimbursement and economic conditions in the countries in which we operate;
- our ability to continue as a going concern;
- projected capital expenditures and liquidity;
- changes in our strategy;
- government regulations and approvals;
- changes in customers' budgeting priorities;
- litigation and regulatory proceedings;
- our liquidity; and
- those factors referred to in "Item 3. Key Information – D. Risk Factors," "Item 4. Information on the Company," and "Item 5. Operating and Financial Review and Prospects", as well as in this annual report on Form 20-F generally.

Readers are urged to carefully review and consider the various disclosures made throughout this annual report on Form 20-F, which are designed to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

In addition, the section of this annual report on Form 20-F entitled "Item 4. Information on the Company" contains information obtained from independent industry and other sources that we have not independently verified. You should not put undue reliance on any forward-looking statements. Any forward-looking statements in this annual report are made as of the date hereof, and we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISORS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data

The following consolidated statement of operations data for the years ended December 31, 2014, 2015, and 2016, and the consolidated balance sheet data as of December 31, 2016 and 2015, is derived from our audited consolidated financial statements included elsewhere in this annual report on Form 20-F. These audited financial statements have been prepared in accordance with International Financial Reporting Standards, or IFRS, as set forth by the International Accounting Standard Board. The consolidated statement of operations data for the years ended December 31, 2012 and 2013 and the consolidated balance sheet data as of December 31, 2012, 2013, and 2014 is derived from other consolidated financial statements not included in this Form 20-F. The selected consolidated financial data set forth below should be read in conjunction with and are qualified by reference to "Item 5. Operating and Financial Review and Prospects" and the consolidated financial statements and notes thereto and other financial information included elsewhere in this annual report on Form 20-F.

The December 31, 2015 consolidated financial statements included in this annual report on Form 20-F were recorded in New Israeli Shekels, which was the Company's functional and presentation currency as of such date. Effective January 1, 2016, the Company changed its functional currency to the U.S. Dollar from the New Israeli Shekel. The December 31, 2012, 2013, 2014, and 2015, financial data presented in this annual report on Form 20-F was translated from NIS to USD as follows: (1) all assets and liabilities of the Company were translated using the dollar exchange rate as of December 31st of each year, as applicable; (2) equity items were translated using historical exchange rates at the relevant transaction dates; (3) the statement of comprehensive loss items has been translated at the average exchange rates for the respective year; and (4) the resulting translation differences have been reported as "currency translation differences" within other comprehensive loss.

Consolidated Statements of Operations Data

	As of December 31,				
	2012	2013	2014	2015	2016
	U.S. Dollars, in thousands, except per share and weighted average shares data				
Revenues	777	691	744	624	549
Cost of revenues	301	311	351	277	176
Gross Profit	476	380	393	347	373
Research and development, expenses, net	2,009	2,275	4,025	4,384	3,655
Sales and marketing expenses	461	900	2,341	2,680	2,125
General and administrative expenses	1,218	1,908	2,280	2,842	3,684
Other income, net	56	181	269	3	
Operating loss	(3,156)	(4,522)	(7,984)	(9,556)	(9,091)
Gain on adjusting warrants to fair value		3,228	980	106	25
Finance income (expenses) – net	(42)	(111)	650	(14)	87
Loss before income tax	(3,198)	(1,405)	(6,354)	(9,464)	(8,979)
Income taxes	22	(23)	(4)	(68)	(28)
Loss for the year	(3,176)	(1,428)	(6,358)	(9,532)	(9,007)
Other comprehensive income (loss) for the period, net of tax	(3,121)	408	(1,573)	(211)	
Total comprehensive loss for the period	(6,297)	(1,020)	(7,931)	(9,743)	(9,007)
Basic and diluted loss per ordinary share[(1)]	(0.37)	(0.11)	(0.33)	(0.34)	(0.26)
Weighted average of ordinary shares (in thousands)[(1)]	8,698	13,020	19,500	28,415	34,397

(1) Adjusted to reflect 10:1 reverse share split such that every 10 ordinary shares were converted into one ordinary share effected on November 6, 2015, and a change in the ratio of ordinary shares per ADS from five ordinary shares per ADS to 50 ordinary shares per ADS effected on March 15, 2017. The change in the ordinary shares ratio for the ADSs had the same effect as a 1-for-10 reverse stock split of the ADSs. For more information see "Item 4. Information on the Company A. History and Development of the Company."

	As of December 31,				
	2012	2013	2014	2015	2016
	U.S. Dollars (in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	351	6,893	10,817	10,312	3,001
Short-term investments		2,326			
Financial assets at fair value through profit or loss	289	2,293	2,105		
Total assets	1,789	13,022	14,291	12,141	4,724
Total non-current liabilities	423	884	208	107	463
Accumulated deficit	(26,984)	(28,412)	(34,797)	(44,329)	(53,336)
Total shareholders' equity	787	11,163	13,050	10,181	2,927

The following table sets forth information regarding the exchange rates of U.S. dollars per NIS for the periods indicated. Average rates are calculated by using the daily representative rates as reported by the Bank of Israel on the last day of each month during the periods presented.

NIS per U.S. $

As of December 31,	High	Low	Average	Period End
2016	3.983	3.746	3.832	3.845
2015	4.053	3.761	3.884	3.902
2014	3.994	3.402	3.577	3.889
2013	3.728	3.471	3.601	3.471
2012	4.028	3.715	3.844	3.733

The following table sets forth the high and low daily representative rates for the NIS as reported by the Bank of Israel for each of the prior six months.

NIS per U.S. $

Month	High	Low	Average	Period End
March 2017 [(1)]	3.693	3.614	3.651	3.625
February 2017	3.768	3.659	3.729	3.659
January 2017	3.860	3.769	3.818	3.769
December 2016	3.867	3.787	3.828	3.845
November 2016	3.876	3.799	3.842	3.839
October 2016	3.856	3.778	3.821	3.849
September 2016	3.786	3.746	3.765	3.758

(1) Through March 29, 2017.

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should carefully consider the risks described below, together with all of the other information in this annual report on Form 20-F. The risks described below are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business operations. If any of these risks actually occurs, our business and financial condition could suffer and the price of our shares could decline.

Risks Related to Our Business

Our auditors have expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain further financing.

Our audited financial statements for the year ended December 31, 2016, were prepared under the assumption that we would continue our operations as a going concern. Our independent registered public accounting firm has included a "going concern" explanatory paragraph in its report on our financial statements for the year ended December 31, 2016, indicating that we have suffered recurring losses from operations and have a net capital deficiency that raises substantial doubt about our ability to continue as a going concern. Uncertainty concerning our ability to continue as a going concern may hinder our ability to obtain future financing. Continued operations and our ability to continue as a going concern are dependent on our ability to obtain additional funding in the near future and thereafter, and there are no assurances that such funding will be available to us at all or will be available in sufficient amounts or on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. Without additional funds from private or public offerings of debt or equity securities, sales of assets, sales or out-licenses of intellectual property or technologies, or other transactions, we will exhaust our resources and will be unable to continue operations. If we cannot continue as a viable entity, our shareholders would likely lose most or all of their investment in us.

We will need additional funding. If we are unable to raise capital, we will be forced to reduce or eliminate our operations.

As of December 31, 2016, we had a total cash balance of approximately $3.0 million. We have recently raised approximately $7.5 million (gross) in a public offering of our ADSs and warrants to purchase ADSs. As of March 29, 2017, we had a cash balance of approximately $8.4 million. Based on our projected cash flows and our cash balances as of the date of this annual report on Form 20-F, our management is of the opinion that without further fund raising we will not have sufficient resources to enable us to continue advancing our activities and as a result, there is substantial doubt about our ability to continue as a going concern.

If we are unable to obtain additional sufficient financing, we will be forced to reduce the scope of, or eliminate our operations. We will also have to reduce marketing, customer service or other resources devoted to our products. Any of these factors will materially harm our business and results of operations.

Our management's plans include the continued commercialization of our products and securing sufficient financing through the sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances however, that we will be successful in obtaining the level of financing needed for our operations.

Even if we are able to continue to finance our business, the sale of additional equity or debt securities could result in dilution to our current shareholders and could require us to grant a security interest in our assets. If we raise additional funds through the issuance of debt securities, these securities may have rights senior to those of our ordinary shares and could contain covenants that could restrict our operations. In addition, we may require additional capital beyond our currently forecasted amounts to achieve profitability. Any such required additional capital may not be available on reasonable terms, or at all.

We are currently implementing a cost reduction program which may be unsuccessful in its execution, and, even if successful, may lead to undesirable outcomes.

We are currently implementing a cost reduction program that effects the structure and operation of our business. Such plan reflects assumptions and analyses based on our experience and perception of historical trends, current conditions and expected future developments as well as other factors that we consider appropriate under the circumstances. Whether our cost reduction program will prove successful depends on a number of factors, including but not limited to (i) our ability to substantially raise additional funding and to obtain adequate liquidity; (ii) our ability to maintain suppliers', hospitals', medical facilities' and practitioners' confidence; (iii) our ability to efficiently reduce our operational expenditures, while retaining key employees; and (iv) the overall success of our business. In addition, as long as these cost reduction measurements last, and for a substantial time afterwards, our employees may face considerable distraction and uncertainty and we may experience increased levels of employee attrition. A loss of key personnel could have a material adverse effect on our ability to meet operational and financial expectations. The pursuit of additional funding and the application of the cost reduction program has occupied and will continue to occupy a substantial portion of the time and attention of our management and will impact how our business is conducted.

We have a history of operating losses and expect to incur additional losses in the future.

We have sustained losses in recent years, which as of December 31, 2016, accumulated to $53.3 million, including an operating net loss of $9.1 million and $9.6 million for the year ended December 31, 2016 and December 31, 2015, respectively. We anticipate that we are likely to continue to incur significant net losses for at least the next several years as we continue the development of the MUSE™ system and potentially other products, expand our sales and marketing capabilities in the endoscopy-based products market, continue our commercialization of our MUSE™ system, expand our adoption and clinical implementation, and continue to develop the corporate infrastructure required to sell and market our products. Our losses have had, and will continue to have, an adverse effect on our shareholders' equity and working capital. Any failure to achieve and maintain profitability would continue to have an adverse effect on our shareholders' equity and working capital and could result in a decline in our share price or cause us to cease operations.

The future success of our business depends on our ability to continue to develop and obtain regulatory clearances or approvals for innovative and commercially successful products in our field, which we may be unable to do in a timely manner, or at all. Our success and ability to generate revenue or be profitable also depends on our ability to establish our sales and marketing force, generate product sales and control costs, all of which we may be unable to do.

The commercial success of the MUSE™ system or any future product, if approved, depends upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.

The commercial success of the MUSE™ system and any future product, if approved, depends in part on the medical community, patients, and third-party payors accepting our products as medically useful, cost-effective, and safe. Any product that we bring to the market may or may not gain market acceptance by physicians, patients, third-party payors, and others in the medical community. In addition, since the MUSE™ system is a therapeutic device being used for a quality of life, benign disease, market penetration may be more difficult. To date, we have experienced slower than expected market penetration. If the MUSE™ system or any future product, if approved, does not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of these products, if approved for commercial sale, will depend on a number of factors, including:

- the cost, safety, efficacy, and convenience of the MUSE™ system and any future product in relation to alternative treatments and products;
- the ability of third parties to enter into relationships with us without violating their existing agreements;
- the effectiveness of our sales and marketing efforts;
- the prevalence and severity of any side effects resulting from the procedure;
- the willingness of the target patient population to try new procedures and of physicians to perform new procedures;

- the strength of marketing and distribution support for, and timing of market introduction of, competing products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage or reimbursement.

Even if the MUSE™ system and any future product, if approved, displays a favorable safety and efficacy profile in clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the products may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by conventional technologies.

Insufficient coverage or reimbursement from medical insurers to users of our products could harm our ability to market and commercialize our current and future products.

Our ability to successfully commercialize our products, mainly the MUSE™ system, depends significantly on the availability of coverage and reimbursement for endoscopic procedures from third-party payors, including governmental programs, as well as private insurance and private health plans. Reimbursement is a significant factor considered by hospitals, medical facilities and practitioners in determining whether to acquire and utilize new capital equipment or to implement new procedures such as our technology.

In January 2016, the American Medical Association's, or the AMA's Current Procedural Terminology, or CPT, published a new Category I CPT Code for transoral esophagogastric fundoplasty procedures, which describes procedures conducted with the MUSE™ system. In the U.S., the CPT Editorial Panel assigns specific billing codes for physician services and outpatient hospital procedures, which are used by providers, who are our customers, to bill for procedures. Once a CPT code is established, the Centers for Medicare and Medicaid Services or CMS, in turn establishes payment levels and coverage rules under Medicare, and private payors establish rates and coverage rules. Notwithstanding the issuance of a CPT to report the MUSE procedure and the establishment of payment rates for the code, we cannot guarantee that the MUSE™ system is or will be covered and, if covered, that reimbursement will be sufficient, and furthermore, we cannot guarantee that the MUSE™ system or any future product will be approved for coverage or reimbursement by Medicare, Medicaid or any third-party payor. Reimbursement decisions in the European Union and in other jurisdictions outside of the United States vary by country and region and there can be no assurance that we will be successful in obtaining adequate reimbursement.

We depend on the success of a limited portfolio of products for our revenue, which could impair our ability to achieve profitability.

While we have plans for the development of additional natural orifice surgical products based on our technology, including miniature cameras, flexible stapling and ultrasound, and although we currently derive most of our revenue from the sale of miniature cameras and related imaging equipment, we plan to derive most of our future revenue from product sales of our imaging equipment and the MUSE™ system and its future applications, as well as recurring sales of associated products required to use the MUSE™ system. Our future growth and success is dependent on the successful commercialization of the MUSE™ system. If we are unable to achieve increased commercial acceptance of the MUSE™ system, obtain regulatory clearances or approvals for future products, or experience a decrease in the utilization of our product line or procedure volume, our revenue would be adversely affected.

We may encounter manufacturing issues during the assembly process of MUSE™ system.

Due to the characteristics of the technologies on which the main parts of the MUSE™ system are manufactured, which include plastic and metal injection, sheet metals, laser welding and rubber vulcanization, using production tools such as molds, templates and jigs, in the event that parts are found which are inaccurate and/or which have been rendered defective and/or which have failed preliminary tests, we will be forced to repair the manufacturing tools and re-manufacture and/or re-order the parts, a process which will delay the production timetable. Furthermore, in the event that certain parts are not suitable, due to a situation whereby the manufacturing tools have not produced the part in the appropriate manner, it may be necessary to redesign and re-manufacture the manufacturing tool and to manufacture the parts rapidly and at additional cost.

Furthermore, if we are unable to satisfy commercial demand for our MUSE™ system due to our inability to assemble, test and deliver the system in compliance with applicable regulations, our business and financial results, including our ability to generate revenue, would be impaired, market acceptance of our products could be materially, and adversely affected and customers may instead purchase or use competing products.

We may encounter failure in the operation of our products, which may adversely harm patients operated by using our products.

Users of our products may encounter failures in mechanical components, which could result in difficulties in operation, possibly leading to the need for surgical procedures to correct the mechanical failure, in which case, a patients' medical condition may worsen.

Additionally, in the event that our products do are not use in accordance with the instructions for use (which appear on the screen during the performance of the procedure) the foregoing may cause injury and in certain cases, could even cause death. This could reduce the rate of progress of, or even prevent, the marketing for the MUSE™ system and our other products.

Furthermore, users of our products may encounter failure in electronic components of our products used in the system software, which could lead to incorrect interpretation by the users or to failure in the operation of the endoscope and injury to the patient's critical internal organs.

We have only limited clinical data to support the value of the MUSE™ system, as well as our other products, which may make patients, physicians and hospitals reluctant to accept or purchase our products.

Physicians, hospitals and patients will only accept or purchase our products if they believe them to be safe and effective, with advantages over competing products or procedures. To date, we have collected only limited clinical data with which to assess our products' (mainly the MUSE™ system's) clinical and economic value. The collection of clinical and economic data and the process of generating peer review publications in support of our products and procedures is an ongoing focus for us.

If future publications of clinical studies indicate that medical procedures using the MUSE™ system are less safe or less effective than competing products or procedures, the patients may choose not to undergo our procedure, and physicians or hospitals may choose not to purchase or use our system. Furthermore, unsatisfactory patient outcomes or patient injury could cause negative publicity for our products, particularly in the early phases of product introduction.

Current economic conditions could delay or prevent our customers from obtaining budgetary approval to purchase a MUSE™ system or other products, which would adversely affect our business, financial condition and results of operations.

The concerns related to current economic conditions and healthcare reimbursement changes, customers and distributors may be delayed in obtaining, or may not be able to obtain, budgetary approval or financing for their purchases or leases of medical equipment including our products. These delays may in some instances lead to our customers or distributors postponing the shipment and use of previously ordered systems and products, cancelling their orders, or cancelling their agreements with us. An increase in delays and order cancellations of this nature could adversely affect our products sales and revenues and, therefore, harm our business and results of operations.

In addition, unstable worldwide economic and market conditions may make it increasingly difficult for us, our customers, our distributors and our suppliers to accurately forecast future product demand trends, which could cause us to produce excess products increasing our inventory carrying costs and resulting in obsolete inventory. Alternatively, this forecasting difficulty could cause a shortage of products, or materials used in our products, that could result in an inability to satisfy demand for our products and a material loss of potential revenue.

Our reliance on third-party suppliers for most of the components of our products could harm our ability to meet demand for our products in a timely and cost effective manner.

Though we attempt to ensure the availability of more than one supplier for each important component in our products, the number of suppliers engaged in the provision of miniature video sensors which are suitable for our CMOS technology products is very limited and, therefore, in some cases we engage with a single supplier, which may result in dependency on such supplier. This is the case regarding sensors for the CMOS type technology that is produced by a single supplier in the United States. Currently, there is no contractual commitment on the part of such supplier for any set quantity of such sensors. The loss of our sole supplier in providing us with miniature sensors for our CMOS technology products, and our inability or delay in finding a suitable replacement supplier, could significantly affect our business, financial condition, results of operations and reputation.

Modifications to our currently approved products or the introduction of new products may require new regulatory clearances or approvals or require us to recall or cease marketing the modified products until clearances or approvals are obtained.

The MUSE™ system has received marketing clearance from the U.S. Food and Drug Administration, or FDA, based on several 510(k) applications, bears the CE Mark (a mark assigned to a product certifying its fulfillment of the Medical Devices Directive of the European Union), as required in order to market the system in European Union countries and has obtained the necessary licenses to market the product in Canada, Turkey and Israel.

Ongoing modifications to our products may require new regulatory approvals, as with prior 510k clearances, or require us to recall or cease marketing the modified products until these clearances or approvals are obtained. Any modification to one of our approved products that would constitute a major change in its intended use, or any change that could significantly affect the safety or effectiveness of the product would require us to obtain a new 510(k) marketing clearance and may even, in some circumstances, require the submission of a premarket approval, or PMA, track application if the change raises complex or novel scientific issues or the product has a new intended use. The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. We may make modifications to the MUSE™ system without seeking additional clearances or approvals if we believe such clearances or approvals are not necessary. However, it is possible that the FDA could change existing policy and practices regarding the assessment of whether a new 510(k) clearance is required for changes or modifications to existing devices. Under these changed circumstances, the FDA may disagree with our past or future decisions not to seek a new 510(k) for changes or modifications to existing devices and require new clearances or approvals. In that case, we may be required to recall and stop marketing our modified products, redesign our products, conduct clinical trials to support any modifications, and pay significant regulatory fines or penalties. In addition, the FDA may not approve or clear our products for the indications that are necessary or desirable for successful commercialization or could require additional clinical trials to support any modifications.

Significant changes that could be reasonably expected to affect the safety or effectiveness of one of our devices may require us to obtain a license amendment or possibly a new license from Health Canada, Turkey, or Israel. In addition, we have started the process for receiving a regulatory clearance in China by the China Food and Drug Administration, which could be significantly affected by such changes. Substantial changes to the quality system or changes to the CE marked device which could affect compliance with the essential requirements of the device or its intended use must be reported to the Notified Body (an independent and neutral institution appointed to conduct conformity assessment). This may result in a decision that an existing certificate is in valid, an addendum to the certificate is needed or a new certificate must be obtained. Any failure to maintain our existing clearances or approvals, or delay or failure in obtaining required clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. Any of these actions would harm our operating results. Further, we may also be required to seek regulatory clearance in additional countries as we expand our marketing efforts.

Moreover, clearances and approvals by the applicable regulator are subject to continual review, and the later discovery of previously unknown problems can result in product labeling restrictions or withdrawal of the product from the market. The loss of previously received approvals or clearances, or the failure to comply with existing or future regulatory requirements could reduce our sales, profitability and future growth prospects.

We are currently required by the FDA to refrain from using certain terms to label and market our products, which could harm our ability to market and commercialize our current or future products.

The FDA's 510(k) clearances include a specification of a product's indication for use, and also authorize specific labeling and marketing claims and language in promotional materials for the U.S. market. Failure to conform with the specified labeling of our products or corporate promotional material would be considered mislabeling or off-label promotion which might lead to:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications, refunds, detention or seizure of our products;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;

- withdrawing 510(k) marketing clearances or PMA approvals that have already been granted;
- refusing to provide Certificates for Foreign Government;
- refusing to grant export approval for our products; or
- criminal prosecution.

Any of these sanctions could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and financial condition.

***If we or our third-party manufacturers or suppliers fail to comply with the FDA's Quality System Regulation or other regulatory authorities, our manufacturing operations could be interrupted and our product sales and operating results could suffer*.**

We and some of our third-party manufacturers and suppliers are required to comply with the FDA's Quality System Regulation, or QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. We and our manufacturers and suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process if we or our distributors market our products abroad. We monitor our quality management in order to improve our overall level of compliance. Our facilities are subject to periodic and unannounced inspection by U.S. and foreign regulatory agencies, including notified bodies, to audit compliance with the QSR and comparable foreign regulations. If our facilities or those of our third-party manufacturers or suppliers are found to be in violation of applicable laws and regulations, or if we or our manufacturers or suppliers fail to take satisfactory corrective action in response to an adverse inspection, the regulatory authority could take enforcement action, including any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) marketing clearances that have already been granted, or PMA approvals that we may receive in the future;
- refusing to provide Certificates for foreign government;
- refusing to grant export approval for our products; or
- pursuing criminal prosecution.

Any of these sanctions could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands, and could have a material adverse effect on our reputation, business, results of operations and financial condition. We may also 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.

We face possible competition from the pharmaceutical sector, which could harm our ability to market and commercialize our current and future products.

The development of more powerful drug treatments to assist in the suppression of GERD or other medical problems which compete with our products, may reduce the size of our target markets and may reduce the need for the use of our systems and products, either available now, or which will be developed in the future, thus adversely affecting our ability to market and commercialize our current and future products. While we are unaware of any current pharmaceutical product that could directly compete with the MUSE™ system at this time, there may be new pharmaceutical market entrants in the future.

There can be no assurance that we will be able to compete successfully against current or future competitors or that competition will not have a material adverse effect on our future revenues and, consequently, on our business, operating results and financial condition.

We face competition from medical device companies that develop and market similar related products and systems, or may launch products in the future, as well as new techniques and devices for treatments performed by our products.

Several medical device companies have commercial products which compete with the MUSE™ system for the treatment of GERD using an endoscopic method. While we believe that the MUSE™ system has several advantages over competing devices, such as the requirement of one operator, inclusion of visualization and ultrasound apparatuses, use of standard titanium staples, and reduced risk of harm to adjacent organs, there can be no assurance that we will be able to compete successfully against current or future competitors or that competition will not have a material adverse effect on our future revenues and, consequently, on our business, operating results and financial condition.

Reporting requirements on payments to physicians in the United States may deter doctors from providing advice to the Company.

The implementation of the reporting and disclosure obligations of the Physician Payment Sunshine Act, which is part of the Affordable Care Act of 2010, or the Sunshine Act, could adversely affect our business.

The Sunshine Act has imposed new reporting and disclosure requirements for drug and device manufacturers with regard to payments or other transfers of value made to certain practitioners (including physicians, dentists and teaching hospitals), and for such manufacturers and for group purchasing organizations with regard to certain ownership interests held by physicians in the reporting entity. On February 1, 2013, the CMS, released the final rule to implement the Sunshine Act. Under this rule, data collection activities began on August 1, 2013, and first disclosure reports were due by March 31, 2014, for the period August 1, 2013, through December 31, 2013. As required under the Sunshine Act, CMS publishes information from these reports on a publicly available website, including amounts transferred and physician, dentist and teaching hospital identities.

The final rule implementing the Sunshine Act is complex, ambiguous, and broad in scope. Accordingly, we are required to collect and report detailed information regarding certain financial relationships we have with U.S. licensed physicians, dentists (if any) and teaching hospitals in the United States. It is difficult to predict how the new requirements may impact existing relationships among manufacturers, distributors, physicians, dentists and teaching hospitals. The Sunshine Act preempts similar state reporting laws, although we, or our subsidiaries, may be required to continue to report under certain of such state laws. While we expect to have substantially compliant programs and controls in place to comply with the Sunshine Act requirements, and we have completed our initial registration with CMS and our 2015 report with respect to Sunshine Act reporting, our continued compliance with the Sunshine Act imposes continuing additional costs on us.

Medical device development is costly and involves continual technological change which may render our current or future products obsolete.

Innovation is rapid and continuous in the medical device industry, and our competitors in the medical device industry make significant investments in research and development. If new products or technologies emerge that provide the same or superior benefits as our products at equal or lower cost, they could render our products obsolete or unmarketable. We must anticipate changes in the marketplace and the direction of technological innovation and customer demands. In addition, we face increasing competition from well-financed medical device companies to develop new technologies and may face competition should we attempt to acquire new technologies, products and businesses. As a result, we cannot be certain that our products will be competitive with current or future products and technologies.

We may be subject to product liability claims, product actions, including product recalls, and other field or regulatory actions that could be expensive, divert management's attention and harm our business.

Our business exposes us to potential liability risks, product actions and other field or regulatory actions that are inherent in the manufacturing, marketing and sale of medical device products. We may be held liable if our products cause injury or death or is found otherwise unsuitable or defective during usage. The MUSE™ system incorporates mechanical and electrical parts, complex computer software and other sophisticated components, any of which can contain errors or failures. Complex computer software is particularly vulnerable to errors and failures, especially when first introduced. In addition, new products or enhancements to our existing products may contain undetected errors or performance problems that, despite testing, are discovered only after installation.

If any of our products are defective, whether due to design or manufacturing defects, improper use of the product, or other reasons, we may voluntarily or involuntarily undertake an action to remove, repair, or replace the product at our expense. In some circumstances we will be required to notify regulatory authorities of an action pursuant to a product failure.

The medical device industry has historically been subject to extensive litigation over product liability claims. We anticipate that as part of our ordinary course of business we will be subject to product liability claims alleging defects in the design, manufacture or labeling of our products. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs and high punitive damage payments. Although we maintain product liability insurance, the coverage may not be adequate to cover future claims. Additionally, we may be unable to maintain our existing product liability insurance in the future at satisfactory rates or adequate amounts.

Broad-based domestic and international government initiatives to reduce spending, particularly those related to healthcare costs, may reduce reimbursement rates for endoscopic procedures, which will reduce the cost-effectiveness of our products.

Healthcare reforms, changes in healthcare policies and changes to third-party coverage and reimbursements, including legislation enacted reforming the U.S. healthcare system, and any future changes to such legislation, may affect demand for our products and may have a material adverse effect on our financial condition and results of operations. There can be no assurance that current levels of reimbursement will not be decreased in the future, or that future legislation, regulation, or reimbursement policies of third-parties will not adversely affect the demand for our products or our ability to sell products on a profitable basis. The adoption of significant changes to the healthcare system in the United States, Europe or other jurisdictions in which we may market our products, could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products, could limit the acceptance and availability of our products, reduce medical procedure volumes and increase operational and other costs. For example, U.S. President Donald Trump has recently publicly indicated an intent to lower healthcare costs through various potential initiatives. In addition, President Trump and other U.S. lawmakers have made statements about potentially repealing or replacing the Affordable Care Act, although specific legislation for such a repeal or replacement has not yet been introduced. While we are unable to predict what changes may ultimately be enacted, to the extent that future changes affect how our products are paid for and reimbursed by government and private payers our business could be adversely impacted.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or internationally, or the effect that any future legislation or regulation will have on us. The expansion of government's role in any country's healthcare industry may result in decreased profits to us, lower reimbursements by third-parties for procedures in which our products are used, and reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

We depend on key employees, and if we fail to attract and retain employees with the expertise required for our business and provide for the succession of senior management, we cannot grow or achieve profitability.

We are dependent on the continued service and performance of members of our senior management and other key personnel, for example our Chief Executive Officer, Chris Rowland. We do not maintain key-man life insurance. Our future success will depend in part on our ability to retain our management and scientific teams, to identify, hire and retain additional qualified personnel with expertise in research and development and sales and marketing, and to effectively provide for the succession of senior management. Competition for qualified personnel in the medical device industry is intense. We may be unable to replace key persons if they leave or to fill new positions requiring key persons with appropriate experience.

The loss of key employees, the failure of any key employee to perform or our inability to attract and retain skilled employees, as needed, or an inability to effectively plan for and implement a succession plan for key employees could harm our business.

If we or our contractors or service providers fail to comply with regulatory laws and regulations, we or they could be subject to regulatory actions, which could affect our ability to develop, market and sell our products and any other or future products that we may develop and may harm our reputation.

If we or our manufacturers or other third-party contractors fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to regulatory actions, which could affect our ability to develop, market and sell our current products or any future products which we may develop in the future and could harm our reputation and lead to reduced demand for or non-acceptance of our proposed products by the market.

If our employees commit fraud or other misconduct, including noncompliance with regulatory standards and requirements and insider trading, our business may experience serious adverse consequences.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state health-care fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

Our board of directors adopted our Code of Ethics in March 2016. However, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

In addition, during the course of our operations, our directors, executives and employees may have access to material, nonpublic information regarding our business, our results of operations or potential transactions we are considering. If a director, executive or employee was to be investigated, or an action was to be brought against a director, executive or employee for insider trading, it could negatively impact on our reputation and the market price of our securities. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

If we fail to withhold our position against the Israeli tax authorities in connection with tax withholding, we may be required to pay additional taxes.

Following a tax deduction assessment conducted by the Israeli Tax Authorities, or the ITA, in October 2016, we are deemed to be in debt of approximately $1.45 million of additional withholding taxes, including penalties and interest. It is our management's opinion, based on the assessment of our legal counsel, that the chances of the claims of the ITA being dismissed are more likely than not. Therefore, no allowance regarding this assessment was recorded in our financial statements. However, if our position is not accepted in the event this case is litigated, our business can be materially adversely affected.

Risks Related to Our Intellectual Property

If we are unable to secure and maintain patent or other intellectual property protection for the intellectual property used in our products, our ability to compete will be harmed.

Our commercial success depends, in part, on obtaining and maintaining patent and other intellectual property protection for the technologies used in our products. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. Furthermore, we might in the future opt to license intellectual property from other parties. If we, or the other parties from whom we may license intellectual property, fail to obtain and maintain adequate patent or other intellectual property protection for intellectual property used in our products, or if any protection is reduced or eliminated, others could use the intellectual property used in our products, resulting in harm to our competitive business position. In addition, patent and other intellectual property protection may not provide us with a competitive advantage against competitors that devise ways of making competitive products without infringing any patents that we own or have rights to.

U.S. patents and patent applications may be subject to interference proceedings, and U.S. patents may be subject to re-examination proceedings in the U.S. Patent and Trademark Office. Foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent offices. Any of these proceedings could result in loss of the patent or denial of the patent application, or loss or reduction in the scope of one or more of the claims of the patent or patent application. Changes in either patent laws or in interpretations of patent laws may also diminish the value of our intellectual property or narrow the scope of our protection. Interference, re-examination and opposition proceedings may be costly and time consuming, and we, or the other parties from whom we might potentially license intellectual property, may be unsuccessful in defending against such proceedings. Thus, any patents that we own or might license may provide limited or no protection against competitors. In addition, our pending patent applications and those we may file in the future may have claims narrowed during prosecution or may not result in patents being issued. Even if any of our pending or future applications are issued, they may not provide us with adequate protection or any competitive advantages. Our ability to develop additional patentable technology is also uncertain.

Non-payment or delay in payment of patent fees or annuities, whether intentional or unintentional, may also result in the loss of patents or patent rights important to our business. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. In addition, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States, particularly in the field of medical products and procedures.

If we are unable to prevent unauthorized use or disclosure of our proprietary trade secrets and unpatented know-how, our ability to compete will be harmed.

Proprietary trade secrets, copyrights, trademarks and unpatented know-how are also very important to our business. We rely on a combination of trade secrets, copyrights, trademarks, confidentiality agreements and other contractual provisions and technical security measures to protect certain aspects of our technology, especially where we do not believe that patent protection is appropriate or obtainable. We require our office holders, employees, consultants and distributers of our products and most third parties (such as contractors or clinical collaborators) to execute confidentiality agreements in connection with their relationships with us. However, these measures may not be adequate to safeguard our proprietary intellectual property and conflicts may, nonetheless, arise regarding ownership of inventions. Such conflicts may lead to the loss or impairment of our intellectual property or to expensive litigation to defend our rights against competitors who may be better funded and have superior resources. Our office holders, employees, consultants and other advisors may unintentionally or willfully disclose our confidential information to competitors. In addition, confidentiality agreements may be unenforceable or may not provide an adequate remedy in the event of unauthorized disclosure. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. As a result, other parties may be able to use our proprietary technology or information, and our ability to compete in the market would be harmed.

We could become subject to patent and other intellectual property litigation that could be costly, result in the diversion of management's attention, require us to pay damages and force us to discontinue selling our products.

Our industry is characterized by competing intellectual property and a substantial amount of litigation over patent and other intellectual property rights. Determining whether a product infringes a patent involves complex legal and factual issues, and the outcome of a patent litigation action is often uncertain. No assurance can be given that patents containing claims covering our products, parts of our products, technology or methods do not exist, have not been filed or could not be filed or issued. Furthermore, our competitors or other parties may assert that our products and the methods we employ in the use of our products are covered by U.S. or foreign patents held by them. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications with claims that we infringe. There could also be existing patents that one or more of our products or parts may infringe and of which we are unaware. As the number of competitors in the endoscopic procedure market grows, and as the number of patents issued in this area grows, the possibility of patent infringement claims against us increases.

Infringement actions and other intellectual property claims and proceedings brought against or by us, whether with or without merit, may cause us to incur substantial costs and could place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation. Some of our competitors may be able to sustain the costs of complex patent or intellectual property litigation more effectively than we can because they have substantially greater resources**.**

We cannot be certain that we will successfully defend against allegations of infringement of patents and intellectual property rights of others. In the event that we become subject to a patent infringement or other intellectual property lawsuit and if the other party's patents or other intellectual property were upheld as valid and enforceable and we were found to infringe the other party's patents or violate the terms of a license to which we are a party, we could be required to pay damages. We could also be prevented from selling our products unless we could obtain a license to use technology or processes covered by such patents or will be able to redesign the product to avoid infringement. A license may not be available at all or on commercially reasonable terms or we may not be able to redesign our products to avoid infringement. Modification of our products or development of new products could require us to conduct clinical trials and to revise our filings with the applicable regulatory bodies, which would be time consuming and expensive. In these circumstances, we may be unable to sell our products at competitive prices or at all, our business and operating results could be harmed.

For example, on October 28, 2016, we settled all litigation and administrative proceedings with EndoChoice, Inc., or EndoChoice, including those actions pending in the U.S. District Court for the District of Delaware C.A. Nos. 15-505-LPS-CJB and C.A. No. 15-1215-LPS-CJB and the trademark opposition proceedings in the State of Israel involving Trademark Application Nos. 257172, 260433 and 262423. Under the terms of the confidential settlement, we were granted a covenant not to sue with respect to EndoChoice FUSE-related trademarks and EndoChoice was granted a non-exclusive license to our U.S. Patent No. 6,997,871 and related patents. Each party has agreed to bear its own costs and fees associated with the litigation.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or, that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Certain of our employees and personnel were previously employed at universities, medical institutions, or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants, and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Furthermore, universities or medical institutions who employ some of our key employees and personnel in parallel to their engagement by us may claim that intellectual property developed by such person is owned by the respective academic or medical institution under the respective institution intellectual property policy or applicable law.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other intellectual property. Ownership disputes may arise in the future, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Risks Related to Regulatory Compliance

If we fail to comply with the extensive government regulations relating to our business, we may be subject to fines, injunctions and other penalties that could harm our business.

Our medical device products and operations are subject to extensive regulation by the FDA, pursuant to the Federal Food, Drug, and Cosmetic Act, or FDCA, and various other federal, state and foreign governmental authorities. Government regulations and requirements specific to medical devices are wide ranging and govern, among other things:

- design, development and manufacturing;
- testing, labeling and storage;
- clinical trials;

- product safety;
- marketing, sales and distribution;
- premarket clearance or approval;
- record keeping procedures;
- advertising and promotions; and
- product recalls and field corrective actions.

For the purpose of receiving FDA clearance through the 510(k) track, the applicant must prove, inter alia, that the device subject to the application is substantially equivalent to one or more products which have already been approved by the FDA (predicate device). Additionally, the applicant is required to provide a detailed description of the device, including specifications and technical information, labeling, instructions for use, and the relevant indications for use of the device which is the subject of the application.

Clinical trials are usually not required under the 510(k) track, unless the FDA suspects the device subject to application contains new technical characteristics requiring clinical results regarding safety and efficacy. Clinical trials whose results are attached to the application for marketing approval are subject to advance approval by the FDA regarding the protocol of the trial of the Investigative Device Exemption (IDE) type.

Approval for marketing of medical devices in the United States can be submitted through a PMA, which is required when the device subject to approval is not substantially equivalent to a previously approved device, particularly high risk life-saving devices.

Though the PMA track consists of more stringent requirements than the 510(k) track and can be expensive and lengthy and entail significant fees, unless exempt. The FDA's 510(k) marketing clearance process usually takes from three to 12 months, but it can last longer. The process of obtaining PMA approval is more expensive and uncertain than the 510(k) marketing clearance process. It generally takes from one to three years, or even longer, from the time the PMA application is submitted to the FDA, until an approval is obtained. There is no assurance that we will be able to obtain FDA clearance or approval for any new products on a timely basis, or at all.

In addition, we are subject to annual regulatory audits in order to maintain our quality system certifications, CE mark permissions, FDA Clearance and Canadian medical device license. We do not know whether we will be able to continue to affix the CE mark for new or modified products or that we will continue to meet the quality and safety standards required to maintain the permissions and license we have already received. If we are unable to maintain our quality system certifications and permission to affix the CE mark to our products, we will no longer be able to sell our products in member countries of the European Union or other areas of the world that require CE's or FDA's approval of medical devices. If we are unable to maintain our quality system certifications and Canadian medical device license, we will not be able to sell our products in Canada.

Our medical device products and operations are also subject to regulation by the Medical Devices and Accessories Division in the Israeli Ministry of Health, or AMAR, which is responsible for the registration of medical devices in Israel, issuance of import licenses and monitoring marketing of medical equipment. We have received an AMAR approval in Israel.

Failure to obtain regulatory approval in additional foreign jurisdictions will prevent us from expanding the commercialization of our products.

To be able to market and sell our products in most 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. Obtaining and maintaining foreign regulatory approvals are expensive and time consuming, and we cannot be certain that we will receive regulatory approvals in the various countries in which we plan to market our products. Failure to obtain or maintain regulatory approval in such countries could have an adverse effect on our financial condition and results of operations.

Our products may be subject to product actions in the future that could harm our reputation, business operations and financial results.

The FDA and similar foreign health or governmental authorities have the authority to require an involuntary recall of commercialized products in the event of material deficiencies or defects in design, or manufacturing or labeling. In the case of the FDA, the authority to require a recall must be based on an FDA finding. In addition, foreign governmental bodies have the authority to require a recall of our products in the event of material deficiencies or defects in design or manufacture. Product actions involving any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations.

If our products, or malfunction of our products, cause or contribute to adverse medical events such as death or a serious injury, we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that would materially harm our business.

Our marketed products are subject to Medical Device Reporting, or MDR, obligations, which require that we report to the FDA any incident in which our products may have caused or contributed to a death or serious injury, or in which our products malfunctioned and, if the malfunction were to recur, it could likely cause or contribute to a death or serious injury. The timing of our obligation to report under the MDR regulations is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected. In addition, all manufacturers placing medical devices in the European Union, Israel and Canada markets are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the relevant authority in whose jurisdiction the incident occurred.

If we fail to comply with our reporting obligations, the FDA or other agencies in whose jurisdiction the incident occurred, could take action including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearances, seizure of our products, or delay in clearance of future products. 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 materially harm our reputation and financial results.

We may be subject to fines, penalties or injunctions if we promote the use of our products for unapproved uses, resulting in damage to our reputation and business.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of a medical device for a use that has not been cleared or approved by FDA. Use of a device outside its cleared or approved indications is known as "off-label" use. We are not allowed to promote the MUSE™ system for off label use. If the FDA determines that we promote an off-label use, it could request that we modify our promotional materials or subject us to regulatory or enforcement actions, which could have an adverse impact on our reputation and financial results. Similarly, a CE mark and an AMAR approval is invalidated if any part of the device is modified or used in a manner that is outside of its intended use.

Regulatory reforms may adversely affect our ability to sell our products profitably.

From time to time, legislation is drafted and introduced in the United States, European Union or other countries in which we operate, that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of medical devices. In addition, regulations and guidance may often be revised or reinterpreted by the regulatory authorities in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or interpretations changed, and what the impact of such changes, if any, may be.

On September 24, 2013, the FDA published a final rule establishing a unique device identification system, or the UDI Rule. The UDI Rule mandates new labeling requirements that will impact our medical products. We will be required to meet compliance dates as early as September 24, 2015 for implantable devices (such as staples and cartridges), and additional compliance dates of September 24, 2016 and September 24, 2018 for all other Class II (such as staplers) and reusable components (such as consoles), respectively. Compliance may involve increases costs and require new equipment, quality systems and manufacturing processes. As of the date of this annual report on Form 20-F, we are on schedule with the UDI Rule compliance.

If we fail to comply with federal or state fraud and abuse laws, we could be subject to criminal and civil penalties, loss of licenses and exclusion from Medicare, Medicaid and other federal and state healthcare programs which could have a material adverse effect on our business, financial condition and results of operations.

There are numerous United States federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws, false claims, and physician transparency laws. Section 1128B(b) of the Social Security Act, or the SSA, commonly referred to as the "Anti-Kickback Statute", prohibits the offer, payment, solicitation or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing or arranging for or recommending the ordering, purchasing or leasing of items or services payable by the Medicare and Medicaid programs or any other federally funded healthcare program. The Anti-Kickback Statute is very broad in scope, and many of its provisions have not been uniformly or definitively interpreted by courts or regulations. We have consulting or fee for services arrangements with physicians, hospitals and other entities, which may be subject to scrutiny. To the extent we are found to not be in compliance, we could face potentially significant fines and penalties in addition to other more significant sanctions and we may be required to restructure our operations.

Another development affecting the healthcare industry is the increased use of the federal Civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought against healthcare providers by private individuals has increased dramatically. In addition, various states have enacted false claim laws analogous to the Civil False Claims Act.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended, created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. Violations can result in criminal and civil liabilities.

Compliance with complex foreign and U.S. laws and regulations that apply to our international operations increases our cost of doing business in international jurisdictions and could expose us or our employees to fines and penalties in the U.S. and abroad. These numerous and sometimes conflicting laws and regulations include the Foreign Corrupt Practices Act. 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.

Violations of any fraud and abuse may result in significant fines, imprisonment and exclusion from the Medicare, Medicaid and other federal or state healthcare programs which could have a material adverse effect on our business, financial condition and results of operations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from federal healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Dealing with investigations can be time and resource consuming and can divert management's attention from the business. In addition, settlements with law enforcement agencies have forced healthcare providers to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could have a material adverse effect on our reputation, business and financial condition. See "Item 4. Information on the Company - B. Business Overview - Health Care Laws and Regulations - Fraud and Abuse Laws".

The new disclosure rules regarding the use of conflict minerals may affect our relationships with suppliers and customers.

The Securities and Exchange Commission adopted disclosure rules in August 2012 for companies that use conflict minerals in their products, with substantial supply chain verification requirements in the event that the materials come from, or could have come from, the Democratic Republic of the Congo or adjoining countries. These new rules and verification requirements may impose additional costs on us and on our suppliers, and limit the sources or increase the prices of materials used in our products. Among other things, this new rule could affect sourcing at competitive prices and availability in sufficient quantities of certain minerals used in the manufacture of components that are incorporated into our products. In addition, the number of suppliers who provide conflict-free minerals may be limited, and there may be material costs associated with complying with the disclosure requirements, such as costs related to the process of determining the source of certain minerals used in our products, as well as costs of possible changes to products, processes, or sources of supply as a consequence of such verification activities. We may not be able to sufficiently verify the origins of the relevant minerals used in components manufactured by third parties through the procedures that we implement, and we may encounter challenges to satisfy those customers who require that all of the components of our products be certified as conflict-free, which could place us at a competitive disadvantage if we are unable to do so. If we are unable to certify that our products are conflict free, we may face challenges with our customers, which could place us at a competitive disadvantage, and our reputation may be harmed.

Risks Related to Our Operations in Israel

Our headquarters, manufacturing facilities, and most of our administrative offices are located in Israel and, therefore, our results may be adversely affected by military instability in Israel.

Our offices are located in Israel. In addition, the majority of our officers and directors are residents of Israel. Accordingly, geopolitical or military conditions in Israel and its region may directly or indirectly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. During July and August 2014, Hamas and Israel were engaged in a military conflict that caused damage and disrupted economic activities in Israel. During November 2012, Hamas and Israel were engaged in an armed conflict and during the summer of 2006, Israel was engaged in an armed conflict with Hezbollah, a Lebanese Islamist Shiite militia group and political party. These conflicts involved missile strikes against civilian targets in various parts of Israel, including areas in which our employees and consultants are located, and negatively affected business conditions in Israel. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations and could make it more difficult for us to raise capital. The conflict situation in Israel could cause situations where medical product certifying or auditing bodies could not be able to visit our manufacturing facilities in order to review our certifications or clearances, thus possibly leading to temporary suspensions or even cancellations of our clearances or manufacturing certifications. The conflict situation in Israel could also result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements. Furthermore, several countries, principally in the Middle East, restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies if hostilities in the region continue or intensify. Such restrictions may seriously limit our ability to sell our products to customers in those countries.

Although the Israeli government is currently committed to covering the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure 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. Any armed conflicts would likely negatively affect business conditions generally and could harm our results of operations.

Our operations may be disrupted as a result of the obligation of management or key personnel to perform military service.

Many of our male employees in Israel are obligated to perform one month, and in some cases more, of annual military reserve duty until they reach the age of 40 (or older, for officers or reservists with certain occupations) and, in the event of a military conflict, may be called to active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists, and recently some of our employees have been called up in connection with armed conflicts. It is possible that there will be military reserve duty call-ups in the future. Our operations could be disrupted by the absence of a significant number of our employees or of one or more of our key employees. Such disruption could materially adversely affect our business, financial condition and results of operations.

Exchange rate fluctuations between foreign currencies and the U.S. Dollar may negatively affect our earnings.

Our reporting and functional currency is the U.S. dollar. Our revenues are currently primarily payable in U.S. dollars and Euros and we expect our future revenues to be denominated primarily in U.S. dollars and Euros. However, certain amount of our expenses are in NIS and as a result, we are exposed to the currency fluctuation risks relating to the recording of our expenses in U.S. dollars. We may, in the future, decide to enter into currency hedging transactions. These measures, however, may not adequately protect us from material adverse effects.

The government tax benefits that we currently are entitled to receive require us to meet several conditions and may be terminated or reduced in the future.

Some of our operations in Israel may entitle us to certain tax benefits under the Law for the Encouragement of Capital Investments, 5719-1959, or the Investments Law, once we begin to produce revenues. From time to time, the government of Israel has considered reducing or eliminating the tax benefits available to Benefitted Enterprise programs such as ours. If we do not meet the requirements for maintaining these benefits, they may be reduced or cancelled and the relevant operations would be subject to Israeli corporate tax at the standard rate, which was set at 25% for 2016 (to be reduced to 24% in 2017 and 23% in 2018 and thereafter). In addition to being subject to the standard corporate tax rate, we could be required to refund any tax benefits that we have already received, plus interest and penalties thereon. Even if we continue to meet the relevant requirements, the tax benefits that our current "Benefitted Enterprise" is entitled to may not be continued in the future at their current levels, or at all. If these tax benefits were reduced or eliminated, the amount of taxes that we would have to pay if we produce revenues would likely increase, as all of our operations would consequently be subject to corporate tax at the standard rate, which could adversely affect our results of operations. Additionally, if we increase our activities outside of Israel, for example, by way of acquisitions, our increased activities may not be eligible for inclusion in Israeli tax benefits programs. See "Item 10. Additional Information - E. Taxation."

In the past, we received Israeli government grants for certain of our research and development activities. The terms of those grants may require us, in addition to payment of royalties, to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel. If we fail to comply with the requirements of the Innovation Law (as defined below), we may be required to pay penalties in addition to repayment of the grants, and may impair our ability to sell our technology outside of Israel.

Some of our research and development efforts were financed in part through royalty-bearing grants, in an amount of $0.2 million that we received from the Israeli National Authority for Technological Innovation of the Israeli Ministry of Economy and Industry (formerly known as the Office of the Chief Scientist, or the OCS), or NATI. When know-how is developed using OCS grants, the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984 (formerly known as the Law for the Encouragement of Research and Development in Industry 5744-1984), or the Innovation Law and the regulations thereunder, restricts our ability to manufacture products and transfer technology and know-how, developed as a result of OCS funding, outside of Israel.

Under the Innovation Law and the regulations thereunder, a recipient of OCS grants is required to return the grants by the payment of royalties of 3% to 6% on the revenues generated from the sale of products (and related services) developed (in whole or in part) under the OCS program up to the total amount of the grants received from the OCS, linked to the U.S. dollar and bearing interest at an annual rate of LIBOR applicable to U.S. dollar deposits, as published on the first business day of each calendar year.

Transfer of OCS funded know-how and related intellectual property rights outside of Israel, including by way of license for research and development purpose, where the transferring company remains an operating Israeli entity or where the transferring company ceases to exist as an Israeli entity, requires pre-approval by the OCS and imposes certain conditions, including, in certain circumstances, requirement of payment of a redemption fee calculated according to the formula provided in the Innovation Law which takes into account, among others, the consideration for such know-how paid to us in the transaction in which the technology is transferred, research and development expenses, the amount of OCS support, the time of completion of the OCS supported research project and other factors, while the redemption fee will not exceed 600% of the grants amount plus interest.

Approval of the transfer of OCS funded know-how and related intellectual property rights to an Israeli company is required, and may be granted if the recipient abides by the provisions of Innovation Law, including the restrictions on the transfer of know-how and the manufacturing rights outside of Israel and the obligation to pay royalties (note that there will be an obligation to pay royalties to the OCS from the income of such sale transaction as part of the royalty payment obligation). No assurance can be given that approval to any such transfer, if requested, will be granted.

In addition, the products may be manufactured outside Israel by us or by another entity only if prior approval is received from the OCS (such approval is not required for the transfer of less than 10% of the manufacturing capacity in the aggregate, and in such event a notice to the OCS is required). As a condition for obtaining approval to manufacture outside Israel, we would be required to pay increased royalties, which usually amount to 1% in addition to the standard rate, up to an increased royalties cap of between 120% and 300% of the grants we received from the OCS, depending on the manufacturing volume that is performed outside Israel (less royalties already paid to the OCS). This restriction may impair our ability to outsource manufacturing rights abroad, however, does not restrict export of our products that incorporate OCS funded know-how.

A company also has the option of declaring in its OCS grant application its intention to exercise a portion of the manufacturing capacity abroad, thus avoiding the need to obtain additional approval and pay the increased royalties cap.

The restrictions under the Innovation Law (such as with respect to transfer of manufacturing rights abroad or the transfer of OCS funded know-how and related intellectual property rights abroad) will continue to apply even after we repay the full amount of royalties payable pursuant to the grants.

These restrictions may impair our ability to sell our technology assets or to perform or outsource manufacturing outside of Israel, or otherwise transfer our know-how outside of Israel and require us to obtain the approval of the OCS for certain actions and transactions and pay additional royalties and other amounts to the OCS. We cannot be certain that any approval of the OCS will be obtained. Furthermore, in the event that we undertake a transaction involving the transfer to a non-Israeli entity of technology developed with OCS funding pursuant to a merger or similar transaction, the consideration available to our shareholders may be reduced by the amounts we are required to pay to the OCS. Any approval, if given, will generally be subject to additional financial obligations. Failure to comply with the requirements under the Innovation Law may subject us to mandatory repayment of grants received by us (together with interest and penalties), as well as expose us to criminal proceedings.

The Innovation Law was amended as of July 29, 2015, or the 2015 Amendment. On January 1, 2016, pursuant to the 2015 Amendment the National Authority for Technological Innovation, or NATI, was established and in June 2016, NATI was fully constituted. Pursuant to the 2015 Amendment, NATI is authorized to change the current restrictions imposed on the recipients of grants under the Innovation Law with a new set of arrangements in connection with ownership obligations of know-how (including with respect to restrictions on transfer of know-how and manufacturing activities outside of Israel), as well as royalties obligations associated with approved programs. The Innovation Law as existed prior to the 2015 Amendment will continue to be in effect with respect to research and development programs which were in effect prior to January 1, 2016 until: (i) June 2017, which is one year following the date of appointment of all members of the NATI council; or (ii) earlier, if otherwise resolved by the NATI council. The Innovation Law in its form following the 2015 Amendment also includes new provisions with respect to sanctions imposed for violations of the Innovation Law. As of the date of this annual report on Form 20-F, we are unable to determine whether NATI will promulgate a new set of arrangements or adopt the arrangements which were stipulated under the Innovation Law as existed prior to the 2015 Amendment, therefore, as of the date of this annual report on Form 20-F, we are unable as assess the effect, if any, of the promulgation of such arrangements on us.

We were members of an OCS-related consortium, in which certain of our technologies were developed. We are required to provide licenses to the other members of the consortium to use such technologies for no consideration, which could reduce our profitability.

Certain of our miniaturized imaging equipment may be based on technological models developed as part of the Bio Medical Photonic Consortium in the framework of Magnet program of the OCS. The property rights in and to "new information" (as such term is defined therein) which has been developed by a member of the Consortium, in the framework of a research and development program conducted as part of the Consortium, belongs solely to the Consortium member that developed it. The developing member is obligated to provide the other members in the Consortium a non-sublicensable license to use of the "new information" developed by such member, without consideration, provided that the other members do not transfer such "new information" to any entity which is not a member of the Consortium, without the consent of such member.

Provisions of Israeli law and our articles of association may delay, prevent or otherwise impede a merger with, or an acquisition of, our company, which could prevent a change of control, even when the terms of such a transaction are favorable to us and our shareholders.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to such types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date on which a merger proposal is filed by each merging company with the Israel Registrar of Companies and at least 30 days have passed from the date on which the shareholders of both merging companies have approved the merger. In addition, a majority of each class of securities of the target company must approve a merger. Moreover, a tender offer for all of a company's issued and outstanding shares can only be completed if the acquirer receives positive responses from the holders of at least 95% of the issued share capital. Completion of the tender offer also requires approval of a majority of the offerees that do not have a personal interest in the tender offer, unless, following consummation of the tender offer, the acquirer would hold at least 98% of the Company's outstanding shares. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, claim that the consideration for the acquisition of the shares does not reflect their fair market value, and petition an Israeli court to alter the consideration for the acquisition accordingly, unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek such appraisal rights, and the acquirer or the company published all required information with respect to the tender offer prior to the tender offer's response date.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax.

These and other similar provisions could delay, prevent or impede an acquisition of us or our merger with another company, even if such an acquisition or merger would be beneficial to us or to our shareholders**.**

It may be difficult to enforce a judgment of a U.S. court against us and our officers and directors and the Israeli experts named in this annual report on Form 20-F in Israel or the U.S., to assert United States securities laws claims in Israel or to serve process on our officers and directors and these experts.

We are incorporated in Israel. Certain of our executive officers and directors reside in Israel and most of our assets and most of the assets of these persons are located outside of the United States. Therefore, a judgment obtained against us, or any of these persons in the United States, including one based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not necessarily be enforced by an Israeli court. It may also be difficult to affect service of process on these persons in the United States or to assert United States securities law claims in original actions instituted in Israel.

Even if an Israeli court agrees to hear such claim, it may determine that Israeli law, and not U.S. law is applicable to the claim. Under Israeli law, if U.S. law is found to be applicable to such claim, 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, and certain matters of procedure would also be governed by Israeli law. There is little binding case law in Israel that addresses the matters.

The rights and responsibilities of a shareholder will be governed by Israeli law which differs in some material respects from the rights and responsibilities of shareholders of U.S. companies.

The rights and responsibilities of the holders of our ordinary shares are governed by our articles of association and by Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders in typical U.S.-registered corporations. In particular, a shareholder of an Israeli company has certain duties to act in good faith and fairness towards the company and other shareholders, and to refrain from abusing its power in the company. There is limited case law available to assist us in understanding the nature of this duty or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U.S. corporations.

The ability of any Israeli company to pay dividends is subject to Israeli law and the amount of cash dividends payable may be subject to devaluation in the Israeli currency.

The ability of an Israeli company to pay dividends is governed by Israeli law, which provides that cash dividends may be paid only out of retained earnings or earnings derived over the two most recent fiscal years, whichever is higher, as determined for statutory purposes in Israeli currency, provided that there is no reasonable concern that payment of a dividend will prevent a company from satisfying its existing and foreseeable obligations as they become due. In the event of a devaluation of the Israeli currency against the U.S. dollar, the amount in U.S. dollars available for payment of cash dividends out of prior years' earnings will decrease.

The termination or reduction of tax and other incentives that the Israeli Government provides to domestic companies may increase the costs involved in operating a company in Israel.

The Israeli government currently provides major tax and capital investment incentives to domestic companies, as well as grant and loan programs relating to research and development and marketing and export activities. In recent years, the Israeli Government has reduced the benefits available under these programs and the Israeli Governmental authorities have indicated that the government may in the future further reduce or eliminate the benefits of those programs. We currently take advantage of these programs. There is no assurance that such benefits and programs would continue to be available in the future to us. If such benefits and programs were terminated or further reduced, it could have an adverse effect on our business, operating results and financial condition.

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

A significant portion of our intellectual property has been developed by our employees in the course of their employment for us. Under the Israeli Patent Law, 5727-1967, or the Patent Law, inventions conceived by an employee in the course and as a result of or arising from his or her employment with a company are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Patent Law also provides that if there is no such agreement between an employer and an employee, the Israeli Compensation and Royalties Committee, or the Committee, a body constituted under the Patent Law, shall determine whether the employee is entitled to remuneration for his inventions. Decisions by the Committee (which have been upheld by the Israeli Supreme Court on appeal) have created uncertainty in this area, as it held that employees may be entitled to remuneration for their service inventions despite having specifically waived any such rights. However, a later decision by the Committee held that such right can be waived by the employee. The Committee further held that an explicit reference to the waived right is not necessary in every circumstance in order for the employee's waiver of such right to be valid. Such waiver can be formalized in writing or orally or be implied by the actions of the parties in accordance with the rules of interpretation of Israeli contract law. We generally enter into assignment-of-invention agreements with our employees pursuant to which such individuals assign to us all rights to any inventions created in the scope of their employment or engagement with us. Although our employees have agreed to assign to us service invention rights and have specifically waived their right to receive any special remuneration for such assignment beyond their regular salary and benefits, we may face claims demanding remuneration in consideration for assigned inventions.

Risks Related to an Investment in the Securities

We may be a passive foreign investment company, or PFIC, for U.S. federal income tax purposes in 2016 or in any subsequent year. This may result in adverse U.S. federal income tax consequences for U.S. taxpayers that are holders of our securities.

We will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (1) at least 75% of our gross income is "passive income" or (2) on average at least 50% of our assets by value produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, certain dividends, interest, royalties, rents and gains from commodities and securities transactions and from the sale or exchange of property that gives rise to passive income. Passive income also includes amounts derived by reason of the temporary investment of funds, including those raised in a public offering. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account. We do not believe we were a PFIC for 2015 or 2016 but there can be no assurance that we were not a PFIC in 2015 or 2016 and will not be a PFIC in subsequent years, as our operating results for any such years may cause us to be a PFIC. If we are a PFIC in 2016, or any subsequent year, and a U.S. shareholder does not make an election to treat us as a "qualified electing fund," or QEF, or make a "mark-to-market" election, then "excess distributions" to a U.S. shareholder, and any gain realized on the sale or other disposition of our securities will be subject to special rules. Under these rules: (1) the excess distribution or gain would be allocated ratably over the U.S. shareholder's holding period for the securities; (2) the amount allocated to the current taxable year and any period prior to the first day of the first taxable year in which we were a PFIC would be taxed as ordinary income; and (3) the amount allocated to each of the other taxable years would be subject to tax at the highest rate of tax in effect for the applicable class of taxpayer for that year, and an interest charge for the deemed deferral benefit would be imposed with respect to the resulting tax attributable to each such other taxable year. In addition, if the IRS determines that we are a PFIC for a year with respect to which we have determined that we were not a PFIC, it may be too late for a U.S. shareholder to make a timely QEF or mark-to-market election. U.S. shareholders who hold or have held our securities during a period when we were or are a PFIC will be subject to the foregoing rules, even if we cease to be a PFIC in subsequent years, subject to exceptions for U.S. shareholders who made a timely QEF or mark-to-market election. A U.S. shareholder can make a QEF election by completing the relevant portions of and filing IRS Form 8621 in accordance with the instructions thereto. If applicable, upon request, we will annually furnish U.S. shareholders with information needed in order to complete IRS Form 8621 (which form would be required to be filed with the IRS on an annual basis by the U.S. shareholder) and to make and maintain a valid QEF election for any year in which we or any of our subsidiaries are a PFIC.

The market prices of our securities are subject to fluctuation, which could result in substantial losses by our investors.

The stock market in general and the market prices of our ordinary shares on the TASE and the ADSs and warrants, if listed, on the NASDAQ Capital Market, or the NASDAQ, in particular, are or will be subject to fluctuation, and changes in these prices may be unrelated to our operating performance. We anticipate that the market prices of our securities will continue to be subject to wide fluctuations. The market price of our securities are, and will be, subject to a number of factors, including:

- announcements of technological innovations or new products by us or others;
- announcements by us of significant acquisitions, strategic partnerships, in-licensing, out-licensing, joint ventures or capital commitments;

- expiration or terminations of licenses, research contracts or other collaboration agreements;
- public concern as to the safety of our equipment we sell;
- general market conditions;
- the volatility of market prices for shares of medical devices companies generally;
- developments concerning intellectual property rights or regulatory approvals;
- developments concerning standard-of-care in endoscopic procedures;
- variations in our and our competitors' results of operations;
- changes in revenues, gross profits and earnings announced by the company;
- changes in estimates or recommendations by securities analysts, if our ordinary shares or the ADSs are covered by analysts;
- changes in government regulations or patent decisions; and
- general market conditions and other factors, including factors unrelated to our operating performance.

These factors may materially and adversely affect the market price of our securities s and result in substantial losses by our investors.

Raising additional capital by issuing securities may cause dilution to existing shareholders.

We may seek additional capital through a combination of private and public equity offerings, debt financings and collaborations and strategic and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest will be diluted, and the terms of any such offerings may include liquidation or other preferences that may adversely affect the then existing shareholders rights. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt or making capital expenditures. If we raise additional funds through collaboration, strategic alliance or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates, or grant licenses on terms that are not favorable to us.

We do not know whether a market for the ADSs will be sustained or what the trading price of the ADSs will be and as a result it may be difficult for you to sell your ADSs.

Although the ADSs now trade on NASDAQ, an active trading market for the ADSs may not be sustained. It may be difficult for you to sell your ADSs without depressing the market price for the ADSs or at all. As a result of these and other factors, you may not be able to sell your ADSs. Further, an inactive market may also impair our ability to raise capital by selling ADSs and ordinary Shares and may impair our ability to enter into strategic partnerships or acquire companies or products by using our ordinary shares as consideration.

Future sales of our securities could reduce their market price.

Substantial sales of our securities, either on the TASE or on NASDAQ, may cause the market price of our securities to decline. All of our outstanding ordinary shares are registered and available for sale in Israel. Sales by us or our security holders of substantial amounts of our securities, or the perception that these sales may occur in the future, could cause a reduction in the market price of our securities.

The issuance of any additional ordinary shares, ADSs, warrants or any securities that are exercisable for or convertible into our ordinary shares or ADSs, may have an adverse effect on the market price of our securities and will have a dilutive effect on our existing shareholders and holders of ADSs.

Holders of ADSs may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, you may not receive dividends or other distributions on our ordinary shares and you may not receive any value for them, if it is illegal or impractical to make them available to you.

The Depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying the ADSs, after deducting its fees and expenses. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent. However, the Depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act of 1933, as amended, or the Securities Act, but that are not properly registered or distributed under an applicable exemption from registration. In addition, conversion into U.S. dollars from foreign currency that was part of a dividend made in respect of deposited ordinary shares may require the approval or license of, or a filing with, any government or agency thereof, which may be unobtainable. In these cases, the Depositary may determine not to distribute such property and hold it as "deposited securities" or may seek to effect a substitute dividend or distribution, including net cash proceeds from the sale of the dividends that the Depositary deems an equitable and practicable substitute. We have no obligation to register under U.S. securities laws any ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. In addition, the Depositary may withhold from such dividends or distributions its fees and an amount on account of taxes or other governmental charges to the extent the Depositary believes it is required to make such withholding. This means that you may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, you may not receive any value for such distributions or dividends if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of the ADSs.

Holders of ADSs must act through the Depositary to exercise their rights as shareholders of our company.

Holders of ADSs do not have the same rights of our shareholders and may only exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the Deposit Agreement. Under Israeli law and our articles of association, the minimum notice period required to convene a shareholders meeting is no less than 21 or 35 calendar days, depending on the proposals on the agenda for the shareholders meeting. When a shareholder meeting is convened, holders of ADSs may not receive sufficient notice of a shareholders' meeting to permit them to withdraw their ordinary shares to allow them to cast their vote with respect to any specific matter. In addition, the Depositary and its agents may not be able to send voting instructions to holders of ADSs or carry out their voting instructions in a timely manner. We will make all reasonable efforts to cause the Depositary to extend voting rights to holders of the ADSs in a timely manner, but we cannot assure holders that they will receive the voting materials in time to ensure that they can instruct the Depositary to vote their ordinary shares underlying the ADSs. Furthermore, the Depositary and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of ADSs may not be able to exercise their right to vote and they may lack recourse if their ordinary shares underlying the ADSs are not voted as they requested. In addition, in the capacity as a holder of ADSs, they will not be able to call a shareholders' meeting.

We do not intend to pay any cash dividends on our ordinary shares in the foreseeable future and, therefore, any return on your investment in our securities must come from increases in the value and trading price of our securities.

We have never declared or paid cash dividends on our securities and do not anticipate that we will pay any cash dividends on our securities in the foreseeable future, therefore, any return on your investment in our securities must come from increases in the value and trading price of our securities.

We intend to retain our earnings to finance the development and expenses of our business. Any future determination relating to our dividend policy will be at the discretion of our board of directors and will depend on a number of factors, including future earnings, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, applicable Israeli law and other factors our board of directors may deem relevant.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our securities less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements. We cannot predict whether investors will find our securities less attractive if we rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the price of our securities may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are choosing to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted. This decision to opt out of the extended transition period is irrevocable.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our securities will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us, or provide favorable coverage. If one or more analysts downgrade our share or change their opinion of our securities, the price of our securities would likely decline. In addition, if one or more analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Our securities are traded on different markets and this may result in price variations.

Our ordinary shares have been traded on the TASE since February 2006. The ADSs have been traded on the NASDAQ since August 5, 2015. Trading in these securities on these markets takes place in different currencies (dollars on the NASDAQ and NIS on the TASE), and at different times (resulting from different time zones, different trading days and different public holidays in the United States and Israel). The trading prices of these securities on these two markets may differ due to these and other factors. Any decrease in the price of these securities on one of these markets could cause a decrease in the trading price of these securities on the other market.

We incur additional costs as a result of the listing of the ADSs for trading on the NASDAQ, and our management is required to devote substantial time to new compliance initiatives and reporting requirements.

As a public company in the United States, we incur significant accounting, legal and other expenses as a result of the listing of the ADSs on the NASDAQ. These include costs associated with corporate governance requirements of the SEC and the Marketplace Rules of the NASDAQ, as well as requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. These rules and regulations will increase our legal and financial compliance costs, introduced new costs such as investor relations, stock exchange listing fees and shareholder reporting, and made some activities more time consuming and costly. Any future changes in the laws and regulations affecting public companies in the United States and Israel, including Section 404 and other provisions of the Sarbanes-Oxley Act, the rules and regulations adopted by the SEC and the rules of the NASDAQ Stock Market, as well as compliance with the applicable full Israeli reporting requirements which currently apply to us as a company listed on the TASE (for so long as they apply to us, pending shareholder approval by special majority of a change to our TASE reporting requirements to allow us to report to the TASE in the same manner in which we report to the SEC), will result in increased costs to us as we respond to such changes. These laws, rules and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of applicable SEC and the NASDAQ requirements, which may result in less protection than is accorded to investors under rules applicable to domestic issuers.

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of those otherwise required under the rules of the NASDAQ for domestic issuers. For instance, we may follow home country practice in Israel with regard to: distribution of annual and quarterly reports to shareholders, director independence requirements, director nomination procedures, approval of compensation of officers, approval of related party transactions, shareholder approval requirements, equity compensation plans and quorum requirements at shareholders' meetings. In addition, we follow our home country law, instead of the rules of the NASDAQ, which require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or more interest in the company and certain acquisitions of the stock or assets of another company. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on the NASDAQ, may provide less protection than is accorded to investors under the rules of the NASDAQ applicable to domestic issuers. For more information, see "Item 16G. Corporate Governance - Nasdaq Stock Market Listing Rules and Home Country Practices."

In addition, as a foreign private issuer, we are exempt from the rules and regulations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as domestic companies whose securities are registered under the Exchange Act.

We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses.

We are a foreign private issuer, as such term is defined in Rule 405 under the Securities Act, and therefore, we are not required to comply with all the periodic disclosure and current reporting requirements of the Exchange Act and related rules and regulations. Under Rule 405, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, the next determination will be made with respect to us on June 30, 2017.

In the future, we would lose our foreign private issuer status if a majority of our shareholders, directors or management are U.S. citizens or residents and we fail to meet additional requirements necessary to avoid loss of foreign private issuer status. Although we have elected to comply with certain U.S. regulatory provisions, our loss of foreign private issuer status would make such provisions mandatory. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly higher. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the U.S. Securities and Exchange Commission, or the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. For example, the annual report on Form 10-K requires domestic issuers to disclose executive compensation information on an individual basis with specific disclosure regarding the domestic compensation philosophy, objectives, annual total compensation (base salary, bonus, equity compensation) and potential payments in connection with change in control, retirement, death or disability, while the SEC forms applicable to foreign private issuers permit them to disclose compensation information on an aggregate basis if executive compensation disclosure on an individual basis is not required or otherwise has not been provided in the issuer's home jurisdiction. We disclose individual compensation information, but this disclosure is not as comprehensive as that required of U.S. domestic issuers since we are not required to disclose more detailed information in Israel. We intend to continue this practice as long as it is permitted under the SEC's rules and Israel's rules do not require more detailed disclosure. We will also have to mandatorily comply with U.S. federal proxy requirements, and our officers, directors and principal shareholders will become subject to the short-swing profit disclosure and recovery provisions of Section 16 of the Exchange Act. We may also be required to modify certain of our policies to comply with good governance practices associated with U.S. domestic issuers. Such conversion and modifications will involve additional costs. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers.

If we are unable to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 as they apply to a foreign private issuer that is listing on a U.S. exchange for the first time, or our internal control over financial reporting is not effective, the reliability of our financial statements may be questioned and our securities price may suffer.

Section 404 of the Sarbanes-Oxley Act requires a company subject to the reporting requirements of the U.S. securities laws to do a comprehensive evaluation of its and its subsidiaries' internal control over financial reporting. When applicable, to comply with this statute, we will be required to document and test our internal control procedures; our management will be required to assess and issue a report concerning our internal control over financial reporting. In addition, our independent registered public accounting firm may be required to issue an opinion on the effectiveness of our internal control over financial reporting at a later date.

The continuous process of strengthening our internal controls and complying with Section 404 is complicated and time-consuming. Furthermore, as our business continues to grow both domestically and internationally, our internal controls will become more complex and will require significantly more resources and attention to ensure our internal controls remain effective overall. During the course of its testing, our management may identify weaknesses or deficiencies, which may not be remedied in a timely manner. If our management cannot favorably assess the effectiveness of our internal controls over financial reporting, or if our independent registered public accounting firm identifies material weaknesses in our internal control, investor confidence in our financial results may weaken, and the market price of our securities may suffer.

The right of the investors of our December 2016 offering to participate in future financings of our securities could impair our ability to raise capital.

Pursuant to the terms of the securities purchase agreements relating to an offering of our ADSs and warrants which closed on December 6, 2016, we granted the purchasers in such offering an eighteen month contractual preemptive right to participate in future financings, subject to certain exceptions, in an amount equal to up to 50% of the amount raised in such future financings. The existence of such preemptive rights, or the exercise of such rights, may deter potential investors from providing us needed financing, or may deter investment banks from working with us. This may have a material adverse effect on our ability to finance our company which, in turn, could lead to our inability to continue our business.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Our legal and commercial name is Medigus Ltd. We were incorporated in the State of Israel on December 9, 1999, as a private company pursuant to the Israeli Companies Ordinance (New Version), 1983. In February 2006, we completed our initial public offering in Israel, and our ordinary shares have since traded on the TASE, under the symbol "MDGS". In May 2015, we listed the ADSs on NASDAQ, and since August 2015 the ADSs have been traded on the NASDAQ under the symbol "MDGS". Each ADS represents 50 ordinary shares.

We are a public limited liability company and operate under the provisions of the Companies Law. Our registered office and principal place of business are located at Omer Industrial Park, No. 7A, P.O. Box 3030, Omer 8496500, Israel and our telephone number in Israel is + 972 (8) 646 6880. Our website address is http://www.medigus.com. The information contained on our website or available through our website is not incorporated by reference into and should not be considered a part of this Annual Report on Form 20-F.

On July 22, 2007, we formed a wholly owned subsidiary in the State of Delaware under the name Medigus USA LLC, or the U.S. Subsidiary. Our U.S. Subsidiary currently employs only our Chief Executive Officer, and on October 1, 2013, a service agreement was executed between the Company and the U.S. Subsidiary whereby the U.S. Subsidiary would render services to the Company against reimbursement of its direct expenses as well as a premium at a reasonable rate.

On November 6, 2015, we effected a 10:1 reverse share split such that every 10 ordinary shares par value NIS 0.01 were converted into one ordinary share par value NIS 0.10, without changing the rights attached to each share. In connection with the reverse share split, our share option plans and outstanding options and warrants to purchase our ordinary shares were also adjusted to reflect the reverse share split and the ratio of the ADSs was adjusted to five ordinary shares per ADS.

On March 15, 2017, we effected a change in the ratio of ordinary shares per ADS from five ordinary shares per ADS to 50 ordinary shares per ADS. The change in the ordinary shares ratio for the ADSs had the same effect as a 1-for-10 reverse stock split of the ADSs.

Based on the projected cash flows and its cash balances as of December 31, 2016, our management is of the opinion that without further fund raising it will not have sufficient resources to enable it to continue its operating activities including the development, manufacturing and marketing of its products for a period of at least 12 months from the date of approval of the financial statements. As a result, there is substantial doubt about our ability to continue as a going concern. For more information see "Item 5. Operating and Financial Review and Prospects—Operating Capital and Capital Expenditure Requirements and Note 1c to our financial statements.

To date, substantially all of our revenues have derived from our miniaturized imaging equipment for use within the medical and industrial fields. However, we are currently focused on the marketing and continued development of our MUSE™ product as described below.

We engage in the development, production and marketing of innovative medical devices, including flexible surgical staplers with direct vision systems for minimally invasive medical procedures. Our expertise is in the development, production and marketing of innovative endoscopic surgical devices for the treatment of Gastroesophageal Reflux Disease (GERD), a common ailment which is predominantly treated by medical therapy (e.g., proton pump inhibitors – see discussion below under "*Treatment of GERD")* or in more chronic cases, conventional open or laparoscopic surgery. Our FDA-cleared and CE-marked product (a mark assigned to a product certifying its fulfillment of the Medical Devices Directive of the European Union), known as the MUSE™ System, enables a trans-orifice procedure, or scarless procedure through a natural opening in the body, that requires no incision for the treatment of GERD by reconstruction of the esophageal valve where the stomach and the esophagus meet. We believe this procedure offers a safe, effective and economical alternative to the current surgical methods of GERD treatment. In addition, this trans-orifice approach has the ability to provide results which are equivalent to those of standard surgical procedures while reducing pain and trauma, minimizing hospital stays, and delivering economic value to hospitals and payors.

The key elements of the MUSE™ system include a single-use, flexible stapler (also called an Endostapler) containing several sophisticated innovative technologies such as a surgical stapler, miniature camera and ultrasound sensor, as well as a control console, offering a video image transmitted from the tip of the Endostapler.

In addition to the MUSE™ system for the treatment of GERD, we are engaged in the development of other minimally invasive endosurgical tools, as well as miniaturized imaging equipment for use in medical procedures as well as various industrial applications.

Principal Capital Expenditures

We had capital expenditures of approximately USD 38,000 in the year ended on December 31, 2016, USD 96,000 in the year ended on December 31, 2015, and USD 111,000 in the year ended on December 31, 2014. Our capital expenditures consisted mainly of acquisitions of machinery, equipment and computers. We have financed our capital expenditures from our available cash and short-term investments. We expect to increase our capital expenditures in 2017 especially in production equipment due to the need to increase the volume of products and to reduce production costs subject to a pre-approved budget.

There are no significant capital expenditures or divestitures currently in progress by the Company.

B. Business Overview

Overview

We are a medical device company dedicated to the development, manufacturing and marketing of surgical endostaplers and direct vision systems for minimally invasive medical procedures. Our expertise is in the development, production and marketing of innovative surgical devices with direct visualization capabilities for the treatment of Gastroesophageal Reflux Disease, or GERD, a common ailment, which is predominantly treated by medical therapy (e.g. proton pump inhibitors) or in chronic cases, conventional open or laparoscopic surgery. Our Federal Drug Administration-cleared and CE-marked endosurgical system, known as the Medigus Ultrasonic Surgical Endostapler, or MUSE™ Medigus Ultrasonic Surgical Endostapler system, enables minimally-invasive and incisionless procedures for the treatment of GERD by reconstruction of the esophageal valve via the mouth and esophagus, eliminating the need for surgery in eligible patients. We believe that this procedure offers a safe, effective and economical alternative to the current modes of GERD treatment for certain GERD patients, and has the ability to provide results which are equivalent to those of standard surgical procedures while reducing pain and trauma, minimizing hospital stays, and delivering economic value to hospitals and payors.

The key elements of the MUSE™ system include a single-use endostapler containing several sophisticated innovative technologies such as flexible stapling technology, a miniature camera and ultrasound sensor, as well as a control console offering a video image transmitted from the tip of the endostapler.

In addition to the MUSE™ system for the treatment of GERD, we have developed miniaturized video cameras for use in various medical procedures as well as specialized industrial applications.

Prevalence of GERD

GERD, is a worldwide disorder, with evidence suggesting an increase in GERD prevalence since 1995. The sample size weighted mean for the GERD population in the United States and Europe is 19.8% and 15.2% respectively. In the United States alone, over 49 million adults are affected by GERD, with over 29 million adults suffering from GERD daily. Proton pump inhibitors, or PPIs, are a class of effective and generally safe medications to treat GERD, but not everyone who experiences heartburn needs a PPI. Several PPIs have been widely advertised to consumers and heavily promoted by physicians. This has led to their overuse drugs. PPIs are the third highest selling class of drugs in the U.S. and Nexium, a PPI, has the second highest retail sales among all drugs at $4.8 billion in 2008. This figure does not include sales of other brands of PPIs.

After being swallowed, food descends through the esophagus to the stomach, which contains acids and enzymes intended to digest and break down food. GERD is caused by the defective operation of the lower esophageal sphincter, or LES, a valve which controls the flow of ingested food from the esophagus into the stomach. While eating and between eating periods, a properly operating LES prevents stomach contents from entering the esophagus. Generally among GERD sufferers, the valve opens spontaneously or is unable to close properly. This results in acidic stomach contents rising into the esophagus, causing irritation, acid reflux and heartburn, as well as other potentially dangerous conditions.

Beyond painful symptoms, GERD may also increase sufferers' susceptibility to cancer. Whereas the stomach is lined by the "gastric mucosal barrier" which allows acidic material to be contained harmlessly, the surface of the esophagus consists of flat, thin cells called squamous cells, which are not resistant to acid. Repeated episodes of acid reflux can cause inflammation of the esophagus, a condition called esophagitis. The flat cells lining the esophagus can also undergo genetic changes due to exposure to acid, causing these cells to resemble those found in the stomach lining, a condition known as Barrett's Esophagus. Studies have shown that people exhibiting Barrett's Esophagus have a higher risk of developing cancer of the esophagus.

Barrett Esophagus is a complication of GERD and predisposes patients to esophageal adenocarcinoma, a tumor that has increased in incidence more than 7-fold over the past several decades. Studies have also shown, that compared to patients not exhibiting GERD symptoms, patients exhibiting weekly symptoms of GERD have a five times higher probability for developing esophageal cancer while patients exhibiting daily symptoms of GERD have a seven times higher probability for developing esophageal cancer. The most common risk factors for cancer in Barrett's esophagus patients include chronic GERD, hiatal hernia, advanced age, male sex, white race, cigarette smoking and obesity.

Treatment of GERD

Treatment of GERD involves a stepwise approach. Treatment goals include controling symptoms and healing esophagitis and preventing recurrent esophagitis. Treatment usually involves lifestyle modification and control of gastric acid through medical treatment (antacids, PPI's, H2 blockers or other reflux inhibitors) or antireflux surgery. Mild GERD may be defined as intermittent reflux symptoms that can be managed with lifestyle changes or over-the-counter medications. Moderate to severe GERD represents more chronic symptoms that may require stronger drugs, long term medication or surgical intervention.

Proton pump inhibitors (PPI)

For moderate to severe GERD, physicians usually prescribe PPIs. This class of drugs reduces acid production by the stomach, and thereby relieves the patients of their symptoms. Drugs of this class are among the most commonly prescribed medications in the world. There are several well-known brands on the market, including Prilosec (omeprazole), Prevacid (lansoprazole) and Nexium (esomeprazole). Certain PPI drugs are available over the counter in the United States and in other countries, but the over the counter dosages may be inadequate to control moderate to severe GERD symptoms, except in mild cases.

While PPI can reduce the severity and frequency of GERD symptoms, they have a number of drawbacks:

a) In approximately 30% of patients, symptom control is incomplete;

b) PPIs do not treat GERD, they only control its manifestations. Therefore they must be taken for life at a dosage which requires a prescription. Accumulated costs may be substantial; and

c) Long term use is associated with a number of serious adverse effects. In particular, they increase the risk of osteoporosis and fractures of the hip, wrist and spine. The FDA has issued a warning on this effect as well as warnings against other adverse effects on absorption of other essential minerals, which may lead to chronic kidney disease, irregular heartbeat, diarrhea and increased flatulence.

Interventional treatment

The most common operation for GERD is called a surgical fundoplication, a procedure that prevents reflux by wrapping or attaching the upper part of the stomach around the lower esophagus and securing it with sutures. Due to the presence of the wrap or attachment, increasing pressure in the stomach compresses the portion of the esophagus which is wrapped or attached by the stomach, and prevents acidic gastric content from flowing up into the esophagus. Today, the operation is usually performed laparoscopically: instead of a single large incision into the chest or abdomen, four or five smaller incisions are made in the abdomen, and the operator uses a number of specially designed tools to operate under video control.

The operation does not completely eliminate the use of PPIs, and up to approximately 60% of the GERD sufferers who undergo this surgery still require some form of long term medical treatment including PPIs. Nevertheless, the dose is usually lower – in the over the counter range – and the response rate is high. Since the majority of patients referred to surgeons are incomplete responders, or require a high dose of PPI, the patients are generally satisfied with the operation, and the overall costs of treatment are lower in the long run.

Despite the high success rate of surgery, relatively few patients elecet to undergo the operation. We estimate that large numbers of patients who are candidates for surgery are either not referred by their treating physician or decline it. We believe that many patients decline to undergo operations to avoid scarring or the violation of the abdominal cavity.

Given the current environment in which the vast majority of GERD sufferers in North America and Europe must choose between long-term pharmaceutical therapy and surgery, leading to what is known in the medical industry as the "treatment gap", we believe there is a demand for a minimally-invasive, incision-less procedure which treats the root cause of GERD. We believe that the MUSE™ system is positioned to fill this need.

Our system achieves the general physiological result of surgical fundoplication, by inserting the MUSE™ endostapler through the mouth and the esophagus, and stapling the top of the stomach to the side of the esophagus. The endostapler contains a video camera and stapling system. Staples have long been used in surgical procedures in place of sutures, and we believe that they are at least as reliable and potentially more durable. Our endostapler uses standard surgical staples.

First line therapy for GERD includes a combination of lifestyle modifications and PPIs. Unfortunately, 25% to 42% of patients with GERD do not respond to an initial 4-8-week treatment of PPIs. For those who do respond to therapy, the effectiveness of PPI treatment decreases over time. Antireflux surgery controls acid reflux and treats an incompetent lower esophageal sphincter, while also improving patient quality of life in the long term. Thus, PPIs and lifestyle modifications are frequently eliminated.

Despite the effectiveness of surgical fundoplication, it is invasive, requires hospitalization, and carries the risk of short and long-term complications, including dysphagia, diarrhea, and gas bloat syndrome. Thus, endoscopic therapies that mimic the mechanism through which surgical fundoplication works and can reduce surgical morbidity have gained popularity for the treatment of GERD.

The market for medical devices, including the market for endoscopic therapies, is very broad, with an increasing demand for new less invasive alternatives to the existing surgical procedures for the treatment of various diseases. This increasing need for minimally-invasive and incision-less treatments, such as endoscopy-based procedures, is also augmented by the increase in the average age of global population. In 2000, the worldwide population of persons aged more than 65 years was an estimated 420 million. During 2000-2030, the worldwide population aged more than 65 years is projected to increase by approximately 550 million to 973 million. This increase in age will potentially lead to increased healthcare costs and may have dramatic consequences for public health and the healthcare financing and delivery systems.

Endoscopy is a minimally invasive method of performing investigative, diagnostic and therapeutic medical procedures, employing an endoscope, which allows real-time visual observation of the patient's internal organs during the procedure. Endoscopic procedures are most commonly performed through natural orifices, including the mouth, to avoid incisions. Because of the accessibility of the digestive tract through the mouth, the endoscopy field is largely focused on disorders of the gastrointestinal tract such as disorders of the colon, esophagus, stomach and duodenum.

Endoscopes are commonly composed of a flexible tube with a camera installed at its tip. Endoscopes often include "working channels" through which catheters or other endoscopic tools or devices may be inserted directly into the patient's digestive system. The primary advantage of endoscopy is the elimination of incisions to the patient's body during a medical procedure. We believe that this is safer, prevents most post-operative pain and facilitates faster recuperation. Patient perception or preference is important as well. The perception of endoscopy procedures as being safer, and less painful than, corresponding surgical procedures may have the effect of minimizing patient fears.

Endoscopic procedures generally involve less recovery time and patient discomfort than conventional open or laparoscopic surgery. These procedures are also typically performed in the outpatient hospital setting as opposed to an inpatient setting. Typically, outpatient procedures cost the hospital or the insurer less money since there is no overnight stay in the hospital.

Our Solution and Products

The MUSE™ system

Our primary product, the MUSE™ system for transoral fundoplication, is a single use innovative device for the incisionless treatment of GERD, which is based on our proprietary platform technology and know-how. While at present substantially all of our revenue is derived from the miniature video camera and related equipment, our strategy is focused on the development and promotion of its MUSE™ system, which we therefore refer to as our "primary product".

Transoral means the procedure is performed through the mouth, rather than through incisions in the abdomen. The MUSE™ system for transoral fundoplication was previously known as the SRS™ Endoscopic Stapling System. We rebranded to the MUSE™ system following the launch of the most recent generation of the product. The MUSE™ system is used to perform a procedure as an alternative to a surgical fundoplication. The MUSE™ system offers an endoscopic, incisionless alternative to surgery. A single surgeon or gastroenterologist can perform the MUSE™ procedure, unlike in a laparoscopic fundoplication which requires incisions.

The system consists of the MUSE™ controller console, the MUSE™ endostapler and several accessories, including an overtube, irrigation bottle, tubing supplies and staple cartridges. The endostapler incorporates a video camera, a flexible surgical stapler and an ultrasonic sight, which is used to measure the distance between the anvil and the cartridge of the stapler, to ensure their proper alignment and tissue thickness. The device also contains an alignment pin, which is used for initial positioning of the anvil against the cartridge, two anvil screws, which are used to reduce the thickness of the tissue that needs to be stapled and to fix the position of the anvil and the MUSE™ endostapler during stapling. The system allows the operator to staple the fundus of the stomach to the esophagus, in two or more locations, typically around the circumference, thereby creating a fundoplication, without any incisions.

The clearance by the FDA, or "Indications for Use", of the MUSE™ system is "for endoscopic placement of surgical staples in the soft tissue of the esophagus and stomach in order to create anterior partial fundoplication for treatment of symptomatic chronic Gastro-Esophageal Reflux Disease in patients who require and respond to pharmacological therapy". As such, the FDA clearance covers the use by an operator of the MUSE™ endoscopic stapler as described in the above paragraph. In addition, in the pivotal study that was presented to the FDA in order to gain clearance, only patients who were currently taking GERD medications, or pharmacological therapy, were allowed in the study. In addition, all patients had to have a significant decrease in their symptoms when they were taking medication compared to when they were off the medication. As such, the FDA clearance included the indication that MUSE™ system is intended for patients who require and respond to pharmacological therapy. The MUSE™ system indication does not restrict its use with respect to GERD severity from a regulatory point of view. However, clinicians typically only consider interventional treatment options for moderate to severe GERD. Therefore, it is reasonable to expect the MUSE™ System would be primarily used to treat moderate and severe GERD in practice. The system has received 510(k) marketing clearance from the FDA in the United States, as well as a CE mark in Europe and a license from Health Canada. It is also cleared for use in Turkey and in Israel.

Clinical studies

The original FDA submission for the MUSE™ system included six month results from a multi-center clinical trial. The trial was conducted in support of the 510(k) marketing clearance submission for the system and pursuant to an FDA-issued Investigational Device Exemption (IDE).

Enrollment was completed in November 2010. A total of 72 patients were enrolled and 69 were treated with the MUSE™ system during the study. A manuscript detailing the results of this study was published in Surgical Endoscopy and is currently available online. Publication in the hardcopy of the journal was in the January 2015 issue.

The primary objective of the study was to assess the safety and efficacy of the system in the treatment of subjects with GERD. The primary efficacy endpoint was at least a 50% improvement in the GERD Health Related Quality of Life, or HRQL, scores in 53% of the subjects. GERD-HRQL is the standard assessment of how an individual's well-being may be affected over time by a disease. Secondary efficacy assessments included PPI intake, esophageal acid exposure during a 24-hour period and anatomical changes. The follow-up period was set at six months following each procedure.

The primary endpoint was met in that 73% of subjects exhibited at least a 50% reduction in GERD-HRQL at six months. In addition, 85% of subjects reduced their PPI intake by at least 50%, with 65% of subjects eliminating PPI use completely at six months.

FDA marketing clearance for our system was granted in May 2012 following the original FDA submission. Subsequent improvements to the system included improvements to the camera, illumination and alignment mechanisms, the addition of an electronic stapling motor, and condensing two control consoles into a single unit. FDA clearance for the modified system was obtained in June 2015. The modified system has also obtained a CE mark in Europe, a license from Health Canada and was approved for use in Turkey and Israel.

In May 2013, we received five years of follow-up results for a precursor IRB (Institutional Review Board) approved pilot study of the system conducted in 2007 at Deenanath Mangeshkar Hospital and Research Center in the city of Pune, India. The results of this follow-up study were published in the peer review journal Surgical Endoscopy in March 2015. As noted in the journal article, the five-year results are similar to the results obtained from subjects who received-laparoscopic procedures for GERD in the same period. Each year, eleven of the thirteen patients were reached (although not always the same eleven). All thirteen patients had at least a four year follow-up. Throughout the follow up period,GERD-HRQL scores were normal in all but one patient. All patients indicated that they would agree to do the procedure again. Out of the initial thirteen patients, seven (54%) had eliminated their PPI intake and another three (23%) reduced PPI use by 50% or more. It should be emphasized that for this trial patients were selected with GERD severity at a higher than average level (moderate to severe), a fact which may indicate an even greater outcome of the effect of the system in an average GERD level patient population.

In November 2015, a follow-up study conducted in the United States looked at evaluating the long-term clinical outcome of 37 patients who received GERD treatment with the MUSE™ system in the multi-center study mentioned above was concluded. Efficacy and safety data were analyzed up to four years post-procedure. No new complications have been reported in such long-term analysis. The proportions of patients who remained off daily PPIs were 83.8% (31/37) at six months, and 69.4% (25/36) at 4 years post-procedure. GERD-HRQL scores off PPIs were significantly decreased following six months and four years post-procedure. The authors concluded that the MUSE™ system appeared to be safe and effective in improving symptom scores as well as reducing PPI use in patients with GERD. These results appeared to be equal to or better than those of the other devices for endoluminal GERD therapy.

In February 2017, we received an approval to start a multi-center MUSE™ system clinical study in China after the China Food and Drug Administration, or the CFDA reviewed the ethics committees' approval and agreements were in place with each study location. Under Principal Investigator, Yunsheng Yang, Director of Gastroenterology Department Clinical center at 301 Hospital and Chairman of Chinese Society of Gastroenterology, The General Hospital of People's Liberation Army in Beijing, the clinical study will include approximately 62 patients, will take place at 5 centers across China: The General Hospital of People's Liberation Army, Renji Hospital of Shanghai, Shanghai General Hospital, Peking University Third Hospital and Navy General Hospital.

Procedures started in March 2017 and are expected to continue through 2017, with results being reported to the CFDA in 2018 as part of the CFDA submission for clearance to sell MUSE™ system in China.

Miniature Video Cameras

By definition all endoscopes must include vision apparatus to facilitate the operator's view of the patient's internal organs. In the past, fiber optics were utilized for this purpose, and have been gradually replaced with electronic video systems offering higher resolution and higher-quality images. We have developed several models of miniaturized digital video cameras and video processing equipment, for use in medical endoscopy products as well as industrial uses. Our cameras range between 3.45mm to 0.99 mm in diameter, and are based on single-use mentary Metal Oxide Semiconductor, or CMOS image sensors. In some cases, our cameras are relatively inexpensive, allowing them to be used in single-use devices.

Our miniature cameras are intended for use in medical applications in which it has not yet been feasible to use miniature video cameras, and may be integrated into devices developed by the company, or by third parties who source the camera from us. We expect that the growing demand for single-use medical devices will increase demand for the CMOS cameras in particular, in fields such as gastroenterology, orthopedics, gynecology, ears nose throat, urology, cardio-vascular, and other fields in which diagnostic and surgical procedures may be performed endoscopically. Small-diameter video cameras permit not only smaller camera-based endoscopes which are able to penetrate previously inaccessible organs or visualize them in improved image quality, but also allows for the addition of working channels and other features in the valuable space freed by the reduction in camera size.

Our most advanced camera is a prototype CMOS-based camera measuring only 0.99 mm in diameter transmitting 45,000 pixels in HDMI format, which we believe to be the smallest video camera ever produced. This camera is based on "through-silicon-via" technology whereby the electronics pass vertically through the sensor, permitting smaller diameter devices. This prototype camera will not be commercially available in the foreseeable future.

Other products

We have utilized the MUSE™ system technological platform for the development of prototypes for other endoscopy and direct vision products, including a device aiding colonoscopy, a device used in dental surgery and others. To date, we have not yet applied for regulatory approvals for these devices, nor have we entered into agreements for the commercialization of these devices.

Our strategy

Our primary goal is to generate recurring revenues by driving sales of our MUSE™ system and establishing it as the standard-of-care procedure and device for the treatment of moderate to severe GERD. We believe that we can achieve this goal by continuing to accumulate clinical data and promote reimbursement for the procedure in the principal markets of North America, Europe and Asia. Our strategy includes the following key elements:

Driving MUSE™ system sales

We intend to continue to focus on commercializing the MUSE™ system in principal markets. We have begun expanding our distribution network for further commercialization in key European markets including Italy and Germany. During 2017, we anticipate additional European distribution agreements to be implemented. In addition, we have successfully completed the technical testing for CFDA approval in China and have already begun the necessary clinical trial in March 2017. In the US, we will continue marketing the MUSE™ system through a direct effort at key U.S. institutions.

Collaborating and co-developing with established companies

We seek to initiate co-development or licensing collaborations with leading companies which have existing marketing channels or significant marketing power in critical geographies and sales channels.

Licensing our products

We may consider plans to issue a license for various endoscopic systems which are based on owned and patent-protected technology which has been developed by us. We continue to work to engage in agreements with companies which produce and market medical devices, to include the production of systems for the foregoing companies which will be integrated by them in the endoscopic systems which they produce or that we will develop or produce for them.

Developing additional products

Additionally, we intend to develop other products which will be based on the integrated and platform technology which we have developed to date, including our miniaturized visualization imaging products, combined with our flexible stapling platform, similar to the MUSE™ system. Additional products could include a fully integrated, endoscopic platform designed for endoscopic surgical tissue dissection or for endoscopic sleeve gastrectomy.

Substantially all of our revenues in recent years are based on the sale of miniature cameras which we develop and manufacture. The following data reflects our total revenue arising from the following services:

	Revenues		
	Year Ended December 31,		
	2014	2015	2016
	(Thousands of U.S. dollars)		
Sales of Miniature Cameras and related equipment	653	558	449
Sales of the MUSE™ System	91	66	100
Total	744	624	549

The following data reflects our total revenue broken down by geographic region:

	Revenues		
	Year Ended December 31,		
	2014	2015	2016
	(Thousands of U.S. dollars)		
United States	460	446	345
Europe	113	84	33
Asia	134	51	5
Other	37	43	166
Total	744	624	549

Seasonality of Business

During the last few years we have not seen any seasonality in our sales.

Raw Materials and Suppliers

The main raw materials required for the assembly and production of our various products mainly include electronic components, mechanical components, lighting components, tubes, lenses, sensors and cables, which we purchase from various suppliers and subcontractors in Israel and around the world.

We generally engage with our suppliers and subcontractors in routine purchase orders for the performance of specific orders of goods, and not via long-term contracts. We are not required to provide collateral of any kind with respect to our orders, though occasionally we have to pay some, or all, of the purchase order amount up front. The payment is usually made in various currencies as agreed by the parties.

Though we attempt to ensure the availability of more than one supplier for each important component in our products, the number of suppliers engaged in the provision of miniature video sensors which are suitable for our CMOS technology products is very limited, and therefore in some cases we engage with a single supplier, which may result in dependency on such supplier. This is the case regarding sensors for the CMOS type technology that is produced by a single supplier in the United States. As we do not have a contract in place with this supplier, there is no contractual commitment on the part of such supplier for any set quantity of such sensors. The loss of our sole supplier in providing us with miniature sensors for our CMOS technology products, and our inability or delay in finding a suitable replacement supplier, could significantly affect our business, financial condition, results of operations and reputation.

In general, alternative suppliers can be trained within a short period. However, we do have a small number of suppliers who the replacement of which could be longer, due to the adjustment of their products to our needs.

Marketing and Distribution

Company Sales and Marketing Efforts

In the United States, Europe and China, our commercial goals in the short term are to initiate highly selective sites for procedural experience. We will support these physicians and hospitals through a number of activities, including: marketing materials to help drive GERD patient awareness, hands-on training, animations, procedure simulator, attendance at key physician society meetings and trade shows, training courses, reimbursement analysis, and procedural assistance.

Engagement in External Distribution Agreements for the MUSE™ System

We currently have distribution agreements with local distributors in Italy and China for the distribution of the MUSE™ system, (in China the distribution arrangement is pending achievement of regulatory clearance for the MUSE™ system which is to be sought by the distributor). To date, a few commercial procedures have been performed for treatment of GERD using the MUSE™ system, which were provided in accordance with distribution agreements.

In general, the distribution agreements with respect to the MUSE™ system are uniform and provide the following:

- The distributor serves as the exclusive distributor in the territory relevant to the agreement;
- The distributor must obtain all local approvals required to import and market the systems in the relevant country;
- A distribution period of one to several years is determined;
- The distributor undertakes to market the systems in accordance with an annual plan coordinated with us, and serves as a service center for the systems in that country; and
- The distributor undertakes to purchase a minimum quantity of systems throughout the preliminary period of the agreement.

China Multi-Center Clinical Study

We have previously entered into an exclusive distribution agreement with China National Pharmaceutical Group Corporation, or Sinopharm, which granted the Chinese pharmaceutical company exclusive rights to distribute the MUSE™ system in China following its approval by the CFDA. Under the agreement, Sinopharm has also committed to purchasing a minimum of $17.6 million worth of the MUSE™ system and related products over the course of four years, from the date of CFDA approval. The agreement also provides Sinopharm with the discretionary right to appoint Shanghai Golden Grand-Medical Instruments Ltd., or Golden, a Chinese company specializing in the distribution of medical devices, as its exclusive sub-distributor in China. Under the agreement, Golden will manage sales and customer service, marketing and training, and recording of clinical trials.

Recently, we have received the approval of the China Food and Drug Administration, or the CFDA, for the commencement of the first multi-center MUSE™ system clinical study in China. As part of our efforts to obtain CFDA approval for MUSE™ system, the company entered into an addendum to its current agreement with Golden, under which we paid Golden an aggregate sum of $175,000 to be used in financing of the efforts of the study. On March 4, 2017, we completed our first human MUSE™ procedure in China.

Italian Distribution Agreement

With respect to our distribution agreement in Italy, on November 22, 2016, we entered into an exclusive distribution agreement with Innovamedica S.p.A., or Innovamedica, a privately owned distributor of minimally invasive medical devices. Under the terms of the agreement Innovamedica, will act as our exclusive distributor in Italy for a period of four years commencing as of January 1, 2017. The agreement requires Innovamedica to purchase minimum annual quantities of our products, which are expected to amount to at least €1 million during the term of the Agreement. Innovamedica's exclusivity is conditioned upon ordering the minimum annual quantities.

Marketing of Imaging Equipment

With respect to our visualization technology, we sell and market our off-the-shelf and customized products globally and also engage in co-development efforts when possible. We also maintain a dedicated web-site for our imaging products.

Intellectual Property

Our commercial success depends, in part, on obtaining and maintaining patent and other intellectual property protection, in the United States and internationally, for the technologies used in our products. We cannot be sure that any of our patents will be commercially useful in protecting our technology. We also rely on trade secrets to protect our product candidates. Our commercial success also depends in part on our non-infringement of the patents or proprietary rights of third parties. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. For additional information see "Item 4. Information on the Company—D. Risk Factors—Risks Related to Our Intellectual Property."

We own 19 U.S. patents and have filed 3 additional patent applications. In addition, we own 50 patents that were granted in other countries. We also have 12 pending patent applications outside of U.S. and one patent application with the Patent Cooperation Treaty. Our patents, and any patents which may be granted under our pending patent applications, expire between the years 2021 and 2036.

We cannot be sure that any patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future. There is also a significant risk that any issued patents will have substantially narrower claims than those that are currently sought.

We also protect our proprietary technology and processes, in part, by confidentiality and invention assignment agreements with our employees, consultants, scientific advisors and other contractors. These agreements may be breached, and we may not have adequate remedies for any breach. We also rely on trade secrets to protect our product candidates. However, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, scientific advisors or other 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.

On October 28, 2016, we settled all litigation and administrative proceedings with EndoChoice, Inc., or EndoChoice, including those actions pending in the U.S. District Court for the District of Delaware C.A. Nos. 15-505-LPS-CJB and C.A. No. 15-1215-LPS-CJB and the trademark opposition proceedings in the State of Israel involving Trademark Application Nos. 257172, 260433 and 262423. Under the terms of the confidential settlement, we were granted a covenant not to sue with respect to EndoChoice FUSE-related trademarks and EndoChoice was granted a non-exclusive license to our U.S. Patent No. 6,997,871 and related patents. Each party has agreed to bear its own costs and fees associated with the litigation.

Competition

The rapidly changing market for the treatment of GERD, which is comprised of pharmaceutical products, surgical procedures, medical devices and potential other treatments, can be significantly affected by new product introductions and other market activities of industry participants. We believe that the principal competitive factors in our market include:

- safety, efficacy and clinically effective performance of products;
- product benefits, including the ability to offer users (both physicians and patients) a solution for treatment of GERD using endoscopic-based methods or other;
- ease of use and comfort for the physician and patient;
- the cost of product offerings and the availability of product coverage and reimbursement from third-party payors, insurance companies and other parties;
- the strength of acceptance and adoption by physicians and hospitals;
- the ability to deliver new product offerings and enhanced technology to expand or improve upon existing applications through continued research and development;
- the quality of training, services and clinical support provided to physicians and hospitals;
- effective sales, marketing and distribution;
- the ability to provide proprietary products protected by strong intellectual property rights; and
- the ability to offer products that are intuitive and easy to learn and use.

Competition with the MUSE™ system

We have several competitors in the medical device and pharmaceutical industries. Patients and physicians may opt for more established existing therapies to treat GERD, including PPI pharmaceutical treatment or laparoscopic fundoplication surgery. PPIs are currently being offered by several large pharmaceutical manufacturers, most of whom have significantly greater financial, clinical, manufacturing, marketing, distribution and technical resources and experience than we have.

Over the last few years a number of different medical devices and treatments have been introduced to address the "treatment gap" in GERD treatments and therapies which is found between long-term pharmaceutical therapy on one hand and surgery on the other. These devices and treatments seek to treat GERD less invasively than fundoplication and without the need for long-term use of drug therapy, and include the following options that, to our knowledge, are currently commercialized:

- EsophyX™ Transoral Incisionless Fundoplication (EndoGastric Solutions) — a device to endoscopically replicate a partial fundoplication.
- LINX™ Reflux Management System (Torax Medical) — an implantable magnetic mechanical collar around the LES.
- Stretta™ (Mederi Therapeutics) — a catheter to deliver radiofrequency energy to the lower esophageal sphincter to stimulate collagen deposition (scarring) in the LES.
- GERDX (G-Surg) – An endoscopic plication device for the LES.

Due to the fact that the market is broad, it is also possible that there are additional companies who are working on the development of endoscopic devices for the treatment of GERD. However, we do not have any indications concerning any commercial product or product approaching commercialization, beyond information published publicly, from time to time, in medical journals and databases of the FDA.

In addition, new companies have been, and are likely to continue to be, formed to pursue opportunities in our market. For example, EndoStim Inc. is a medical device company focused on the development and commercialization of a neurostimulation system for the treatment of GERD, via an implant which includes electrodes which stimulates the LES through a permanent electrical current, and is intended for the treatment of GERD. The Endostim device is implanted in the body by means of a laparoscopic surgery.

There is also a relatively new surgical technology without the use of a dedicated device, called Anti-Reflux Mucosectomy to treat GERD.

Competition with Miniature Video Cameras

The main devices that compete with our miniature cameras are manufactured by Awaiba, Fujikura, MicroCam (Sanovas), Precision Optics, and Opcom. The miniature cameras of each of these vendors differ in various factors include image quality and resolution, camera shape and dimensions, sensor technology, optic characteristics, and user flexibility/customization.

Government Regulation

The healthcare industry, and thus our business, is subject to extensive federal, state, local and foreign regulation. 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 interpretations. In addition, these laws and their interpretations are subject to change.

Both federal and state governmental agencies continue to subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. As indicated by work plans and reports issued by these agencies, the federal government will continue to scrutinize, among other things, the billing practices of healthcare providers and the marketing of healthcare products.

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. In addition, because there is a risk that our products are used off label, we believe we are subject to increased risk of prosecution under these laws and by these entities even if we believe we are acting appropriately. We discuss below the statutes and regulations that are most relevant to our business and most frequently cited in enforcement actions.

U.S. Food and Drug Administration

All of our products sold in the U.S. are subject to regulation as medical devices under the FDA, as implemented and enforced by the FDA. The FDA governs the following activities that we perform or that are performed on our behalf, to ensure that medical products we manufacture, promote and distribute domestically or export internationally are safe and effective for their intended uses:

- product design, preclinical and clinical development and manufacture;
- product premarket clearance and approval;
- product safety, testing, labeling and storage;
- record keeping procedures;
- product marketing, sales and distribution; and
- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths, serious injuries or device malfunctions and repair or recall of products.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either premarket notification, or 510(k) marketing clearance or approval of a premarket approval application, or PMA, from the FDA. The FDA classifies medical devices into one of three classes. Class I devices, considered to have the lowest risk, are those for which safety and effectiveness can be assured by adherence to the FDA's general regulatory controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials (General Controls). Class II devices are subject to the FDA's General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device (Special Controls). Manufacturers of most class II and some class I devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. This process is generally known as 510(k) marketing clearance. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in class III, requiring approval of a PMA.

510(k) Marketing Clearance Pathway

To obtain 510(k) marketing clearance, we must submit a premarket notification demonstrating that the proposed device is "substantially equivalent" to a legally marketed "predicate device" that is either in class I or class II, or to a class III device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a PMA. A Special 510(k) is an abbreviated 510(k) application which can be used to obtain clearance for certain types of device modification such as modifications that do not affect the intended use of the device or alter the device's fundamental scientific technology. A Special 510(k) generally requires less information and data than a complete, or Traditional 510(k). In addition, a Special 510(k) application often takes a shorter period of time, which could be as short as 30 days, than a Traditional 510(k) marketing clearance application, which can be used for any type of 510(k) device. The FDA's 510(k) marketing clearance pathway usually takes from three to twelve months, but may take significantly longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. There is no guarantee that the FDA will grant 510(k) marketing clearance for our future products and failure to obtain necessary clearances for our future products would adversely affect our ability to grow our business.

The FDA is currently considering proposals to reform its 510(k) marketing clearance process and such proposals could include increased requirements for clinical data and a longer review period. In response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) regulatory pathway, the FDA initiated an evaluation of the 510(k) program, and in January 2011, announced several proposed actions intended to reform the review process governing the clearance of medical devices. The FDA intends these reform actions to improve the efficiency and transparency of the clearance process, as well as bolster patient safety. For example, in July 2011, the FDA issued a draft guidance document entitled "510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device," which was intended to assist manufacturers in deciding whether to submit a new 510(k) for changes or modifications made to the manufacturer's previously cleared device. While this draft guidance was subsequently withdrawn, the FDA is expected to replace the 1997 guidance document on the same topic. As part of FDASIA, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms which are further intended to clarify and improve medical device regulation both pre- and post-approval. One of these provisions obligates the FDA to prepare a report for Congress on the FDA's approach for determining when a new 510(k) will be required for modifications or changes to a previously cleared device. After submitting this report, the FDA is expected to issue revised guidance to assist device manufacturers in making this determination. Until then, manufacturers may continue to adhere to the FDA's 1997 guidance on this topic when making a determination as to whether or not a new 510(k) is required for a change or modification to a device, but the practical impact of the FDA's continuing scrutiny of these issues remains unclear. It is possible that any new guidance will make substantive changes to existing policy and practice regarding the assessment of whether a new 510(k) is required for changes or modifications to existing devices. Specifically, industry has interpreted the withdrawn draft guidance to take a more conservative approach in requiring a new 510(k) for certain changes or modifications to existing, cleared devices that might not have triggered a new 510(k) under the 1997 guidance. As of July 28, 2014, the FDA released final guidance entitled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications" which is intended to identify, explain, and clarify each of the critical decision points in the decision-making process FDA uses to determine substantial equivalence. We cannot predict which of the 510(k) marketing clearance reforms currently being discussed or proposed might be enacted, finalized or implemented by the FDA and whether the FDA will propose additional modifications to the regulations governing medical devices in the future. Any such modification could have a material adverse effect on our ability to commercialize our products.

Medical devices can be marketed only for the indications for which they are cleared or approved. After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) marketing clearance or, depending on the modification, PMA approval. The FDA requires each manufacturer to determine whether the proposed changes requires submission of a 510(k) or a PMA, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing or recall the modified device until 510(k) marketing clearance or PMA approval is obtained. Also, in these circumstances, we may be subject to significant regulatory fines or penalties. We have made, and plan to continue to make, additional product enhancements to MUSE™ system and other products that we believe do not require new 510(k) marketing clearances. We cannot be assured that the FDA would agree with any of our decisions not to seek 510 (k) marketing clearance or PMA approval. For risks related to 510(k) marketing clearance, see "Item 4. Information on the Company —D. Risk Factors – Risks Related to Regulatory Compliance."

PMA Approval Pathway

A PMA must be submitted to the FDA if the device cannot be cleared through the 510(k) process or is not otherwise exempt from the FDA's premarket clearance and approval requirements. A PMA must generally be supported by extensive data, including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR.

New PMAs or PMA supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. None of our products are currently approved under a PMA approval. However, we may in the future develop devices which will require the approval of a PMA. There is no guarantee that the FDA will grant PMA approval of our future products and failure to obtain necessary approvals for our future products would adversely affect our ability to grow our business.

C*linical Trials*

Clinical trials are generally required to support a PMA application and are sometimes required for 510(k) marketing clearance. Such trials generally require an Investigational Device Exemption application, or IDE, approved in advance by the FDA for a specified number of patients and study sites, unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an Institutional Review Board, or IRB, for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. To conduct a clinical trial, we are also required to obtain the patient's informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the United States. Similarly, in Europe the clinical study must be approved by a local ethics committee and in some cases, including studies with high-risk devices, by the ministry of health in the applicable country.

Pervasive and Continuing Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply. In addition to the requirements below, the Medical Device Reporting, or MDR, regulations require that we report to the FDA any incident in which our products may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. See "Item 4. Information on the Company —D. Risk Factors – Risks Related to Regulatory Compliance," for further information regarding our reporting obligations under MDR regulations. Additional regulatory requirements include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;

- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all phases of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our approved devices;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply, when necessary, to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- notices of corrections or removals.

We must also register with the FDA as a medical device manufacturer and must obtain all necessary state permits or licenses to operate our business.

Failure to comply with applicable regulatory requirements, including delays in or failures to report incidents to the FDA as required under the MDR regulations, can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) marketing clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

In January 2016, we performed an FDA mock audit by an FDA veteran specialist, following which we implemented improvements in our quality management system. We cannot be assured that we have adequately complied with all regulatory requirements or that one or more of the referenced sanctions will not be applied to us as a result of a failure to comply.

Marketing Approvals Outside the United States

Sales of medical devices outside the United States are subject to foreign government regulations, which vary substantially from country to country. 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 has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Each European Union member state has implemented legislation applying these directives and standards at the national level. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. Devices that comply with the requirements of the laws of the relevant member state applying the applicable European Union directive are entitled to bear CE conformity marking and, accordingly, can be commercially distributed throughout the member states of the European Union and other countries that comply with or mirror these directives. The method of assessing conformity varies depending on the type and class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a "Notified Body," an independent and neutral institution appointed to conduct conformity assessment. This third-party assessment consists of an audit of the manufacturer's quality system and clinical information, as well as technical review of the manufacturer's product. An assessment by a Notified Body in one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. In addition, compliance with ISO 13845 on quality systems issued by the International Organization for Standards, among other standards, establishes the presumption of conformity with the essential requirements for a CE marking. In addition, many countries apply requirements in their reimbursement, pricing or health care systems that affect companies' ability to market products.

We have been authorized by Health Canada and have received AMAR approval in Israel. In addition, we received approval form the MedCert Zertifizierungs und Prufungsgsesellschaft fur die Medizin GmbH of Germany, and are entitled to print the CE Mark on our products, after having examined the EU Technical File for each new product.

Health Care Laws and Regulations

Reimbursement

In the United States and elsewhere, health care providers that perform surgical procedures using medical devices such as ours generally rely on third-party payors, including governmental payors such as Medicare and Medicaid and private payors, to cover and reimburse the associated medical and surgical costs. Consequently, sales of medical devices are dependent in part on the availability of reimbursement to the customer from third-party payors. The manner in which reimbursement is sought and obtained varies based upon the type of payor involved and the setting in which the product is furnished and utilized. In general, third-party payors will provide coverage and reimbursement for medically reasonable and necessary procedures and tests that utilize medical devices and may provide separate payments for the implanted or disposable devices themselves. Most payors, however, will not pay separately for capital equipment. Instead, payment for the cost of using the capital equipment is considered to be covered as part of payments received for performing the procedure. In determining payment rates, third-party payors are increasingly scrutinizing the prices charged for medical products and services in comparison to other therapies. The procedures in which our products are used may not be reimbursed by these third-party payors at rates sufficient to allow us to sell our products on a competitive and profitable basis.

In addition, in many foreign markets, including the countries in the European Union, pricing of medical devices is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to limit payments by governmental payors for medical devices, and the procedures in which medical devices are used.

In March 2010, comprehensive health care reform legislation was enacted through the passage of the Affordable Care Act of 2010. Significant measures contained in the health care reform legislation include initiatives to revise Medicare payment methodologies, initiatives to promote quality indicators in payment methodologies (including the bundling of hospital and physician payments), initiatives related to the coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, and annual reporting requirements related to payments to physicians and teaching hospitals. At this time it is not possible to predict whether these initiatives will have a positive or negative impact on us. The health care reform legislation also includes new taxes impacting certain health-related industries, including medical device manufacturers. As of 2013, each medical device manufacturer or importer has to pay an excise tax (or sales tax) in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. In addition to the health care reform legislation, various healthcare reform proposals have also emerged at the state level. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or internationally, or the effect any future legislation or regulation will have on us. The taxes imposed by the health care reform legislation and the expansion in government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursements by payors for our products, and reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations, possibly materially.

Medicare and Medicaid

The Medicare program is a federal health benefit program administered by the CMS that covers and pays for certain medical care items and services for eligible elderly persons. The Medicaid program is a federal-state partnership under which states receive matching federal payments to fund healthcare services for the poor. In January 2016, the American Medical Association's (AMA) Current Procedural Terminology (CPT) published a new Category I CPT Code for transoral esophagogastric fundoplasty procedures, which describes procedures conducted with the MUSE™ system. In the U.S., the CPT Editorial Panel assigns specific billing codes for physician services and outpatient hospital procedures, which are used by providers, who are our customers, to bill for procedures. Once a CPT code is established, the Centers for Medicare and Medicaid Services (CMS) in turn establishes payment levels and coverage rules under Medicare, and private payors establish rates and coverage rules. Notwithstanding the issuance of a CPT to report the MUSE procedure and the establishment of payment rates for the code, we cannot guarantee that the MUSE™ system is or will be covered and, if covered, that reimbursement will be sufficient, and furthermore, we cannot guarantee that the MUSE™ system or any future product will be approved for coverage or reimbursement by Medicare, Medicaid or any third-party payor. Reimbursement decisions in the European Union and in other jurisdictions outside of the United States vary by country and region and there can be no assurance that we will be successful in obtaining adequate reimbursement.

Commercial Insurers

Many private payors look to CMS policies as a guideline in setting their coverage policies and payment amounts. A decrease of, or limitation on, reimbursement payments for physicians and hospitals by CMS or other agencies may affect coverage and reimbursement determinations by many private payors. Additionally, some private payors may reimburse only a portion of the costs associated with the use of our products, or not at all.

Fraud and Abuse Laws

Because of the significant federal funding involved in Medicare and Medicaid, Congress and the states have enacted, and actively enforce, a number of laws whose purpose is to eliminate fraud and abuse in federal health care programs. Our business is subject to compliance with these laws.

Anti-Kickback Statutes and Federal False Claims Act

The federal healthcare programs' Anti-Kickback Statute prohibits persons from soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. There are a number of statutory exceptions as well as regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, however, the exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny. Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

Government officials have focused their enforcement efforts on marketing of healthcare services and products, among other activities, and recently have brought cases against companies, and certain sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business. Another development affecting the healthcare industry is the increased use of the federal Civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The federal civil False Claims Act prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowing and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. Violation of the False Claims Act can result in significant civil and administrative penalties, up to treble damages and exclusion from participation in federal health care programs like Medicare and Medicaid. The False Claims Act also allows a private individual or entity to sue on behalf of the government. Medical device manufacturers and other health care companies have been investigated by the U.S. Department of Justice and have reached substantial financial settlements with the federal government under the civil False Claims Act for a variety of alleged improper marketing activities, including providing free product, providing consulting fees, grants, free travel and other benefits to physicians to induce them to prescribe the company's products, and for causing false claims to be submitted as a result of the marketing of their products for unapproved, and thus non-reimbursable, uses. Resolution of such investigations has often included manufacturers entering into corporate integrity agreements with the Office of Inspector General for the U.S. Department of Health and Human Services that require, among other things, substantial reporting and remedial actions.

Additionally, several bills have been passed or are pending, at both the state and federal levels that expand the anti-kickback laws to require, among other things, extensive tracking and maintenance of databases regarding relationships to physicians and healthcare providers. The PPACA imposes new reporting and disclosure requirements on device manufacturers for any "transfer of value" made or distributed to physicians and teaching hospitals, otherwise known as the Physician Payment Sunshine Act. Device manufacturers were required to begin collecting data on August 1, 2013 and were be required to submit reports to CMS by March 31, 2014 (and the 90th day of each subsequent calendar year). In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians. Some states, such as California, Massachusetts and Nevada, mandate implementation of commercial compliance programs, while certain states, such as Massachusetts and Vermont, impose restrictions on device manufacturer marketing practices and tracking and reporting of gifts, compensation and other remuneration to physicians. The implementation of the infrastructure to comply with these bills and regulations could be costly and any failure to provide the required information may result in civil monetary penalties.

We believe our current consulting agreements with physicians represent legitimate compensation for needed documented services actually furnished to us**.** However, engagement of physician consultants by medical device manufacturers has recently been subject to heightened scrutiny. In this environment, our engagement of physician consultants in product development or clinical testing could subject us to similar scrutiny. We are unable to predict whether we would be subject to actions under the Anti-Kickback Statute or False Claims Act or any similar state law, or the impact of such actions.

HIPAA and Other Fraud and Privacy Regulations

Among other things, HIPAA created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The HIPAA health care fraud statute prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment and exclusion from government sponsored programs. The HIPAA false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines and imprisonment.

In addition to federal regulations issued under HIPAA, some states have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA. In those cases, it may be necessary to modify our planned operations and procedures to comply with the more stringent state laws. If we fail to comply with applicable state laws and regulations, we could be subject to additional sanctions.

Anti-Bribery Laws

Compliance with complex foreign and U.S. laws and regulations that apply to our international operations increases our cost of doing business in international jurisdictions and could expose us or our employees to fines and penalties in the U.S. and abroad. These numerous and sometimes conflicting laws and regulations include the FCPA. The FCPA prohibits U.S. companies, companies whose securities are listed for trading in the United States and other entities, and their officers, directors, employees, shareholders acting on their behalf and agents from offering, promising, authorizing or making payments to foreign officials for the purpose of obtaining or retaining business abroad or otherwise obtaining favorable treatment. The FCPA also requires companies to maintain records that fairly and accurately reflect transactions and maintain internal accounting controls. In many countries, hospitals are government-owned and healthcare professionals employed by such hospitals, with whom we regularly interact, may meet the definition of a foreign official for purposes of the FCPA. Additionally, recently enacted U.S. legislation increases the monetary reward available to whistleblowers who report violations of federal securities laws, including the FCPA, which may result in increased scrutiny and allegations of violations of these laws and regulations. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, prohibitions on the conduct of our business, and damage to our reputation.

Israeli Government Programs

Under the Encouragement of Research, Development and Technological Innovation in the Industry Law, 5744-1984, or the Innovation Law, research and development programs which meet specified criteria and are approved by a committee of the Office of Chief Scientist of the Israeli Ministry of Economy (formerly named the Ministry of Industry, Trade and Labor, or the OCS, are eligible for grants from the OCS. The grant amounts are determined by the research committee, and are typically a percentage of the project's expenditures. Under most programs, the grantee is required to pay royalties to the State of Israel from the sale of products developed under the program. Regulations under the Innovation Law generally provide for the payment of royalties of 3% to 6% on sales of products and services based on or incorporating technology developed using grants or know-how deriving therefrom, up to 100% of the grant, linked to the dollar and bearing interest at the LIBOR rate, is repaid. The royalty rates and the aggregate repayment amount may be higher if manufacturing rights are transferred outside of Israel, as further detailed below. The manufacturing rights of products incorporating technology developed thereunder may not be transferred outside of Israel, unless approval is received from the OCS and additional royalty payments are made to the State of Israel, as further detailed below. However, this does not restrict the export of products that incorporate the funded technology.

The pertinent obligations under the Innovation Law are as follows:

- *Local Manufacturing Obligation*. The terms of the grants under the Innovation Law require that we manufacture the products developed with these grants in Israel. Under the regulations promulgated under the Innovation Law, the products may be manufactured outside Israel by us or by another entity only if prior approval is received from the OCS (such approval is not required for the transfer of less than 10% of the manufacturing capacity in the aggregate, in which case a notice should be provided to the OCS). As a condition to obtaining approval to manufacture outside Israel, we would be required to pay royalties at an increased rate (usually 1% in addition to the standard rate and increased royalties cap (between 120% and 300% of the grants, depending on the manufacturing volume that is performed outside Israel). We note that a company also has the option of declaring in its OCS grant application an intention to exercise a portion of the manufacturing capacity abroad, thus avoiding the need to obtain additional approvals and pay the increased royalties cap.

- *Know-How transfer limitation*. The Innovation Law restricts the ability to transfer know-how funded by the OCS outside of Israel. Transfer of OCS funded know-how outside of Israel requires prior OCS approval and in certain circumstances is subject to certain payment to the OCS calculated according to formulae provided under the Innovation Law. If we wish to transfer OCS funded know-how, the terms for approval will be determined according to the character of the transaction and the consideration paid to us for such transfer. The OCS approval to transfer know-how created, in whole or in part, in connection with an OCS-funded project to third party outside Israel where the transferring company remains an operating Israeli entity is subject to payment of a redemption fee to the OCS calculated according to a formula provided under the Innovation Law that is based, in general, on the ratio between the aggregate OCS grants to the company's aggregate investments in the project that was funded by these OCS grants, multiplied by the transaction consideration, considering depreciation mechanism and less royalties already paid to the OCS. The transfer of such know-how to a party outside Israel where the transferring company ceases to exist as an Israeli entity is subject to a redemption fee formula that is based, in general, on the ratio between aggregate OCS grants received by the company and the company's aggregate research and development expenses, multiplied by the transaction consideration considering depreciation mechanism and less royalties already paid to the OCS. The regulations promulgated under the Innovation Law establish a maximum payment of the redemption fee paid to the OCS under the above mentioned formulas and differentiates between two situations: (i) in the event that the company sells its OCS funded know-how, in whole or in part, or is sold as part of an M&A transaction, and subsequently ceases to conduct business in Israel, the maximum redemption fee under the above mentioned formulas will be no more than six times the amount received (plus annual interest) for the applicable know-how being transferred, or the entire amount received from the OCS, as applicable; (ii) in the event that following the transactions described above (i.e. asset sale of OCS funded know-how or transfer as part of an M&A transaction) the company continues to conduct its research and development activity in Israel (for at least three years following such transfer and maintain staff of at least 75% of the number of research and development employees it had for the six months before the know-how was transferred and keeps the same scope of employment for such research and development staff), then the company is eligible for a reduced cap of the redemption fee of no more than three times the amounts received (plus annual interest) for the applicable know-how being transferred, or the entire amount received from the OCS, as applicable.

- Approval of the transfer of OCS funded technology to another Israeli company may be granted only if the recipient abides by the provisions of the Innovation law and related regulations, including the restrictions on the transfer of know-how and manufacturing rights outside of Israel (note that there will be an obligation to pay royalties to the OCS from the income of such sale transaction as part of the royalty payment obligation).

Approval to manufacture products outside of Israel or consent to the transfer of technology, if requested, might not be granted. Furthermore, the OCS may impose certain conditions on any arrangement under which it permits us to transfer technology or development out of Israel.

The Innovation Law was amended as of July 29, 2015, or the 2015 Amendment. On January 1, 2016, pursuant to the 2015 Amendment, the National Authority for Technological Innovation, or NATI, was established and in June 2016, NATI was fully constituted. Pursuant to the 2015 Amendment, NATI is authorized to change the current restrictions imposed on the recipients of grants under the Innovation Law with a new set of arrangements in connection with ownership obligations of know-how (including with respect to restrictions on transfer of know-how and manufacturing activities outside of Israel), as well as royalties obligations associated with approved programs. The Innovation Law as existed prior to the 2015 Amendment will continue to be in effect with respect to research and development programs which were in affect prior to January 1, 2016 until: (i) June 2017, which is one year following the date of appointment of all members of the NATI council; or (ii) earlier, if otherwise resolved by the NATI council. The Innovation Law in its form following the 2015 Amendment also includes new provisions with respect to sanctions imposed for violations of the Innovation Law. As of the date of this annual report on Form 20-F, we are unable to determine whether NATI will promulgate a new set of arrangements or adopt the arrangements which were stipulated under the Innovation Law as existed prior to the 2015 Amendment, therefore, as of the date of this annual report on Form 20-F, we are unable as assess the effect, if any, of the promulgation of such arrangements on us.

Grants Received from the Chief Scientist

We have received grants from the OCS as part of our participation in two programs as described below:

Membership in the Activities of the Bio Medical Photonic Consortium

The Bio Medical Photonic Consortium, or the Consortium, commenced its activities in June 2007, and concluded its activities on December 31, 2012. The purpose of the Consortium was to develop generic photonic technologies in the field of diagnostics and therapeutics in the biomedical industry in Israel, and specifically on the subject of the digestive system. The activities of the Consortium were performed under our management and the management of Given Imaging Ltd., where each would develop technological models which are based on their internal developments and on developments of the members of the Consortium.

Within the framework of the activities of the Consortium, the Company worked to develop the next generation technology of miniature cameras. The cameras were integrated, within the framework of the Consortium, in technological models for minimally invasive procedures which were developed by the members of the Consortium. The various combinations of surgical tools and advanced visual capabilities with miniature endoscopes are innovative, and we predict that the Consortium framework will continue serving as a fruitful basis for the development of innovative medical procedures through the creation of intellectual property. Additionally, we will cooperate with research groups which develop indicators for early detection of colorectal cancer, with the aim of integrating the visualization techniques and key products in this field.

The following are details regarding the rights and obligations within the framework of our activity in the Consortium, which continue to apply notwithstanding the conclusion of the program:

(i) The property rights to information which has been developed belongs to the Consortium member that developed it. However, the developing entity is obligated to provide the other members in the Consortium a license for the use of the new information, without consideration, provided that the other members do not transfer such information to any entity which is not a member of the Consortium. The provision of a license or of the right to use the new information to a third party is subject to approval by the administration of the MAGNET Program at the OCS;

(ii) We are is entitled to register a patent for the new information which has been developed by it within the framework of its activity in the Consortium. The foregoing registration does not require approval from the administration; and

(iii) The know-how and technology developed under the program is subject to the restrictions set forth under the Innovation Law, including restrictions on the transfer of such know-how and any manufacturing rights with respect thereto, without first obtaining the approval of the OCS. Such approval may entail additional payments to the OCS, as determined under the Innovation Law and regulations, and as further detailed above.

Collaboration Grant for the Development of a Miniature Diameter Endoscope for Use in Dental Implants

In July 2011, the OCS approved our application for support for a joint project regarding the development of an innovative, miniature diameter endoscopic product in the field of dental surgery, or the Dental Project. In October 2012, the Company received a notice according to which approval was given for continued support for the Dental Project for a second year. The OCS support for the Dental Project concluded on July 31, 2013.

The Dental Project was performed in collaboration with Qioptiq GmbH, a German corporation, or Qioptiq, in the field of sophisticated medical micro-optics, including in the medical and life sciences sector. The collaboration between the Company and Qioptiq was performed within the framework of the Eureka organization, a Pan-European organization which includes approximately 40 member states, including the State of Israel, and which acts to coordinate and to finance research and development enterprises in and outside of Europe.

In accordance with the outline of the Dental Project, we and Qioptiq collaborated on the development of an innovative miniature-diameter endoscope, with side viewing capabilities, intended for use in various dental implant procedures, the Dental Endoscope. During the Dental Project, each of the parties developed different parts of the Dental Endoscope. In accordance with the terms of the collaboration, the intellectual property which originated from the development of the Dental Endoscope remained the exclusive property of the party which developed it. Subject to the completion of the project, the parties agreed to conduct negotiations regarding the method used to produce and market the Product (the foregoing negotiations have not yet been conducted and we have notified the OCS that there are no revenues from this project).

Implantation procedures are complex, and in many cases, damage is caused to the tissue of the mouth and the jaw due to the dentist's inability to see the entire operating area. The Dental Endoscope is intended to allow improved visual monitoring of the surgical procedure using a miniature video camera which has been developed by us, which is installed on the edge of the endoscope, thereby significantly reducing the risk to the patient. It is estimated that hundreds of thousands of procedures of the kind for which the product is intended are performed each year in Europe. Construction of a prototype for the product concluded in November 2012. The prototype is intended for use in pre-clinical trials and in human clinical trials.

As of the date hereof, there is no certainty that it will be possible to produce and market the product, which may be developed or that the regulatory approvals required for the product's marketing will be received. At present, we and Qioptiq are not acting to commercialize the Dental Project.

Grants and Royalty Obligations

We received various grants from the OCS in connection with our participation in its programs. We received a grant of approximately $2.3 million in connection with our participation in the Bio Medical Photonics Consortium in the production of generic technology related to the partial development of miniature or the Consortium Grant. Under the terms of the Consortium Grant we are not required to pay royalties. In addition, we received a grant of approximately $0.2 million in connection with a collaboration within the framework of the Eureka organization related to miniature endoscope for dental implants, or the Eureka Grant. Under the terms of the Eureka Grant, we would have to pay royalties at a rate of 3%-5% from the actual sales of the relevant device, up to the repayment of the grant, with the addition of interest and linkage. As of December 31, 2016, there have been no sales that requires us to pay royalties under the Eureka Grant and we believe that the probability we could generate income from the miniature endoscope for dental implants is low.

C. Organizational Structure

We currently have one wholly owned subsidiary: Medigus USA LLC, a limited liability company, incorporated in the State of Delaware, United States.

D. Property, Plant and Equipment

Our offices and main research and development facility are located at Omer Industrial Park, No. 7A, P.O. Box 3030, Omer 8496500 Israel, where we occupy approximately 902 square meters. We lease our facilities and our lease ends on December 31, 2017.

We consider that our current office space is sufficient to meet our anticipated needs for the foreseeable future and is suitable for the conduct of our business. We have no current plans to construct, expend or improve our facilities.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this annual report. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this annual report, particularly those in "Item 3. Key Information — Risk Factors."

A. Operating Results

Overview

We are a medical device company specializing in developing innovative endoscopic procedures and devices. We are a developer of a unique proprietary endoscopic system for the treatment of GERD, a common chronic disease. We have an advanced technology platform for performing a wide range of endoscopic procedures. The platform includes various types of rigid, semi-flexible and flexible video endoscopes, as well as respective endoscopy suites.

From our date of incorporation, we have invested the majority of our research and development efforts on the MUSE™ system, intended for the minimally invasive and endoscopic treatment of GERD, one of the most widespread chronic diseases in the western world. The MUSE™ system has also been given marketing approval by the FDA through the 510(k) track and bears a CE mark, as required in order to market the system in European Union countries. In addition, we have an approval from Health Canada and AMAR for marketing in Canada and Israel, respectively, and we are also in the process of obtaining regulatory approvals in China.

For the year ended December 31, 2016 we derived approximately $ 0.45 million of revenues from miniature camera and related equipment (82%), and $100,000 of revenues from the MUSE™ system and related equipment (18%). For the year ended December 31, 2015 we derived approximately $0.56 million of revenues from miniature camera and related equipment (89%), and $66,000 from the MUSE™ system and related equipment (11%). For the year ended December 31, 2014, we derived approximately $0.65 million of revenues from miniature camera and related equipment (88%), and $91,000 of revenues from the MUSE™ system and related equipment (12%).

While at present substantially all of our revenue is derived from the miniature camera and related equipment, our strategy is focused on the development and promotion of our MUSE System.

We have incurred net losses in all years since our inception, and, as of December 31, 2016, we had an accumulated deficit of approximately $53.3 million. We anticipate that we are likely to continue to incur significant net losses for at least the next several years as we continue development of the MUSE™ system and potentially other products, expand our sales and marketing capabilities in the endoscopy-based products market, continue the commercialization of the MUSE™ system and work to expand its adoption and clinical implementation, and continue to develop the corporate infrastructure required to sell and market our products.

Recent business events and key milestones in the development of our business, include the following:

- In March 2017, pursuant to a registration statement we in the United States, we raised approximately $ 7.5 million (gross) through the issuance of ADSs and warrants. See "Item 10. Additional Information – C. Material Contracts."

- In December 2016, pursuant to a shelf prospectus in the United States, we raised approximately $0.76 million (gross) through the issuance of ADSs and warrants. See "Item 10. Additional Information – C. Material Contracts."

- In November 2016, we entered into an exclusive distribution agreement with Innovamedica pursuant to which Innovamedica will act as our exclusive distributor in Italy for a period of four years commencing as of January 1, 2017. See "Item 10. Additional Information – C. Material Contracts."

- In September 2016, pursuant to a shelf prospectus in the United States, we raised approximately $1.47 (gross) million through the issuance of ADSs. See "Item 10. Additional Information – C. Material Contracts."

- In January 2016 a Category 1 CPT code # 43210 was implemented to provide Medicare payment in the U.S. for a TransOral procedure for GERD.

- In July 2015, pursuant to a shelf prospectus in Israel, we raised approximately NIS 26.8 million (gross), which are approximately $7 million, through an issuance of shares and warrants to the public. See "Item 10. Additional Information – C. Material Contracts".

- In June 2014, we signed private equity placement agreements in an aggregate amount of approximately $11.1 (gross) million including shares and warrants. The offerings closed in August 2014. Approximately half of the amount was raised from Israeli investors, with the largest portion coming from entities within the Migdal Insurance Group, and with the remainder consisting of U.S. institutional investors Sabby Management, Armistice Capital and Senvest. OrbiMed Israel Partners Limited Partnership ("OrbiMed"), our controlling shareholder, also participated. See "Item 10. Additional Information – C. Material Contracts".

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of financial statements in conformity with IFRS requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates.

The accounting estimates used in the preparation of our financial statements require management to make assumptions regarding circumstances and events that involve considerable uncertainty. Management prepares the estimates on the basis of past experience, various facts, external circumstances, and reasonable assumptions according to the pertinent circumstances of each estimate.

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any affected future periods.

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements as of December 31, 2016. However, certain of our accounting policies are particularly important to the description of our financial position and results of operations. In applying these critical accounting policies, our management uses its judgment to determine the appropriate assumptions to be used in making certain estimates. Those estimates are based on our historical experience, the terms of existing contracts, our observation of trends in the industry, information provided by our customers and information available from other outside sources, as appropriate. These estimates are subject to an inherent degree of uncertainty. Our critical accounting policies include:

Functional Currency

The December 31, 2015 consolidated financial statements included in this annual report on Form 20-F were recorded in New Israeli Shekels, which was the Company's functional and presentation currency as of such date. Effective January 1, 2016, the Company changed its functional currency to the U.S. dollar from the New Israeli Shekel. The December 31, 2012, 2013, 2014, and 2015, financial data presented in this annual report on Form 20-F was translated from NIS to USD as follows: (1) all assets and liabilities of the Company were translated using the dollar exchange rate as of December 31st of each year, as applicable; (2) equity items were translated using historical exchange rates at the relevant transaction dates; (3) the statement of comprehensive loss items has been translated at the average exchange rates for the respective year; and (4) the resulting translation differences have been reported as "currency translation differences" within other comprehensive loss.

Revenue Recognition

Our revenue in recent years is primarily derived from the sale of imaging equipment which we develop and manufacture. We also derive revenue from the sale of the MUSE ™ system. Our revenues from the imaging equipment originate from medical device companies and research institutions which are engaged in the research and development of medical products in the United States, Japan and Europe. However, these video cameras are also sold to other customers.

We recognize revenues in accordance with International Accounting Standard No. 18, or IAS 18. Under IAS 18, revenues from the sale of goods are recognized when all of the following criteria have been met as of the applicable balance sheet date:

- The significant risks and rewards that are derived from the ownership of the goods have been transferred to the purchaser;
- We do not retain continuing managerial involvement at a level that generally typifies ownership and we do not retain effective control over the goods being sold;
- The amount of the revenues can be measured reliably;
- It is expected that the economic benefits that are connected to the transaction will flow to us; and
- The costs that have been incurred or that will be incurred in respect of the transaction can be measured reliably.

We also recognize revenues in accordance with International Accounting Standard No. 11, or IAS 11.

A construction contract is defined by IAS 11, "Construction contracts", as a contract specifically negotiated for the construction of an asset.

When the outcome of a construction contract can be estimated reliably and it is probable that the contract will be profitable, contract revenue is recognized over the period of the contract by reference to the stage of completion. Contract costs are recognized as expenses by reference to the stage of completion of the contract activity at the end of the reporting period. When it is probable that total contract costs will exceed total contract revenue, we recognize the expected loss as an expense immediately.

When the outcome of a construction contract cannot be estimated reliably, then we recognize revenue only to the extent of contract costs incurred that it is probable will be recoverable.

Variations in contract work, claims and incentive payments are included in contract revenue to the extent that may have been agreed with the customer and are capable of being reliably measured.

We use the "percentage-of-completion method" to determine the appropriate amount to recognize in a given period. The stage of completion is measured by reference to the contract costs incurred up to the end of the reporting period as a percentage of total estimated costs for each contract. Costs incurred in the year in connection with the future activities on a contract are excluded from contract costs in determining the stage of completion.

On the balance sheet, we report the net contract position for each contract as either an asset or a liability. A contract represents an asset where costs incurred plus recognized profits (less recognized losses) exceed progress billings; a contract represents a liability when the opposite in the case.

Share- Based Compensation

We account for share-based compensation arrangements in accordance with the provisions of IFRS2. IFRS2 requires us to recognize share-based compensation expense for awards of equity instruments based on the grant-date fair value of those awards. The cost is recognized as compensation expense, based upon the grant-date fair value of the equity or liability instruments issued. The fair value of our option grants is computed as of the grant date based on the Black-Scholes model, using standard parameters established in that model. The value of the transactions, measured as described above, is recognized as an expense over the vesting period.

Government Participation in Research and Development Expenses

We received research and development grants from the State of Israel through the OCS. In accordance with the OCS programs, we were entitled to a specific grant with respect to a development project only after we incurred development costs related to the project. Such grants are accounted for as forgivable loans according to International Accounting Standards No. 20, "Accounting for Government Grants and Disclosure of Government Assistance," or IAS 20, since they are repayable only if we generate revenues related to the underlying project.

In accordance with IAS 20, we account for grants received from the OCS as a liability according to their fair value on the date of their receipt, unless on that date it is reasonably certain that the amount we received will not be refunded, in which case the grants are carried to income as a reduction of the research and development expenses.

Upon the initiation of any project for which we have received a grant, we consider if it is reasonably certain that the project will reach the revenue-generating stage during the entire development phase of the project when determining the accounting treatment of the related grant. Our determination is based on various factors including our past experience. We reexamine the liability to the OCS each reporting period by reviewing the estimate of our future payments to the OCS based on our future sales forecasts.

Accounting for Income Taxes

As part of the process of preparing our consolidated financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process requires us to estimate our actual current tax exposures and make an assessment of temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included within our consolidated balance sheet. Significant management judgment is required in determining our provision for income taxes, deferred tax assets and liabilities. Changes to these estimates may result in a significant increase or decrease to our tax provision in the current or subsequent period.

We recognize deferred tax assets for unused tax losses, tax benefits, and deductible temporary differences to the extent that it is probable that future taxable profits will be available against which that can be utilized. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realized.

The calculation of our tax liabilities or reduction in deferred tax asset involves dealing with uncertainties in the application of complex tax regulations and estimates of future taxable income in different geographical jurisdictions. We recognize liabilities for uncertain tax positions if it is probable to be realized. It is inherently difficult and subjective to estimate such amounts, as we have to determine the probability of various possible outcomes. We reevaluate these uncertain tax positions on a quarterly basis. This evaluation is based on factors including, but not limited to, changes in facts or circumstances, changes in tax law, effective settlement of audit issues, and new audit activity. Such a change in recognition or measurement would result in the recognition of a tax benefit or an additional charge to the tax provision.

Warrants

On March 29, 2017, we issued warrants to various investors to purchase up to an aggregate of 2,142,858 ADSs representing 107,142,900 ordinary shares, with an exercise price of $3.50 per ADS, or the Series A Warrants. The Series A Warrants have a term of five years, and are exercisable immediately (or, at the election of the purchaser, six months following the issuance date). The Series A Warrants can also be exercised, under certain conditions, using a cashless exercise mechanism, in which the number of shares issued would be decreased in accordance with the reduced cash realization price. The Series A Warrants exercise price is adjustable upon certain events.

On March 29, 2017, we issued pre-funded warrants to various institutional investors to purchase up to an aggregate of 1,163,144 ADSs representing 58,157,200 ordinary shares, with an exercise price of $0.01 per ADS, or the Series B Warrants. The Series B Warrants will be exercisable immediately until exercised in full. The Series B Warrants can also be exercised, under certain conditions, using a cashless exercise mechanism, in which the number of shares issued would be decreased in accordance with the reduced cash realization price. The Series B Warrants exercise price is adjustable upon certain events.

On March 29, 2017, we issued warrants to Rodman & Renshaw, a unit of H.C. Wainwright & Co., acting as placement agent in our offering closed of such date, to purchase up to an aggregate of 150,000 ADSs representing 7,500,000 ordinary shares, with an exercise price of $4.375 per ADS, or the March 2017 Placement Agent Warrants. The March 2017 Placement Agent Warrants have a term of five years, and are exercisable immediately. The March 2017 Placement Agent Warrants can also be exercised, under certain conditions, using a cashless exercise mechanism, in which the number of shares issued would be decreased in accordance with the reduced cash realization price. The March 2017 Placement Agent Warrants' exercise price is adjustable upon certain events.

On December 6, 2016, we issued warrants to various institutional investors to purchase up to an aggregate of 39,871 ADSs representing 1,993,550 ordinary shares, with an exercise price of $9.00 per ADS. The warrants will be exercisable beginning on the six month anniversary of their issuance date and have a term of five and a half years. The warrants can also be exercised using a cashless exercise mechanism, in which the number of shares issued would be decreased in accordance with the reduced cash realization price. The warrant exercise price is adjustable upon certain events (e.g. dividend, distribution of bonus shares, etc.).

In accordance with International Accounting Standard 32: "Financial Instruments: Presentation", these warrants are a "financial liability", classified in the statement of financial position as a non-current liability on the line "warrants at fair value". As the aforementioned liability is a non-equity derivative financial instrument, it is classified in accordance with IAS 39 to the category of financial liability at fair value through the statement of income, which is measured at its fair value at each date of the statement of financial position, with changes in the fair value currently reflected in the statement of income.

On December 6, 2016, we issued to Rodman & Renshaw, a unit of H.C. Wainwright & Co., acting as placement agent in our offering closed of such date, warrants to purchase up to an aggregate of 3,987 ADSs representing 199,355 ordinary shares, with an exercise price of $7.37 per ADS. The warrants will be exercisable beginning on the six month anniversary of their issuance date and have a term of five years. The warrants can also be exercised by a cashless exercise mechanism, in which the number of shares issued would be decreased in accordance with the reduced cash realization price. The warrant exercise price is adjustable upon certain events (e.g. dividend, distribution of bonus shares, etc.).

On December 6, 2016, we issued to Roth Capital Partners and Maxim Group LLC warrants to purchase up to an aggregate of 1,993 ADSs representing 99,675 ordinary shares, with an exercise price of $9.0 per ADS. The warrants will be exercisable beginning on the six month anniversary of their issuance date and have a term of five and a half years. The warrants can also be exercised by a cashless exercise mechanism, in which the number of shares issued would be decreased in accordance with the reduced cash realization price. The warrant exercise price is adjustable upon certain events (e.g. dividend, distribution of bonus shares, etc.).

On September 12, 2016, we issued to Roth Capital Partners and Maxim Group LLC, acting as co-placement agents in our offering closed on such date, warrants to purchase up to an aggregate of 3,955 ADSs representing 197,750 ordinary shares, with an exercise price of $14.375 per ADS. The warrants have a term of five years. The warrants can also be exercised by a cashless exercise mechanism, in which the number of shares issued would be decreased in accordance with the reduced cash realization price. The warrant exercise price is adjustable upon certain events (e.g. dividend, distribution of bonus shares, etc.).

On August 21, 2014 and August 26, 2014, the Company allotted in a private placement warrants to purchase up to an aggregate of 3,410,861 ordinary shares, with an exercise price of NIS 6.27 per share. The warrants are exercisable during the 36 months following their issuance. 21,847,610 of the warrants which were issued may, under certain circumstances, also be exercised via a cashless exercise mechanism. In addition, the number of warrants outstanding will be adjusted to certain events specified in the warrant agreement (such as: dividends, distribution of bonus shares, etc.)

In calculating the value of warrants a Black & Scholes model was used. The expected volatility is based on fluctuations in the price of the Company's share.

Results of Operations

Comparison of the fiscal years ended December 31, 2016 and December 31, 2015

Revenues

The following tables present our total revenues, in thousands of U.S. Dollar, by geographic area and by products for the fiscal years indicated:

	For the Year Ended December 31,			
	2015		2016	
United States	446	72%	345	63%
Europe	84	13%	33	6%
Asia	51	8%	5	1%
Other	43	7%	166	30%
Total	624	100%	549	100%

	2015		2016	
MUSE™ system and related equipment	66	11%	100	18%
Miniature camera and related equipment	558	89%	449	82%
Total	624	100%	549	100%

Our revenue to date has been primarily based on the sale of imaging equipment, which we develop and manufacture. In the year ended December 31, 2016, we generated $ 0.55 million of total revenues, compared to $0.62 million in the year ended December 31, 2015, a decrease of approximately $75,000, or 12%. This decrease was primarily due to an approximately $109,000 decrease in imaging equipment revenues, offset by an increase of approximately $34,000 in MUSE™ system revenues. The increase/decrease was primarily due to the increase/decrease in the quantity of products sold.

Gross Profit

Gross profit was $0.37 million for the year ended December 31, 2016, or 68% of revenues, compared to $0.35 million, or 56% of revenues for the year ended December 31, 2015. The increase in gross profit of $26,000, or 7.5% and increase in gross profit margin was primarily due to development services provided to the National Aeronautics and Space Administration and to one of Israel's leading industrial companies.

Operating Expenses

The following table presents operating expenses for the periods indicated (in thousands of NIS):

	For the Year Ended December 31,			
	2015	2016	Increase Decrease)	
	(in thousands, U.S. dollars)		%	
Research and development expenses	4,384	3,655	(729)	(17)
Selling and marketing expenses	2,680	2,125	(555)	(21)
General and Administrative expenses	2,842	3,684	842	30
Other income, net	3		(3)	(100)
Total operating expenses, net	9,903	9,464	(439)	(4)

Research and Development Expenses

Research and development cost was $3.7 million for the year ended December 31, 2016, compared to $4.4 million for the year ended December 31, 2015. The decrease of $ 0.7 million, or 17% was primarily due to the decrease in the acquisition of materials by the Company and services rendered to the Company for trainings activities during 2016. This decrease was primarily due to a cost reduction program which was implemented by the Company since the third quarter of 2016.

Sales and Marketing Expenses

Sales and marketing expenses were $ 2.1 million for the year ended December 31, 2016, compared to $2.7 million for the year ended December 31, 2015. The decrease of $ 0.6 million, or 21% resulted primarily from Company's cost reduction program, which is reflected primarily by a reduction in human resources (mainly in the US) and a reduction of our marketing activities including participation in exhibitions.

General and Administrative Expenses

General and administrative expenses were approximately $ 3.7 million for the year ended December 31, 2016, compared to approximately $2.8 million for the year ended December 31, 2015. The increase of $0.9 million, or 30%, resulted primarily from an increase in professional expenses in connection with an intellectual property litigation (see Note 11 to our financial statements).

Profit from Change in Fair Value of Warrants Issued to Investors

Profit from change in the fair value of warrants issued to investors in the financial statements resulted from the revaluation of the warrants which included a cashless exercise mechanism. During the year ended December 31, 2016, a profit of approximately $ 25,000 was recorded, compared to a profit of approximately $106,000 for the year ended December 31, 2015. This profit representing the decrease in the value of these warrants during the reported period. The decrease in value primarily resulted from the decrease in our share price and the reduction in the time remaining for exercising the warrants due to the passage of time.

Finance income (expenses), net

Financial income, net were $87,000 for the year ended December 31, 2016, compared to financial expenses, net of $14,000 for the year ended December 31, 2015. The increase in finance income, net of $101,000 was primarily from an increase in the financing income in respect of currency exchange differences.

Loss and Loss per Share

For the year ended December 31, 2016, the loss was $ 9 million or $ 0.26 per share, compared to loss of $9.5 million or $0.34 per share, for the year ended December 31, 2015. The decrease in loss and loss per share was mainly due to a decrease in operating expenses as described above.

Comparison of the fiscal years ended December 31, 2015 and December 31, 2014

Revenues

The following tables present our total revenues, in thousands of U.S. dollars, by geographic area and by products for the fiscal years indicated:

	For the Year Ended December 31,			
	2014		2015	
United States	460	62%	446	72%
Europe	113	15%	84	13%
Asia	134	18%	51	8%
Other	37	5%	43	7%
Total	744	100%	624	100%

	2014		2015	
MUSE™ system and related equipment	91	12%	66	11%
Miniature camera and related equipment	653	88%	558	89%
Total	744	100%	624	100%

In the year ended December 31, 2015, we generated approximately $0.62 million of total revenues, compared to approximately $0.74 million in the year ended December 31, 2014, a decrease of approximately $120,000, or 16%. This decrease was primarily due to a $95,000 decrease in imaging equipment revenues and a $25,000 decrease in our MUSE™ system revenues. The decrease in revenues was primarily due to the decrease in the quantity of products sold.

Gross Profit

Gross profit was approximately $0.35 million for the year ended December 31, 2015, or 56% of revenues, compared to approximately $0.39 million, or 53% of revenues for the year ended December 31, 2014. The decrease in gross profit of $46,000, or 12% was primarily due the decrease in revenues.

Operating Expenses

The following table presents operating expenses for the periods indicated (in thousands of U.S. dollars):

	For the Year Ended December 31,			
	2014	2015	Increase (Decrease)	
	(in thousands, U.S. dollars)		%	
Research and development expenses	4,025	4,384	359	9
Selling and marketing expenses	2,341	2,680	339	14
General and Administrative expenses	2,280	2,842	562	25
Other income, net	269	3	(266)	(99)
Total operating expenses, net	8,377	9,903	1,526	18

Research and Development Expenses

Research and development cost was approximately $4.4 million for the year ended December 31, 2015, compared to approximately $4 million for the year ended December 31, 2014. The increase of approximately $0.36 million, or 9% was primarily due to the increase in the acquisition of materials by the Company and services rendered to the Company for trainings and registry activities and the recruitment of additional human resources during 2015.

Sales and Marketing Expenses

Sales and marketing expenses were approximately $2.7 million for the year ended December 31, 2015, compared to approximately $2.34 million for the year ended December 31, 2014. The increase of approximately $0.34 million, or 14% resulted primarily from the Company's preparations towards the marketing of its products, which is reflected primarily by recruitment of additional human resources in the U.S.

General and Administrative Expenses

General and administrative expenses were approximately $2.8 million for the year ended December 31, 2015, compared to approximately $2.3 million for the year ended December 31, 2014. The increase of approximately $0.5 million, or 25%, resulted primarily from an increase in professional expenses of approximately $0.25 million in connection with compliance requirements of the SEC and the NASDAQ regulations which we are required to comply with following our listing on the NASDAQ and to the IP litigation (see "Item 4. Information on the Company—B. Business Overview—Intellectual Property") and increase in salary costs of approximately $98,000 attributed primarily to the strengthening of management.

Other Income, Net

Other income, net, in the year ended December 31, 2015 amounted to a total of approximately $3,000, compared to a total of approximately $0.27 million for the year ended December 31, 2014. The decrease of approximately $0.27 million, or 99%, resulted primarily from the composition of other income, net. In the year ended December 31, 2015, other income, net, included the Company's income from its investment portfolio in the amount of approximately $3,000. For the year ended December 31, 2014, other income, net, included the Company's income from its investment portfolio in the amount of approximately $19,000, and income in the amount of approximately $0.25 million in respect of the termination of the Company's agreement with a customer (see note 14 to our financial statements). The decrease in income in respect of our investments resulted from a change in our risk management made in 2013.

Profit from Change in Fair Value of Warrants Issued to Investors

Profit from change in the fair value of warrants issued to investors in the financial statements resulted from the revaluation of the warrants which included a cashless exercise mechanism. During the year ended December 31, 2015, a profit of approximately $106,000 was recorded, compared to a profit of approximately $0.98 million for the year ended December 31, 2014. This profit representing the decrease in the value of these warrants during the reported period. The decrease in value primarily resulted from the decrease in our share price and the reduction in the time remaining for exercising the warrants due to the passage of time.

Finance income (expenses), net

Financial expenses, net were $14,000 for the year ended December 31, 2015, compared to financial income of approximately $0.65 million for the year ended December 31, 2014. The decrease in finance income, net of approximately $0.66 million, was primarily from a decrease in the financing income in respect of currency exchange differences. The increase in the average exchange rate of the U.S. dollar in relation to the NIS in 2014 was approximately 12%, while in 2015 the increase was only 0.33%. As a result, the financing income in respect of currency exchange differences in 2014 amounted to approximately $0.65 million (as a result of the positive effect on our net assets (primarily cash and cash equivalents) denominated in U.S. dollars), compared to financial expenses of $8,000 in 2015.

Loss and Loss per Share

For the year ended December 31, 2015, the loss was approximately $9.53 million or $0.34 per share, compared to loss of approximately $6.34 million or $0.33 per share, for the year ended December 31, 2014. The increase in loss and loss per share in the year ended December 31, 2015, compared to the year ended December 31, 2014, was mainly due to an increase in operating expenses, a decrease in profits due to the change in the fair value of warrants issued to investors and increase in finance expenses as described above.

Effective Corporate Tax Rate

Our effective consolidated tax rate for the years ended December 31, 2016, December 31, 2015 and December 31, 2014 was close to zero percent, primarily due to the tax losses we accrued in Israel in those periods.

Impact of Inflation, Devaluation and Fluctuation in Currencies on Results of Operations, Liabilities and Assets

We generate part of our revenues in different currencies than our functional currency, such as NIS and Euros. As a result, some of our financial assets are denominated in these currencies, and fluctuations in these currencies could adversely affect our financial results. A considerable amount of our expenses are generated in U.S. dollars, but a significant portion of our expenses such as salaries is generated in other currencies such as NIS. In addition to our operations in Israel, we are expanding our international operations in the European Union. Accordingly, we incur and expect to continue to incur additional expenses in non U.S. dollar currencies, such as the Euro. As a result, some of our financial liabilities are denominated in non-U.S. dollar currencies. Due to the foregoing and the fact that our financial results are currently measured in U.S. dollar, our results could be adversely affected as a result of a strengthening or weakening of the U.S. Dollar compared to these other currencies.

We believe that inflation in Israel has not had a material effect on our results of operations.

Effective January 1, 2016, the Company changed its functional currency to the U.S. dollar from the NIS. This change was based on an assessment by Company management that the dollar is the primary currency of the economic environment in which the Company operates.

B. Liquidity and Capital Resources

Since inception, we have funded our operations primarily through public and private offerings of our securities, sales of our products and grants from the OCS.

Since inception, we have raised approximately $ 65 million in aggregate net proceeds from issuing our equity securities. As of December 31, 2016, we held approximately $ 3 million in cash and cash equivalents. On March 29, 2017, we raised approximately $7.5 million (gross) in a public offering in the United States, and as of March 29, 2017, we had a cash balance of approximately 8.4 million. For additional information regarding our revenues and expenses, see “Item 5. Operating and Financial Review and Prospects—Revenues” and “Item 5. Operating and Financial Review and Prospects—Operating Expenses”.

Net cash used in operating activities primarily reflects the operating loss for those periods, sales (acquisitions) of financial assets at fair value through profit or loss and changes in operating assets and liabilities. Net cash used in operating activities was approximately $9.3 million for the year ended December 31, 2016, compared with net cash used in operating activities of approximately $7 million for the year ended December 31, 2015, and approximately $7.8 million for the year ended December 31, 2014. The increase of cash used in operating activities from 2016 to 2015 of approximately $2.3 million was primarily the result of a sales of tradeable securities (financial assets at fair value through profit or loss) of approximately $2.1 million in the first quarter of 2015 compared to no tradeable securities in the 2016. The decrease from 2015 to 2014 of approximately $0.8 million was primarily the result of a sales of tradeable securities (financial assets at fair value through profit or loss) of approximately $2.1 million in the first quarter of 2015 offset the increase of an operating loss of approximately $1.6 million.

Net cash used in investing activities for the year ended December 31, 2016, was approximately $38,000 compared to net cash used in investing activities of approximately $96,000 for the year ended December 31, 2015 and cash generated from investing activities of approximately $2.2 million for the year ended December 31, 2014. The decrease for the year ended December 31, 2015, compared to the year ended December 31, 2014, in the amount of $2.3 million was the result of a withdrawal of short-term deposits in 2014.

Net cash generated from financing activities for the year ended December 31, 2016, was approximately $1.9 million compared to net cash generated from investing activities of approximately $6.8 million for the year ended December 31, 2015, and of approximately $9.3 million for the year ended December 31, 2014. All cash generated from financing activities representing proceeds from issuance of shares and warrants (for additional information see Note 12b to our financial statements).

Operating Capital and Capital Expenditure Requirements

To date, we have not achieved profitability and have sustained net losses in every fiscal year since our inception, including a net loss of $ 9 million for the year ended December 31, 2016, and $9.5 million for the year ended December 31, 2015.

Based on the projected cash flows and our cash balance as of December 31, 2016, the Company's management is of the opinion that without further fund raising it will not have sufficient resources to enable it to continue advancing its activities including the development, manufacturing and marketing of its products for a period of at least 12 months from the date of approval of the financial statements. As a result, there is substantial doubt about our ability to continue as a going concern. Following the closing of the March 2018 offering, at our expected burn rate, our current cash balance will be sufficient until approximately January 2018.

We will need to seek additional sources of funds, including selling additional equity, debt or other securities or entering into a credit facility, take costs reduction steps or modify our current business plan to achieve profitability. If we raise additional funds through the issuance of debt securities, these securities may have rights senior to those of our ordinary shares and could contain covenants that could restrict our operations and ability to issue dividends. We may also require additional capital beyond our currently forecasted amounts. Any required additional capital, whether forecasted or not, may not be available on reasonable terms, or at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could materially harm our business and results of operations.

Because of the numerous risks and uncertainties associated with the development of medical devices and the current economic situation, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to complete the development of our products and successfully deliver commercial products to the market. Our future capital requirements will depend on many factors, including but not limited to the following:

- the revenue generated by sales of our current and future products;
- the expenses we incur in selling and marketing our products and supporting our growth;
- the costs and timing of regulatory clearance or approvals for new products or upgrades or changes to our products;
- the expenses we incur in complying with domestic or foreign regulatory requirements imposed on medical device companies;
- the expenses associated with achieving a reimbursement code for MUSE™ system procedure;
- the rate of progress, cost and success or failure of on-going development activities;
- the emergence of competing or complementary technological developments;
- the costs of filing, prosecuting, defending and enforcing any patent or license claims and other intellectual property rights;

- the terms and timing of any collaborative, licensing, or other arrangements that we may establish;
- the future unknown impact of recently enacted healthcare legislation;
- the acquisition of businesses, products and technologies; and
- general economic conditions and interest rates.

C. Research and Development, Patents and Licenses, Etc.

Our research and development efforts are focused on continuous improvement of the MUSE™ system, as well as investment in future products. We conduct all of our research activity in Israel.

As of December 31, 2016, our research and development team, including regulatory and quality team members, consisted of 8 employees and consultants. In addition, we work with subcontractors for the development of our products when needed. We have assembled an experienced team with recognized expertise in mechanical and electrical engineering, software, control algorithms and systems integration, as well as significant medical and clinical knowledge and expertise.

We finance our research and development activities mainly through sale of our products, capital raising and grants received from the OCS. As of December 31, 2016, we had received total grants from the OCS of $ 2.5 million. For further information See "Item 4. Information on the Company—B. Business Overview — Health Care Laws and Regulations—Israeli Government Programs."

The following table presents research and development cost, for the periods indicated:

	Year Ended December 31,		
	2014	2015	2016
	(U.S. Dollars, in thousands)		
Research and Development cost	$ 4,025	$ 4,384	$ 3,655

We also invest resources in the protection of our intellectual property. For this purpose, we file from time to time applications for patent registration in the certain countries in which we are active and in other countries, which we consider potential markets.

D. Trend Information

The following is a description of factors that may influence our future results of operations, including significant trends and challenges that we believe are important to an understanding of our business and results of operations:

To date, substantially all of our revenues have been generated from the sale of imaging equipment, with the balance being generated from the sale of the MUSE™ system. The level of our future revenues is hard to predict and depends on many factors, which are outside of our control. For instance, future revenues from the sale of our products may be adversely affected by current general economic conditions and the resulting tightening of credit markets, which may cause purchasing decisions to be delayed, our customers to have difficulty securing adequate funding to buy our products or, in an extraordinary event, may cause our customers to experience difficulties in complying with their engagements with us. In addition, revenue growth depends on the acceptance of our technology in the market.

The healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to manage healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. This trend may result in inadequate coverage for procedures, especially those utilizing new technology, or result in new technology not receiving reimbursement coverage, which may negatively impact utilization of our products. In addition, medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, physicians and surgeons may discontinue using our system or may choose to not purchase our system in the future due to the cost or inability to procure insurance coverage. However, we believe there is also a trend for hospitals and physicians to use devices which enable less invasive procedures and to replace older more invasive devices which may result in longer hospital stays and therefore higher medical costs. We believe this trend provides a positive market outlook for our products.

We sell our products using a direct sales force and in certain markets via third-party distributors. Since January 2013, we have entered into certain distribution agreements to sell our MUSE™ system in Italy and China (the latter pending achievement of regulatory clearance for our MUSE™ system in China). We sell our products in the United States and certain parts of Europe using our direct sales force.

E. Off-Balance Sheet Arrangements

We do not currently have any off-balance sheet arrangements that have had, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

F. Tabular Disclosure of Contractual Obligations

The following table summarizes our known contractual obligations and commitments as of December 31, 2016:

	Total	Less than 1 year	1 – 3 years
	(U.S. Dollars, in thousands)		
Car lease obligations	122	82	40
Premises leasing obligations	124	124	-
Total	246	206	40

Other Long-Term Liabilities Reflected on the Company's Balance Sheet:

We have a financial liability in respect of warrants convertible into a variable number of our shares, which is a derivative instrument in the amount $237 thousand, as described in Note 4(2) to our consolidated financial statements as at December 31, 2016.

As of December 31, 2016, the total amount set aside as an actuarial estimate by the Company to provide post-employment benefits for certain employees and office holders was in the aggregate amount of approximately $77. The Company has not set aside amounts to provide post-employment benefits for the remaining employees and office holders. The liability for employees' severance benefits is calculated on the basis of the latest monthly salary paid to each employee multiplied by the number of years of employment. The liability is covered by the amounts deposited by us into employees' managers' insurance or pension fund accounts in respect of severance obligations to such employees, including accumulated income thereon as well as by the unfunded provision reflected on the balance sheet. While the timing of such obligations cannot be pre-determined (and as such were not included in the above table), such liability will be removed, either by termination of employment or retirement.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table lists the names and ages of our directors and senior management:

Name	Age	Position(s)
Dr. Nissim Darvish	52	Chairman of the Board of Directors
Christopher (Chris) Rowland	55	Chief Executive Officer, Director
Eitan Machover[(1)]	55	External Director
Efrat Venkert[(1)(2)]	50	External Director
Doron Birger[(1)(2)]	65	Director
Anat Naschitz[(2)]	49	Director
Oded Yatzkan	51	Chief Financial Officer
Minelu (Menashe) Sonnenschein	52	VP Israel Operations
Yaron Silberman	47	VP Sales and Marketing
Dr. Aviel Roy Shapira	66	Medical Director

(1) Member of audit committee and compensation committee.
(2) Member of the investment committee.

Dr. Nissim Darvish has been serving as the chairman of our Board since March 2013, and on September 29, 2016, was re-elected for service as a director and chairman of our Board until our next annual general meeting. Dr. Darvish serves as a Senior Managing Director in OrbiMed Advisors LLC. Dr. Darvish currently serves as a director of Ornim Medical Inc., RDD Pharma Ltd., Otic Pharma Ltd., Tyto Care., Keystone Heart Ltd., OrbiMed Israel Partner Ltd., OrbiMed Israel Limited Partnership, Asdanit Medical Ltd., Asdan Medical Ltd. and Ramot the Tel Aviv University's (TAU) Technology Transfer Company. Dr. Darvish has served as a General Partner in Pitango VC, which focuses on life sciences investments. Dr. Darvish holds an MD and a D.Sc., Doctor of Medical Science in Biophysics, from The Technion Institute of Technology, Israel.

Christopher (Chris) Rowland has been serving as a member of our Board since March 2013 and as Chief Executive Officer since October 2013. On September 29, 2016, Mr. Rowland was re-elected for service as a director until our next annual general meeting. Between 2011 and 2013, Mr. Rowland served as President of IntraPace Inc., a company that develops medical equipment in the field of obesity. Mr. Rowland has served as President and CEO of Neo Tract Inc., a medical equipment company in the field of urology, and as President of Americas Given Imaging Inc. Mr. Rowland holds a B.Sc. in marketing from the University of Southern Illinois. Mr. Rowland completed the Executive Management Program of Columbia Business School, and the Executive Leadership Program of Harvard Business School.

Eitan Machover has been serving as an external director on our Board since September 29, 2016, and was elected to serve for a three years term. Mr. Machover currently serves as an external director at Electra Real Estate Ltd. and Related Commercial Portfolio Ltd., both Israeli public companies traded on the Tel-Aviv Stock Exchange Ltd. Mr. Machover also serves on the board of directors of Epsilon Underwriting Ltd., Trackimo Ltd., Medtek Inc., VVT Medical Ltd. and MedyMatch Technology Ltd. From 2013 to 2015, Mr. Machover served as the chief executive officer and director of Enhanced Surface Dynamics, Inc. From 2011 to 2012, Mr. Machover served as an interim chief executive officer at Ovalum Vascular, Ltd. From 2002 to 2012, Mr. Machover served as general partner at MediTech Partners, LLC, an advisory and investment firm specializing in medical device technologies. From 1989 to 2010, Mr. Machover served in several positions in General Electric Company including national executive for Israel. Mr. Machover holds a B.A. in business communications from Emerson College, Boston, Massachusetts, and an MBA in finance and marketing from Boston College.

Efrat Venkert has been serving as an external director on our Board since September 2013, and on September 29, 2016, was reelected to serve for an additional three years term. Ms. Venkert is the owner of a law firm specializing in legal advice to companies and in business law. From 2009 to 2010, Ms. Venkert served as a member of an advisory group advising to the Government Investigation Committee for the water sector. From 2007 to 2009, Ms. Venkert served as the chairperson secretary of the Steering Committee, and Chairperson Manager of the Ministry of Justice and Ministry of Welfare pilot project on the subject of changes in the legislation of minors' participation in legal proceedings and from 2004 to 2008 Ms. Venkert served as a lecturer in the Law Faculty of the University of Haifa. Ms. Venkert holds an LL.B. from Hebrew University, Jerusalem, Israel and an MBA from Haifa University, Haifa, Israel. Ms. Venkert is a Certified Mediator of ICNM, a graduate of the Companies Secretary Course of the Israel Management Center, and a graduate of Directors' Course, Lahav, Tel-Aviv University, Israel.

Doron Birger has been serving as a member of our Board since May 2015, and on September 29, 2016, was elected by the Board for service as an independent director until our next annual general meeting. Mr. Birger currently serves as chairman of the board of Insuline and as a director of MCS Medical Compression Ltd, Hadasit Bio-Holdings Ltd. and Icecure Medical Ltd, four life sciences companies publicly traded in Israel, and as chairman and director of several private companies in Israel in the hi-tech sector mainly in the medical device field. From 2002 to 2007, Mr. Birger served as the chairman of the board of directors of Given Imaging Ltd and later on as board member until February 2014. Mr. Birger served as chief executive officer of Elron Electronic Industries, Ltd., or Elron, from August 2002 to April 2009. Prior to that, he held other executive positions at Elron, including President since 2001, Chief Financial Officer from 1994 to August 2002, and Corporate Secretary from 1994 to 2001. Mr. Birger is a director of variety of none profit organizations in Israel Mr. Birger holds a B.A. and an M.A. in economics from the Hebrew University Jerusalem.

Anat Naschitz has been serving as a member of our Board since March 2013, and on September 29, 2016, was re-elected for service as a director until our next annual general meeting. Ms. Naschitz currently serves as a director of Treato Ltd., Tyto Care Ltd., Axiom One Ltd., Nutrinia Ltd. and MDClonce Ltd., privately held companies. Ms. Naschitz currently serves as a Managing Partner at OrbiMed Advisors LLC. Ms. Naschitz has served as a Principal at Apax Partners, specializing in investments in medical equipment companies, and as an Associate Principal at McKinsey and Company, managing international teams that worked with senior management of large pharmaceutical companies on strategy, mergers and acquisitions, establishing new companies, research and development and marketing. Ms. Naschitz holds an MBA from INSEAD and an LLB from Tel-Aviv University, Israel.

Oded Yatzkan has served as our Chief Financial Officer since February 2017 and from September 2003 to August 2015. From August 2015 to February 2017, Mr. Yatzkan served as our VP Director of finance and accounting. Since August 2015, Mr. Yatzkan is also serving as an external director at Oron Group Holdings and Investments. Mr. Yatzkan previously served as Controller and Administrative Director of the Be'er Sheva Municipal Theatre from 1997 to 2003, as an Internal Auditor of Pandor Ltd., a TASE-listed Israeli company, from 1999 to 2001, as Assistant to Chief Financial Manager of Gold & Honey Ltd. Mr. Yatzkan is a licensed CPA, and holds a BA in Economics with a specialization in Accounting and an MBA with specialization in finance, both from Ben-Gurion University of Be'er Sheva, Israel.

Minelu (Menashe) Sonnenschein is a founding member and officer of our company who has been serving as our VP Israel Operations since June 2014. Among other roles, Mr. Sonnenschein previously served as our Director of Research and Development and has been directly responsible for the development of the MUSE™ System since the founding of the Company. Mr. Sonnenschein holds a M.Sc. in Electrical and Electronics Engineering from Ben-Gurion University of Be'er Sheva, Israel.

Yaron Silberman has been serving as VP Sales and Marketing since January 2011. Dr. Silberman has served as Marketing Director of Niti Surgical Solutions Ltd., and as Product Manager of Given Imaging Ltd. Dr. Silberman holds a PhD in Computational Neuroscience and Data Processing from Hebrew University of Jerusalem, Israel, an MBA from the College of Management Academic Studies of Rishon Le'Zion, Israel, and a B.A. in Theoretical Mathematics from The Technion Institute of Technology, Israel.

Dr. Aviel Roy Shapira has served as our Medical Director since January 2000. Dr. Shapira has been serving as a Senior Head Surgeon at Soroka Hospital in Be'er Sheva, Israel since 1993. Dr. Shapira holds an MD from Hebrew University of Jerusalem, Israel. He was trained in surgery at Creighton University in Omaha, Nebraska and underwent fellowships at University of Chicago (1986-1988), and Baylor University in Houston, Texas (1993). He was certified by the American Board of Surgery in 1988, and is registered in the Israeli registry of medical specialists as a specialist in surgery (1989) and critical care (1993). He serves on the faculty of health sciences at Ben-Gurion University in Be'er Sheva, Israel. He is the author of a number of publications on GERD and its treatment.

Family Relationships

There are no family relationships between any members of our executive management and our directors.

Arrangements for Election of Directions and Members of Management

There are no arrangements or understandings with major shareholders, customers, suppliers or others pursuant to which any of our executive management or our directors were appointed.

B. Compensation

Compensation of Executive Officers and Directors

In accordance with the provisions of the Companies Law, the compensation of our directors and officer holders must generally comply with the terms and conditions of our compensation policy, as approved by our compensation committee, board of directors and general meeting of our shareholders, subject to certain exceptions under the Companies Law. Our current compensation policy was approved by our general meeting on December 29, 2015.

The table below reflects the compensation granted to our five most highly compensated office holders (as defined in the Companies Law) during or with respect to the year ended December 31, 2016:

	Annual Compensation	Long-Term Compensation	
	U.S. Dollars in thousands		
Name and Position	**Salary and Related Benefits***	**Shares Underlying Options****	**Total**
Christopher (Chris) Rowland *Chief Executive Officer*	330	19	349
Gilad Mamlok *former Chief Financial Officer*	281	17	298
Jeremy Starkweather, *former Vice President, U.S. Sales & Marketing*	221	0	221
Minelu (Menashe) Sonnenschein *Vice President, Israel Operations*	159	0	165
Yaron Silberman *Vice President, Sales and Marketing*	149	8	157

* Includes car expenses. We did not pay any bonuses to our five most highly compensated office holders during 2016.

** Represents the equity-based compensation expenses recorded in the Company's consolidated financial statements for the year ended December 31, 2016, based on the option's fair value, calculated in accordance with accounting guidance for equity-based compensation.

The aggregate compensation paid by us to our executive officers for the year ended December 31, 2016 was approximately $1.3 million. This amount includes set aside or accrued to provide pension, severance, retirement or similar benefits or expenses, car expenses and value of the ordinary shares underlying the options representing accounting expenses, but does not include business travel, relocation, professional and business association dues and expenses reimbursed to officers, and other benefits commonly reimbursed or paid by companies in Israel. The aggregate amount paid by us to our directors for the year ended December 31, 2016, was approximately $66,000.

Under the Companies Law and the rules and regulations promulgated thereunder, external directors are entitled to fixed annual compensation and to an additional payment for each meeting attended. We currently pay our external directors an annual fee of NIS 37,115 and a per meeting fee of NIS 1,860, in accordance with the external director fees allowed pursuant to applicable regulations under the Companies Law, as applicable to the Company. We currently do not pay Nissim Darvish (our current chairman), Anat Naschitz and Chris Rowland any cash fees for their service as directors. We have not granted any options to directors since 2010. The compensation of our external directors is determined at the time of their election.

Pension, Retirement or Similar Benefits

As of December 31, 2016, the total amount set aside as an actuarial estimate by the Company to provide post-employment benefits for certain office holders was in the aggregate amount of approximately $ 69,000. The Company has not set aside amounts to provide post-employment benefits for the remaining office holders.

Equity Based Compensation of our Executive Officers and Directors

As of March 29, 2017, options to purchase 763,500 of our ordinary shares were outstanding and held by certain current executive officers and directors (consisting of 10 persons) with an average exercise price of NIS 6.07 per ordinary share, of which options to purchase 552,000 of our ordinary shares are currently exercisable or exercisable within 60 days as of March 29, 2017. See "Item 6. Directors, Senior Management and Employees—E. Share Ownership" in this annual report on Form 20-F.

Employment Agreements

We have entered into written employment agreements with each of our executive officers. All of these agreements contain customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. However, the enforceability of the noncompetition provisions may be limited under applicable law. In addition, we have entered into agreements with each executive officer and director pursuant to which we have agreed to indemnify each of them to the fullest extent permitted by law to the extent that these liabilities are not covered by directors and officers insurance.

Our office holders are generally eligible for bonuses each year. The bonuses are established and granted in accordance with our compensation policy and, and are generally payable upon meeting objectives and targets that are approved by our compensation committee and board of directors (and if required by our shareholders).

Employment Agreement with Mr. Rowland

On September 29, 2013, our shareholders approved that as of October 1, 2013, our U.S. Subsidiary, Medigus USA LLC, would enter into an employment agreement with Mr. Rowland, who serves as our Chief Executive Officer and currently carries out his work from our U.S. Subsidiary's office in California, USA. The agreement has a term of 3 years, and may be automatically renewed for additional periods of one year unless either party gives 60 days advance notice of non-renewal of the agreement. The agreement may be terminated by either party by giving 60 days advance notice, or shorter periods in some cases.

In accordance with the employment agreement with Mr. Rowland, he is entitled to an annual base salary of $315,000. In addition, by meeting certain pre-determined milestones or goals, set by our board of directors, Mr. Rowland may be entitled to an annual target bonus, which may not exceed 35% of Mr. Rowland's annual base salary. The annual target bonus may be reduced by our board of directors according to our financial position and Mr. Rowland's performance, and must be returned by Mr. Rowland if later shown to be granted in error which shall be restated in our financial statements. We have not granted Mr. Rowland an annual bonus for the year 2016.

Mr. Rowland is also entitled to various social benefits, such as medical and dental insurance, for himself and his immediate family, participation in a "401(k)" plan (similar to provident fund in Israel), and a manager's insurance plan, which may not exceed total inclusive costs of 25% of his annual salary (approximately $79,000).

In the event that we terminate Mr. Rowland's employment without cause or if we elect not to renew his employment, Mr. Rowland will be entitled to (i) receive the amounts owed to him up to the termination of his employment, (ii) receive a severance payment in an amount equal to six monthly base salaries (total inclusive amount of approximately $158,000), (iii) continue his group health and dental insurance following the date of termination until the earlier of the six months anniversary of the date of termination or until an alternate employer assumes his group health and dental insurance (subject to certain conditions), (iv) a pro-rated incentive payment for the quarter or a year in which his employment is terminated subject to the attainment of established targets, and (v) acceleration of option vesting.

On September 29, 2013, our shareholders approved a grant of 4,500,000 options under the 2013 Share Option and Incentive Plan exercisable into 450,000 of our ordinary shares to Mr. Rowland, for an exercise price of NIS 8.3 per share, of which 3,200,000 options vest over a period of 24 months, commencing one year following the start of his employment, 650,000 options vested on June 30, 2014, following achievement of goals set by the board of directors, and the remaining 650,000 options were to vest on February 1, 2015, subject to achieving the goals set by the board of directors, and the latter 650,000 options expired on March 31, 2015 following a decision by the board of directors. The options granted will expire at the earliest of: (a) following 5 years from the start date of the agreement; (b) 180 days from the date Mr. Rowland's employment shall end or he shall resign; or (c) immediately following the dismissal of Mr. Rowland, for various causes. In addition, options not vested by the termination of Mr. Rowland's employment agreement shall expire at such date.

On December 29, 2015, our shareholders approved a grant of 100,000 options under the 2013 Share Option and Incentive Plan to purchase 100,000 of our ordinary shares to Mr. Rowland, for an exercise price of NIS 2.05, which vest annually in four equal parts over four years. The options granted will expire at the earliest of: (a) 6 years following the grant date; or (b) at the time at which the options expire pursuant to the terms of 2013 Share Option and Incentive Plan. In addition, options not vested by the termination of Mr. Rowland's employment agreement shall expire at such date.

C. Board Practices

Introduction

Under the Companies Law and our articles of association, the management of our business is vested in our board of directors. Our board of directors may exercise all powers and may take all actions that are not specifically granted to our shareholders or to management. Our executive officers are responsible for our day-to-day management and have individual responsibilities established by our board of directors. Our chief executive officer is appointed by the general meeting of our shareholders, subject to his personal contract with the Company.

Under our articles of association, our board of directors must consist of at least three and not more than 12 directors, not including at least two external directors, which are required to be appointed under the Companies Law. Our board of directors currently consists of six members, including our non-executive chairman of the board of directors, which is also appointed by the general meeting of our shareholders. Other than our two external directors, our directors are elected at the annual general meeting of our shareholders by a simple majority. Because our ordinary shares do not have cumulative voting rights in the election of directors, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors, subject to the special approval requirements for external directors (See "Item 6. Directors, Senior Management and Employees — C. Board Practices — External Directors"). The general meeting of the our shareholders may resolve, at any time, by an ordinary majority resolution, to remove from office any director other than external director (for whom a special majority for appointment and removal is required as described below) prior to the termination of his respective term of service and it may appoint another director in his place, provided that the director was given a reasonable opportunity to state his case before the general meeting.

In addition, if a director's office becomes vacant, the remaining serving directors may continue to act in any manner, provided that their number is of the minimal number specified in our articles of association. If the number of serving directors is lower than three, then our board of directors shall not be permitted to act, other than for the purpose of convening a general meeting of the Company's shareholders for the purpose of appointing additional directors. In addition, the directors may appoint, immediately or of a future date, additional director(s) to serve until the subsequent annual general meeting of our shareholders, provided that the total number of directors in office shall not exceed twelve directors (not including external directors).

Pursuant to the Companies Law and our articles of association, a resolution proposed at any meeting of our board of directors at which a quorum is present is adopted if approved by a vote of a majority of the directors present and eligible to vote. A quorum of the board of directors requires at least a majority of the directors then in office who are lawfully entitled to participate in the meeting.

According to the Companies Law, the board of directors of a public company must determine the minimum number of board members that should have financial and accounting expertise while considering, among other, the nature of the company, its size, the scope and complexity of its operations and the number of directors stated in the articles of association. Our board of directors resolved that the minimum number of board members that need to have financial and accounting expertise, including the external director with financial and accounting expertise, is one and that Mr. Eitan Machover has accounting and financial expertise as required under the Companies Law.

External Directors

Under the Companies Law, we are required to appoint at least two external directors to serve on our board of directors. Our external directors are Mr. Machover and Ms. Venkert, both elected by the general meeting of our shareholders to serve for a three years term as of September 29, 2016.

Election and removal of external directors

Under Israeli law, external directors are elected by a special majority vote of the shares present and voting at a shareholders' meeting, provided that either:

- such majority includes at least a majority of the shares held by all shareholders who are non-controlling shareholders and do not have a personal interest in the election of the external director (other than a personal interest not deriving from a relationship with a controlling shareholder) that are voted at the meeting, excluding abstentions, to which we refer as a disinterested majority; or

- the total number of shares voted by non-controlling shareholders and by shareholders who do not have a personal interest in the election of the external director, against the election of the external director, does not exceed 2% of the aggregate voting rights in the company.

The initial term of an external director of an Israeli public company is three years. The external director may be re-elected, subject to certain circumstances and conditions, for up to two additional terms of three years each, and thereafter, subject to conditions set out in the regulations promulgated under the Companies Law, to further three year terms. Each re-election is subject to one of the following:

(i) his or her service for each such additional term is recommended by one or more shareholders holding at least 1% of the company's voting rights and is approved at a shareholders' meeting by a disinterested majority (other than a personal interest not deriving from a relationship with a controlling shareholder), where the total number of shares held by non-controlling, disinterested shareholders voting for such reelection exceeds 2% of the aggregate voting rights in the company. In such event, the external director so reappointed may not be a Related or Competing Shareholder, or a relative of such shareholder, at the time of the appointment, and is not and has not had any affiliation with a Related or Competing Shareholder, at such time or during the two years preceding such person's reappointment to serve an additional term as external director. The term "Related or Competing Shareholder" means a shareholder proposing the reappointment or a shareholder holding 5% or more of the outstanding shares or voting rights of the company, provided, that at the time of the reappointment, such shareholder, the controlling shareholder of such shareholder, or a company controlled by such shareholder, have a business relationship with the company or are competitors of the company. Additionally, the Israeli Minister of Justice, in consultation with the Israeli Securities Authority, may determine matters that under certain conditions will not constitute a business relationship or competition with the company;

(ii) his or her service for each such additional term is recommended by the board of directors and is approved at a shareholders meeting by the same majority required for the initial election of an external director (as described above); or

(iii) the external director proposed his or her own nomination, and such nomination was approved in accordance to the requirements described in the paragraph (i) above.

The term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including the NASDAQ Capital Market, may be extended indefinitely in increments of additional three-year terms, in each case provided that the audit committee and the board of directors of the company determined that in light of the external director's expertise and special contribution to the work of the board of directors and its committees, the reelection for such additional period(s) is in the best interest of the company, and provided that the external director is reelected subject to the same shareholder vote requirements as if elected for the first time (as described above). Prior to the approval of the reelection of the external director at a general shareholders meeting, the company's shareholders must be informed of the term previously served by him or her and of the reasons, which led the board of directors and audit committee to recommend the extension of his or her tenure.

External directors may be removed from office by a special general meeting of shareholders called by the board of directors, which approves such dismissal by the same majority vote required for their election or by a court, in each case, only under limited circumstances, including ceasing to meet the statutory qualifications for appointment, or violating their duty of loyalty towards the company. If an external directorship becomes vacant and there are fewer than two external directors on the board of directors at the time, then the board of directors is required under the Companies Law to call a special shareholders' meeting as soon as practicable to appoint a replacement external director.

If the vacancy of an external directorship causes a company to have fewer than two external directors, the company's board of directors is required under the Companies Law to call a special general meeting of the company's shareholders as soon as practicable to appoint such number of new external directors so that the company thereafter has two external directors.

Qualifications of External Directors

A person may not be appointed as an external director if such person is a relative of a controlling shareholder or if on the date of the person's appointment or within the preceding two years the person or his or her relatives, partners, employers or anyone to whom that person is subordinate, whether directly or indirectly, or entities under the person's control have or had any affiliation with any of (each an "Affiliated Party"): (1) us; (2) any person or entity controlling us on the date of such appointment; (3) any relative of a controlling shareholder; or (4) any entity controlled, on the date of such appointment or within the preceding two years, by us or by a controlling shareholder. If there is no controlling shareholder or any shareholder holding 25% or more of voting rights in the company, a person may not be appointed as an external director if the person has any affiliation to the chairman of the board of directors, the general manager (chief executive officer), any shareholder holding 5% or more of the company's shares or voting rights or the senior financial officer as of the date of the person's appointment.

The term "controlling shareholder" means a shareholder with the ability to direct the activities of the company, excluding such ability deriving solely from his or her position as a director of the company or from any other position with the company. A shareholder is presumed to have "control" of the company and thus to be a controlling shareholder of the company if the shareholder holds 50% or more of the "means of control" of the company. "Means of control" is defined as (1) the right to vote at a general meeting of a company or a corresponding body of another corporation; or (2) the right to appoint directors of the corporation or its general manager. For the purpose of approving transactions with controlling shareholders, the term also includes any shareholder that holds 25% or more of the voting rights of the company if the company has no shareholder that owns more than 50% of its voting rights. For the purpose of determining the holding percentage stated above, two or more shareholders who have a personal interest in a transaction that is brought for the company's approval are deemed as joint holders.

Under the Companies Law, "affiliation" includes:

- an employment relationship;
- a business or professional relationship even if not maintained on a regular basis (excluding insignificant relationships);
- control; and
- service as an office holder, excluding service as a director of a private company prior to the first offering of its shares to the public if such director was appointed as a director of the private company in order to serve as an external director following the initial public offering.

The term "relative" is defined as a spouse, sibling, parent, grandparent, descendant, spouse's sibling, parent or descendant, and the spouse of each of the foregoing.

The term "office holder" is defined under the Companies Law as a general manager, chief business manager, deputy general manager, vice general manager any other person assuming the responsibilities of any of these positions regardless of that person's title, a director and any other manager directly subordinate to the general manager. Each person listed in the table under "Item 6. Directors, Senior Management and Employees—A. Directors and Senior Management" is an office holder.

Under the Companies Law, a person cannot serve as an external director if such person, his or her relative, partner, employer, another person to whom he or she is subordinate, directly or indirectly, or any entity under such person's control, has or had, any professional relationship with an Affiliated Party, except for insignificant relationships, even if such professional relationship are extraordinary or intermediate. In addition, a person who received compensation other than in accordance with the applicable provisions for the compensation of external directors under the Companies Law may not serve as an external director.

In addition, a person cannot serve as an external director if: (i) the person's position or professional or other affairs create, or may create, a conflict of interest with such person's responsibilities as a director or may otherwise interfere with the person's ability to serve as an external director, (ii) if such a person is an employee of the Israeli Securities Authority or of an Israeli stock exchange, (iii) at the time appointment, such person serves as a director of another company and an external director of the other company is also a director of the company, or (iv) such person received direct or indirect compensation from the company in connection with such person's services as an external director, other than as permitted by the Companies Law and the regulations promulgated thereunder. If at the time an external director is appointed, all members of the board of directors who are not controlling shareholders or relatives of controlling shareholders are of the same gender, then the external director to be appointed must be of the other gender.

The Companies Law provides that an external director must meet certain professional qualifications or have financial and accounting expertise and that at least one external director must have financial and accounting expertise. However, if at least one of our other directors (1) meets the independence requirements of the Exchange Act, (2) meets the standards of the NASDAQ Marketplace Rules for membership on the audit committee and (3) has financial and accounting expertise as defined in the Companies Law and applicable regulations, then neither of our external directors is required to possess financial and accounting expertise as long as both possess other requisite professional qualifications. The determination of whether a director possesses financial and accounting expertise is made by the board of directors. is a director who, due to his or her education, experience and skills, possesses an expertise in, and an understanding of, financial and accounting matters and financial statements, such that he or she is able to understand the financial statements of the company and initiate a discussion about the presentation of financial data. In determining whether the director has financial and accounting expertise the board of directors shall consider education, experience and the knowledge in the following subjects: (i) accounting issues and internal auditing issues typical to the company's industry and to companies of the same size and complexity as the company; (ii) the nature of the Internal Auditor's position in the company and his or her duties; and (iii) the preparation of financial statements and their approval subject to the Companies Law and the Israeli Securities Law 5728-1968, or the Israeli Securities Law.

The regulations promulgated under the Companies Law define an external director with requisite "professional qualifications" as a director who satisfies one of the following requirements: (1) the director holds an academic degree in either economics, business administration, accounting, law or public administration, (2) the director either holds an academic degree in any other field or has completed another form of higher education in the company's primary field of business or in an area which is relevant to his or her office as an external director in the company, or (3) the director has at least five years of experience serving in any one of the following, or at least five years of cumulative experience serving in two or more of the following capacities: (a) a senior business management position in a company with a substantial scope of business, (b) a senior position in the company's primary field of business or (c) a senior position in public administration.

Additional provisions

Under the Companies Law, external directors of a company are prohibited from receiving, directly or indirectly, any compensation from the company other than compensation and reimbursement of expenses amounts for their services as external directors except for certain exculpation, indemnification and insurance provided by the company, as specifically allowed by the Companies Law. Compensation of an external director is determined prior to his or her appointment and may not be changed during his or her term (subject to certain exceptions).

In addition, until the lapse of a two-year period from the date that an external director of a company ceases to act in such capacity, the company in which such external director served, and its controlling shareholder or any entity under control of such controlling shareholder may not, directly or indirectly, grant such former external director, or his or her spouse or child, any benefit, including via (i) the appointment of such former director or his or her spouse or his child as an officer in the company or in an entity controlled by the company's controlling shareholder, (ii) the employment of such former director, and (iii) the engagement, directly or indirectly, of such former director as a provider of professional services for compensation, directly or indirectly, including via an entity under his or her control. With respect to a relative who is not a spouse or a child, such limitations shall only apply for one year from the date such external director ceased to be engaged in such capacity.

Alternate directors

Our articles of association provide, as allowed by the Companies Law, that any director may, by written notice to us, appoint another person who is qualified to serve as a director to serve as an alternate director and to terminate such appointment. Under the Companies Law, a person who is not qualified to be appointed as a director, a person who is already serving as a director or a person who is already serving as an alternate director for another director, may not be appointed as an alternate director. Nevertheless, a director who is already serving as a director may be appointed as an alternate director for a member of a committee of the board of directors as long as he or she is not already serving as a member of such committee, and if the alternate director is to replace an external director he must have the relevant qualifications of such external director.

Board committees

The board of directors may, subject to the provisions of the Companies Law, delegate any or all of its powers to committees, each consisting of one or more directors (except the audit and compensation committees, as described below), and it may, from time to time, revoke such delegation or alter the composition of any such committees. Unless otherwise expressly provided by the board of directors, the committees shall not be empowered to further delegate such powers. Each committee of the board of directors that is authorized to exercise the powers of the board of directors must include at least one external director, except that the audit committee and the compensation committee must include all external directors then serving on the board of directors. The composition and duties of our audit committee and compensation committee are established under the Israeli Companies Law and described below.

Audit committee

Our audit committee is currently comprised of Ms. Venkert, Mr. Machover and Mr. Birger. Ms. Venkert acts as the Chairperson of our audit committee.

Companies Law requirements

Under the Companies Law, the board of directors of any public company must also appoint an audit committee comprised of at least three directors, including all of the external directors, one of whom must serve as chairman of the committee. The audit committee may not include:

- the chairman of the board of directors;
- a controlling shareholder or a relative of a controlling shareholder; or
- a director employed by or providing services on a regular basis to the company, to a controlling shareholder or to an entity controlled by a controlling shareholder or a director most of whose livelihood depends on a controlling shareholder.

In addition, the majority of the members of the audit committee are required to be independent directors. The term "independent director" is generally defined under the Companies Law as an external director or a director who meets the following criteria:

- he or she meets the qualifications for being appointed as an external director, except for the requirement that the director be an Israeli resident (which does not apply to companies such as ours whose securities have been offered outside of Israel or are listed outside of Israel); and
- he or she has not served as a director of the company for a period exceeding nine consecutive years, provided that, for this purpose, a break of less than two years in service shall not be deemed to interrupt the continuation of the service.

Any person disqualified from serving as a member of the audit committee may not be present at the audit committee meetings, unless the chairman of the audit committee has determined that such person is required to be present at the meeting or if such person qualifies under one of the exemptions of the Companies Law.

The quorum required for the convening of meetings of the audit committee and for adopting resolutions by the audit committee is a majority of the members of the audit committee, provided such majority is comprised of a majority of independent directors, and at least one of those present is an external director.

Listing requirements

Under the NASDAQ corporate governance rules, we are required to maintain an audit committee consisting of at least three independent directors, all of whom are financially literate and one of whom has accounting or related financial management expertise. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the NASDAQ corporate governance rules. Our board of directors has determined that each of Mr. Birger and Mr. Machover is an audit committee financial expert as defined by the SEC rules and has the requisite financial experience as defined by the NASDAQ Marketplace Rules.

Each of the members of the audit committee is required to be "independent" as such term is defined in Rule 10A-3(b)(1) under the Exchange Act, which is different from the general test for independence of board and committee members.

The approval of the audit committee is required to effect specified actions and transactions with office holders and controlling shareholders and their relatives, or in which they have a personal interest. See "Item 6. Directors, Senior Management and Employees — C. Board Practices — Fiduciary duties and approval of specified related party transactions and compensation under Israeli law." The audit committee may not approve an action or a transaction with a controlling shareholder or with an office holder unless at the time of approval the audit committee meets the composition requirements under the Companies Law.

Audit committee role

Our audit committee provides assistance to our board of directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by pre-approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our audit committee also oversees the audit efforts of our independent accountants and takes those actions that it deems necessary to satisfy itself that the accountants are independent of management.

Under the Companies Law, the audit committee is responsible, among others, for:

(i) determining whether there are deficiencies in the business management practices of our Company, including in consultation with our internal auditor or the independent auditor, and making recommendations to our board of directors to improve such practices;

(ii) determining the approval process for transactions that are 'non-negligible' (i.e., transactions with a controlling shareholder that are classified by the audit committee as non-negligible, even though they are not deemed extraordinary transactions), as well as determining which types of transactions would require the approval of the audit committee, optionally based on criteria which may be determined annually in advance by the audit committee;

(iii) determining whether to approve certain related party transactions (including transactions in which an office holder has a personal interest and whether such transaction is extraordinary or material under Companies Law;

(iv) where the board of directors approves the working plan of the internal auditor, to examine such working plan before its submission to our board of directors and proposing amendments thereto;

(v) examining our internal controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools to dispose of its responsibilities;

(vi) examining the scope of our auditor's work and compensation and submitting a recommendation with respect thereto to our board of directors or shareholders, depending on which of them is considering the appointment of our auditor; and

(vii) establishing procedures for the handling of employees' complaints as to the management of our business and the protection to be provided to such employees.

Compensation Committee

Our compensation committee is currently comprised of Ms. Venkert, Mr. Machover and Mr. Birger. Mr. Machover acts as the Chairman of our compensation committee.

Companies Law requirements

Under the Companies Law, the board of directors of a public company must appoint a compensation committee and adopt a compensation policy. The compensation committee must consist of at least three members. All of the external directors must serve on the committee and constitute a majority of its members. The chairman of the compensation committee must be an external director. However, subject to certain exceptions, Israeli companies whose securities are traded on stock exchanges such as the NASDAQ, and who do not have a controlling shareholder, do not have to meet this majority requirement; provided, however, that the compensation committee meets other Companies Law composition requirements, as well as the requirements of the jurisdiction where the company's securities are listed. Each compensation committee member that is not an external director must be a director whose compensation does not exceed an amount that may be paid to an external director (under the Companies Law and applicable regulations). The compensation committee is subject to the same Companies Law restrictions as the audit committee as to who may not serve as a member of the committee.

Role of the Compensation Committee

Under the Companies Law, the roles of the compensation committee are, among others, as follows:

- to recommend to the board of directors the approval of compensation policy for directors and officers in accordance with the requirements of the Companies Law;

- to oversee the development and implementation of such compensation policy and recommending to the board of directors regarding any amendments or modifications that the compensation committee deems appropriate;

- to determine whether to approve transactions concerning the terms of engagement and employment of office holders that require approval of the compensation committee; and

- to resolve whether to exempt a transaction with a candidate for chief executive officer from shareholder's approval.

In addition, any amendment of existing terms of office and employment of office holders (other than directors or controlling shareholders and their relatives, who serve as office holders) requires the sole approval of the compensation committee, if the committee determines that the amendment is not material in relation to its existing terms and if such amendment is in accordance with the then approved in effect compensation policy of the company.

The compensation policy

The compensation policy must be based on certain considerations, must include certain provisions and needs to reference certain matters as set forth in the Companies Law. The compensation policy must be approved by the company's board of directors after considering the recommendations of the compensation committee. In addition, the compensation policy needs to be approved by the company's shareholders by a simple majority, provided that (i) such majority includes a majority of the votes cast by the shareholders who are not controlling shareholders and who do not have a personal interest in the matter, present and voting (abstentions are disregarded) or (ii) the votes cast by shareholders who are not controlling shareholders and who do not have a personal interest in the matter who were present and voted against the compensation policy, constitute two percent or less of the voting power of the company. Such majority determined in accordance with clause (i) or (ii) is hereinafter referred to as the Compensation Special Majority Requirement.

To the extent a compensation policy is not approved by shareholders at a duly convened shareholders meeting or by the Compensation Special Majority Requirement, the board of directors of a company may override the resolution of the shareholders following a re-discussion of the matter by the board of directors and the compensation committee and for specified reasons, and after determining that despite the rejection by the shareholders, the adoption of the compensation policy is in the best interest of the company. A compensation policy that is for a period of more than three years must be approved in accordance with the above procedure once every three years.

Notwithstanding the above, the amendment of existing terms of office and employment of office holders (other than directors or controlling shareholders and their relatives, who serve as office holders) requires the sole approval of the compensation committee, if such committee determines that the amendment is not material in relation to its existing terms.

The compensation policy must serve as the basis for decisions concerning the financial terms of employment or engagement of office holders, including exculpation, insurance, indemnification or any monetary payment or obligation of payment in respect of employment or engagement. The compensation policy must relate to certain factors, including advancement of the company's objectives, the company's business plan and its long-term strategy, and creation of appropriate incentives for office holders. It must also consider, among other things, the company's risk management, size and the nature of its operations. The compensation policy must furthermore consider the following additional factors:

- the knowledge, skills, expertise and accomplishments of the relevant office holder;

- the office holder's roles and responsibilities and prior compensation agreements with him or her;

- the ratio between the cost of the terms of employment of an office holder and the cost of the compensation of the other employees of the company, including those employed through manpower companies, in particular the ratio between such cost and the average and median compensation of the other employees of the company, as well as the impact such disparities may have on the work relationships in the company;

- the possibility of reducing variable compensation, if any, at the discretion of the board of directors; and the possibility of setting a limit on the exercise value of non-cash variable equity-based compensation; and

- as to severance compensation, if any, the period of service of the office holder, the terms of his or her compensation during such service period, the company's performance during that period of service, the person's contribution towards the company's achievement of its goals and the maximization of its profits, and the circumstances under which the person is leaving the company.

The compensation policy must also include the following principles:

- the link between variable compensation and long-term performance and measurable criteria;
- the relationship between variable and fixed compensation, and the ceiling for the value of variable compensation;
- the conditions under which an office holder would be required to repay compensation paid to him or her if it was later shown that the data upon which such compensation was based was inaccurate and was required to be restated in the company's financial statements;
- the minimum holding or vesting period for variable, equity-based compensation; and
- maximum limits for severance compensation.

In accordance with the Companies Law, and following the recommendation of our compensation committee, our board of directors approved our compensation policy, and our shareholders, in turn, approved the compensation policy at our annual general meeting of shareholders that was held in December 2015.

Investment Committee

Our investment committee consists of three directors, Mr. Birger, Ms. Venkert and Ms. Naschitz. The investment committee's duties include reviewing and making recommendations to the board of directors regarding the company's investment policies, hedging policy and other banking related matters.

Internal auditor

Under the Companies Law, the board of directors of a public company must appoint an internal auditor based on the recommendation of the audit committee. Under the Companies Law, Each of the following may not be appointed as internal auditor:

- a person (or a relative of a person) who holds more than 5% of the company's outstanding shares or voting rights;
- a person (or a relative of a person) who has the power to appoint a director or the general manager of the company;
- an office holder (including a director) of the company (or a relative thereof); or
- a member of the company's independent accounting firm, or anyone on his or her behalf.

The role of the internal auditor is, among other things, to examine whether a company's actions comply with applicable law and orderly business procedure. The audit committee is required to oversee the activities and to assess the performance of the internal auditor as well as to review the internal auditor's work plan. Our internal auditor is Hila Bar of Brightman Almagor Zohar & Co., a member of Deloitte Touche Tohmatsu.

Fiduciary duties and approval of specified related party transactions and compensation under Israeli law

Fiduciary duties of office holders

The Companies Law imposes a fiduciary duties on all office holders of a company comprised of a duty of care and a duty of loyalty.

The duty of care requires an office holder to act in the same degree of proficiency with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of care includes, among other things, a duty to use reasonable means, in light of the circumstances, to obtain:

- information on the business advisability of a given action brought for his or her approval or performed by virtue of his or her position; and
- all other important information pertaining to such action.

The duty of loyalty requires an office holder to act in good faith and for the benefit of the company, and includes, among other things, the duty to:

- refrain from any act involving a conflict of interest between the performance of his or her duties in the company and his or her other duties or personal affairs;
- refrain from any activity that is competitive with the business of the company;
- refrain from exploiting any business opportunity of the company for the purpose of gaining a personal advantage for himself or herself or others; and
- disclose to the company any information or documents relating to the company's affairs which the office holder received as a result of his or her position as an office holder.

We may approve an act specified above, provided that the office holder acted in good faith, the act or its approval does not harm the company's best interest, and the office holder discloses his or her personal interest a sufficient time before the approval of such act, including any relevant document.

Disclosure of personal interests of an office holder and approval of transactions

The Companies Law requires that an office holder promptly disclose to the company any personal interest that he or she may have and all related material information or documents relating to any existing or proposed transaction by the company. An interested office holder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. Under the Companies Law, once an office holder complies with the above disclosure requirement, the board of directors at which the transaction is considered. An office holder is not obliged to disclose such information if the personal interest of the office holder derives solely from the personal interest of his or her relative in a transaction that is not considered an extraordinary transaction.

Under the Companies Law, a company may approve a transaction between the company and the office holder or a third party in which the office holder has a personal interest only if the office holder has complied with the above disclosure requirement, provided, however, that a company may not approve a transaction or action that is not to the company's benefit.

Under the Companies Law, unless the articles of association of a company provide otherwise, a transaction with an office holder or with a third party in which the office holder has a personal interest, which is not an extraordinary transaction, requires approval by the board of directors. Our articles of association do not state otherwise. If the transaction considered with an office holder or third party in which the office holder has a personal interest is an extraordinary transaction, then the audit committee's approval is required prior to approval by the board of directors. For the approval of compensation arrangements with directors and executive officers, see "Item 6. Directors, Senior Management and Employees —C. Board Practices—Compensation of directors and executive officers."

Any person who has a personal interest in the approval of a transaction that is brought before a meeting of the board of directors or the audit committee may not be present at the meeting or vote on the matter. However, if the chairperson of the board of directors or the chairperson of the audit committee has determined that the presence of an office holder with a personal interest is required, such office holder may be present at the meeting for the purpose of presenting the matter. Notwithstanding the foregoing, a director who has a personal interest may be present at the meeting and vote on the matter if a majority of the directors or members of the audit committee have a personal interest in the approval of such transaction' provided, however, that if a majority of the directors at a board of directors meeting have a personal interest in the approval of the transaction, such transaction also requires the approval of the shareholders of the company.

A "personal interest" is defined under the Companies Law as the personal interest of a person in an action or in a transaction of the company, including the personal interest of such person's relative or the interest of any other corporate body in which such person and/or such person's relative is a director or general manager, a 5% shareholder or holds 5% or more of the voting rights, or has the right to appoint at least one director or the general manager, but excluding a personal interest stemming solely from the fact of holding shares in the company. A personal interest also includes (1) a personal interest of a person who votes according to a proxy of another person, including in the event that the other person has no personal interest, and (2) a personal interest of a person who gave a proxy to another person to vote on his or her behalf regardless of whether the discretion of how to vote lies with the person voting or not.

An "extraordinary transaction" is defined under the Companies Law as any of the following:

- a transaction other than in the ordinary course of business;
- a transaction that is not on market terms; or
- a transaction that may have a material impact on the company's profitability, assets or liabilities.

An extraordinary transaction in which an office holder has a personal interest requires approval of the company's audit committee followed by the approval of the board of directors.

Disclosure of personal interests of a controlling shareholder and approval of transactions

The Companies Law also requires that a controlling shareholder promptly disclose to the company any personal interest that he or she may have and all related material information or documents relating to any existing or proposed transaction by the company. A controlling shareholder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. The following require the approval of each of (i) the audit committee (or the compensation committee with respect to the terms of engagement of the controlling shareholder or relative thereof with the company related for the provision of service, including among others as an office holder or employee of the company), (ii) the board of directors and (iii) the shareholders (in that order): (a) extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest (including a private placement in which a controlling shareholder has a personal interest), (b) the engagement with a controlling shareholder or his or her relative, directly or indirectly, for the provision of services to the company, (c) the terms of engagement and compensation of a controlling shareholder or his or her relative as an office holder, and (d) the employment of a controlling shareholder or his or her relative by the company, other than as an office holder (collectively referred as Transaction with a Controlling Shareholder). In addition, the shareholder approval must fulfill one of the following requirements:

- at least a majority of the shares held by shareholders who have no personal interest in the transaction and are voting at the meeting must be voted in favor of approving the transaction, excluding abstentions; or
- the shares voted by shareholders who have no personal interest in the transaction who vote against the transaction represent no more than two percent (2%) of the voting rights in the company.

In addition, any extraordinary transaction with a controlling shareholder or in which a controlling shareholder has a personal interest with a term of more than three years requires the abovementioned approval every three years, however, unless, with respect to certain transactions the audit committee determines that such longer term is reasonable under the circumstances.

Pursuant to regulations promulgated under the Companies Law, certain transactions with a controlling shareholder, a relative thereof, or with a director, that would otherwise require approval of a company's shareholders may be exempt from shareholder approval upon certain determinations of the audit committee and board of directors.

The Companies Law requires that every shareholder that participates, in person, by proxy or by voting instrument, in a vote regarding a transaction with a controlling shareholder, must indicate in advance or in the ballot whether or not that shareholder has a personal interest in the vote in question. Failure to so indicate will result in the invalidation of that shareholder's vote.

Disclosure of Compensation of Executive Officers

For so long as we qualify as a foreign private issuer, we are not required to comply with the proxy rules applicable to U.S. domestic companies, including the requirement applicable to emerging growth companies to disclose the compensation of our chief executive officer and other two most highly compensated executive officers on an individual, rather than an aggregate, basis. Under the Companies Law and the regulations promulgated thereunder we are required to disclose the annual compensation of our five most highly compensated office holders on an individual basis, rather than on an aggregate basis. This disclosure will not be as extensive as that required of a U.S. domestic issuer.

Approval of the compensation of directors and executive officers

The compensation of, or an undertaking to indemnify, insure or exculpate, an office holder who is not a director requires the approval of the company's compensation committee, followed by the approval of the company's board of directors, and, if such compensation arrangement or an undertaking to indemnify or insure is inconsistent with the company's stated compensation policy, or if the said office holder is the chief executive officer of the company (apart from a number of specific exceptions), then such arrangement is subject to the approval of our shareholders, subject to the Compensation Special Majority Requirement.

Directors. Under the Companies Law, the compensation of our directors requires the approval of our compensation committee, the subsequent approval of the board of directors and, unless exempted under the regulations promulgated under the Companies Law, the approval of the general meeting of our shareholders. If the compensation of our directors is inconsistent with our stated compensation policy, then, provided that those provisions that must be included in the compensation policy according to the Companies Law have been considered by the compensation committee and board of directors, shareholder approval will also be required to be approved by the Compensation Special Majority Requirement.

Executive officers other than the chief executive officer. The Companies Law requires the approval of the compensation of a public company's executive officers (other than the chief executive officer) in the following order: (i) the compensation committee, (ii) the company's board of directors, and (iii) if such compensation arrangement is inconsistent with the company's stated compensation policy, the company's shareholders by the Compensation Special Majority Requirement. However, if the shareholders of the company do not approve a compensation arrangement with an executive officer that is inconsistent with the company's stated compensation policy, the compensation committee and board of directors may override the shareholders' decision if each of the compensation committee and the board of directors provide detailed reasons for their decision.

Chief executive officer. Under the Companies Law, the compensation of a public company's chief executive officer is required to be approved by: (i) the company's compensation committee; (ii) the company's board of directors, and (iii) the company's shareholders by the Compensation Special Majority Requirement. However, if the shareholders of the company do not approve the compensation arrangement with the chief executive officer, the compensation committee and board of directors may override the shareholders' decision if each of the compensation committee and the board of directors provide a detailed reasoning for their decision. The approval of each of the compensation committee and the board of directors must be in accordance with the company's stated compensation policy; however, under special circumstances, the compensation committee and the board of directors may approve compensation terms of a chief executive officer that are inconsistent with the company's compensation policy provided that they have considered those provisions that must be included in the compensation policy according to the Companies Law and that shareholder approval was obtained by the Compensation Special Majority Requirement. In addition, the compensation committee may resolve that the shareholder approval is not required for the approval of the engagement terms of a candidate to serve as the chief executive officer, if the compensation committee determines that the compensation arrangement is consistent with the company's stated compensation policy, that the chief executive officer did not had a prior business relationship with the company or a controlling shareholder of the company, and that subjecting the approval to a shareholder vote would impede the company's ability to attain the candidate to serve as the company's chief executive officer.

Duties of shareholders

Under the Companies Law, a shareholder has a duty to refrain from abusing its power in the company and to act in good faith and in an acceptable manner in exercising its rights and performing its obligations to the company and other shareholders, including, among other things, when voting at meetings of shareholders on the following matters:

- an amendment to the articles of association;
- an increase in the company's authorized share capital;
- a merger; and
- the approval of related party transactions and acts of office holders that require shareholder approval.

A shareholder also has a general duty to refrain from discriminating against other shareholders.

The remedies generally available upon a breach of contract will also apply to a breach of the shareholder duties mentioned above, and in the event of discrimination against other shareholders, additional remedies are available to the injured shareholder.

In addition, any controlling shareholder, any shareholder that knows that its vote can determine the outcome of a shareholder vote and any shareholder that, under a company's articles of association, has the power to appoint or prevent the appointment of an office holder, or any other power with respect to a company, is under a duty to act with fairness towards the company. The Companies Law does not describe the substance of this duty except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness, taking each shareholder's position in the company into account.

Approval of private placements

Under the Companies Law and the regulations promulgated thereunder, a private placement of securities does not require approval at a general meeting of the shareholders of a company; provided however, that in special circumstances, such as a private placement completed in lieu of a special tender offer (See "Item 10. Additional Information —Memorandum and Articles of Association—Acquisitions under Israeli law") or a private placement which qualifies as a related party transaction (See "Item 6. Directors, Senior Management and Employees —C. Board Practices—Fiduciary duties and approval of specified related party transactions and compensation under Israeli law"), approval at a general meeting of the shareholders of a company is required.

Exemption, Insurance and Indemnification of Directors and Officers

Under the Companies Law, a company may not exculpate an office holder from liability for a breach of a fiduciary duty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care but only if a provision authorizing such exculpation is included in its articles of association. Our articles of association include such a provision. The company may not exculpate in advance a director from liability arising out of a prohibited dividend or distribution to shareholders.

Under the Companies Law and the Securities Law, 5738-1968, or the Securities Law, a company may indemnify an office holder in respect of the following liabilities, payments and expenses incurred for acts performed by him or her as an office holder, either in advance of an event or following an event, provided its articles of association include a provision authorizing such indemnification:

- a monetary liability incurred by or imposed on the office holder in favor of another person pursuant to a court judgment, including pursuant to a settlement confirmed as judgment or arbitrator's decision approved by a competent court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned foreseen events and amount or criteria;

- reasonable litigation expenses, including reasonable attorneys' fees, which were incurred by the office holder as a result of an investigation or proceeding filed against the office holder by an authority authorized to conduct such investigation or proceeding, provided that such investigation or proceeding was either (i) concluded without the filing of an indictment against such office holder and without the imposition on him of any monetary obligation in lieu of a criminal proceeding; (ii) concluded without the filing of an indictment against the office holder but with the imposition of a monetary obligation on the office holder in lieu of criminal proceedings for an offense that does not require proof of criminal intent; or (iii) in connection with a monetary sanction;

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or which were imposed on the office holder by a court (i) in a proceeding instituted against him or her by the company, on its behalf, or by a third party, (ii) in connection with criminal indictment of which the office holder was acquitted, or (iii) in a criminal indictment which the office holder was convicted of an offense that does not require proof of criminal intent;

- a monetary liability imposed on the office holder in favor of a payment for a breach offended at an Administrative Procedure (as defined below) as set forth in Section 52(54)(a)(1)(a) to the Securities Law;

- expenses expended by the office holder with respect to an Administrative Procedure under the Securities Law, including reasonable litigation expenses and reasonable attorneys' fees; and

- any other obligation or expense in respect of which it is permitted or will be permitted under applicable law to indemnify an office holder, including, without limitation, matters referenced in Section 56H(b)(1) of the Securities Law.

An "Administrative Procedure" is defined as a procedure pursuant to chapters H3 (Monetary Sanction by the Israeli Securities Authority), H4 (Administrative Enforcement Procedures of the Administrative Enforcement Committee) or I1 (Arrangement to prevent Procedures or Interruption of procedures subject to conditions) to the Securities Law.

Under the Companies Law and the Securities Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder if and to the extent provided in the company's articles of association:

- a breach of a fiduciary duty to the company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder;
- a monetary liability imposed on the office holder in favor of a third party;
- a monetary liability imposed on the office holder in favor of an injured party at an Administrative Procedure pursuant to Section 52(54)(a)(1)(a) of the Securities Law; and
- expenses incurred by an office holder in connection with an Administrative Procedure, including reasonable litigation expenses and reasonable attorneys' fees.

Under the Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:

- a breach of fiduciary duty, except for indemnification and insurance for a breach of the fiduciary duty to the company to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;
- a breach of duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a civil or administrative fine or forfeit levied against the office holder.

Under the Companies Law, exculpation, indemnification and insurance of office holders must be approved by the compensation committee and the board of directors and, with respect to directors or controlling shareholders, their relatives and third parties in which such controlling shareholders have a personal interest, also by the shareholders.

Our articles of association permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted or to be permitted by law. Our office holders are currently covered by a directors' and officers' liability insurance policy.

Employment and consulting agreements with executive officers

We have entered into written employment or service agreements with each of our executive officers. See "Item 7. Major Shareholders and Related Party Transactions— B. Related Party Transactions – Employment Agreements" for additional information.

Directors' service contracts

There are no arrangements or understandings between us, on the one hand, and any of our directors, on the other hand, providing for benefits upon termination of their employment or service as directors of our company.

D. Employees

Number of Employees

As of December 31, 2016, we employed 35 employees: 34 in Israel, and one, our Chief Executive Officer, in the United States by U.S. Subsidiary, Medigus USA LLC.

Distribution of Employees

The following is the distribution of our employees (including those employed by our subsidiary) by areas of engagement and geographic location:

	As of December 31,		
	2014	**2015**	**2016**
Numbers of employees by category of activity	5	9	9
Management and administrative	10	12	8
Research and development	8	13	8
Operations	6	9	2
Sales and marketing	11	12	8
Production	40	55	35
Total workforce			
Numbers of employees by geographic location			
Israel	36	47	34
Europe	1	1	-
United States	3	7	1
Total workforce	40	55	35

During the years covered by the above table, we did not employ a significant number of temporary employees. We consider our relations with our employees excellent and have never experienced a labor dispute, strike or work stoppage. None of our employees is represented by a labor union.

In Israel we are subject to certain labor statutes and national labor court precedent rulings, as well as to certain provisions of the collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations including the Industrialists' Associations. These provisions of collective bargaining agreements are applicable to our Israeli employees by virtue of extension orders issued in accordance with relevant labor laws by the Israeli Ministry of Economy and Industry, and which apply such agreement provisions to our employees even though they are not directly part of a union that has signed a collective bargaining agreement. The laws and labor court rulings that apply to our employees principally concern the minimum wage laws, length of the work day and workweek, overtime payment, procedures for dismissing employees, determination of severance pay, leaves of absence (such as annual vacation or maternity leave), sick pay and other conditions for employment. The extension orders which apply to our employees principally concern mandatory contributions to a pension fund or managers' insurance, annual recreation allowance, travel expenses payment and other conditions of employment. We generally provide our employees with benefits and working conditions beyond the required minimums.

Israeli law generally requires severance pay, which may be funded by allocating payments to a managers' insurance and/or a pension fund described below, upon the retirement or death of an employee or termination of employment without cause (as defined in the law). The payments to the managers' insurance and/or pension fund in respect of severance pay amount to approximately 8.33% of an employee's wages, in the aggregate. Furthermore, Israeli employees and employers are required to pay predetermined sums to the National Insurance Institute, which is similar to the United States Social Security Administration. Such amounts also include payments for national health insurance. The payments to the National Insurance Institute are equal to approximately 16% of an employee's wages, of which the employee contributes approximately 62.5% and the employer contributes approximately 37.5%.

The employees of U.S. Subsidiary are subject to local labor laws and regulations in the United States.

E. Share Ownership

Share ownership by Directors and Executive Officers

For information regarding ownership of our ordinary shares by our directors and executive officers, see Item 7.A "Major Shareholders and Related Party Transactions ― Major Shareholders".

Share Option Plans

All of our option plans are administered by our board of directors. Upon the expiration of the plans, no further grants may be made there under, although any existing awards will continue in full force in accordance with the terms under which they were granted. Options granted under any of the plans which are currently outstanding generally may not expire later than six years from the date of grant, unless otherwise specified. Unvested awards that are cancelled and/or forfeited go back into the respective plan.

2013 Share Option and Incentive Plan

In August 2013, our board of directors approved and adopted our 2013 Share Option and Incentive Plan, or the 2013 Plan, which expires in August 2023. The 2013 Plan provides for the issuance of shares and the granting of options, restricted shares, restricted share units and other share-based awards to employees, directors, officers, consultants, advisors, and service providers of us and our U.S. Subsidiary. The Plan provides for awards to be issued at the determination of our board of directors in accordance with applicable law. As of March 29, 2017, there were 4,700,000 ordinary shares reserved under the 2013 Plan and 1,148,964 ordinary shares issuable upon the exercise of awards issued under the 2013 Plan:

Plan	Number of options outstanding – March 29, 2017	exercise price per one ordinary share (NIS)	Number of shares issuable upon the exercise	Expiration date
Series C	3,850,000	8.3	385,000	September 30, 2018
Series D	1,880,000	5.37	188,500	July 17, 2020
Series F	447,075	2.05	447,075	December 29, 2021
Series G	126,389	2.05	126,389	December 29, 2021

The 2013 Plan provides for the grant to residents of Israel of options that qualify under the provisions of Section 102 of the Israeli Income Tax Ordinance (New Version) 1961, as well as for the grant of options that do not qualify under such provisions. The 2013 Plan was submitted to the ITA, as required by applicable law. The 2013 Plan also provides for the grant of options to U.S. resident employees that are "qualified", i.e., incentive stock options, under the U.S. Internal Revenue Code of 1986, as amended, or the Code, and options that are not qualified. In addition to the grant of awards under the relevant tax regimes of the United States and Israel, the 2013 Plan allows for the grant of awards to grantees in other jurisdictions, with respect to which our board of directors is empowered to make the requisite adjustments in the plan.

Series B Option Plan

In February 2012, we adopted our Series B Option Plan. Our directors, officers, employees and certain consultants and dealers were eligible to participate in this plan. As of March 29, 2017, there were 82,000 ordinary shares issuable upon the exercise of outstanding options under the plan. These options have an expiration date of April 23, 2018. No additional options will be issued under this plan. Israeli grantees who were directors, officers and employees could be granted options under the plan that would qualify for special tax treatment under the Capital Gains Route. This plan was submitted to the ITA as required by applicable law. The exercise price for the Series B Options is NIS 6.8 per share, linked to the consumer price index as of February 6 of each calendar year following the grant of the Series B Options, compared to the known consumer price index as of February 6 of the previous calendar year or as of the date of grant. If the rate of increase of the consumer price index is higher than 3%, the exercise price is increased by the difference between 3% and the rate of increase of the consumer price index.

Series A Option Plan

In August 2011, we adopted our Series A Option Plan. Our directors, officers, employees and certain consultants and dealers were eligible to participate in this plan. As of March 29, 2017, there were 116,000 ordinary shares issuable upon the exercise of outstanding options under the plan. These options have an expiration date of between November 2, 2017 and April 23, 2018. No additional options will be issued under this plan. Israeli grantees who were directors, officers and employees could be granted options under the plan that would qualify for special tax treatment in Israel. This plan was submitted to the ITA, as required by applicable law. The exercise price for the Series A Options is NIS 9.1 per share, linked to the consumer price index as of August 1 of each calendar year following the grant of the Series A Options, compared to the known consumer price index as of August 1 of the previous calendar year or as of the date of grant. If the rate of increase of the consumer price index is higher than 3%, the exercise price is increased by the difference between 3% and the rate of increase of the consumer price index.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of March 29, 2017 (unless otherwise noted below), the beneficial ownership of our ordinary shares by:

- each person or entity known by us to own beneficially more than 5% of our outstanding ordinary shares;
- each of our directors and executive officers individually; and
- all of our executive officers and directors as a group.

The beneficial ownership of our ordinary shares is determined in accordance with the rules of the SEC. Under these rules, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security. For purposes of the table below, we deem ordinary shares issuable pursuant to options that are currently exercisable or exercisable within 60 days as of March 29, 2017, if any, to be outstanding and to be beneficially owned by the person holding the options or warrants for the purposes of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. The percentage of ordinary shares beneficially owned is based on 99,628,584 ordinary shares outstanding as of March 29, 2017.

Except where otherwise indicated, we believe, based on information furnished to us by such owners, that the beneficial owners of the ordinary shares listed below have sole investment and voting power with respect to such shares. In addition, none of our shareholders will have different voting rights from other shareholders. To the best of our knowledge, we are not owned or controlled, directly or indirectly, by another corporation or by any foreign government. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

As of March 29, 2017, there was one shareholder of record of our ordinary shares, which was located in Israel. The number of record holders is not representative of the number of beneficial holders of our ordinary shares, as the shares of all shareholders for a publicly traded company such as ours which is listed on the Tel Aviv Stock Exchange are recorded in the name of our Israeli share registrar, Bank Hapoalim Registration Company Ltd.

Unless otherwise noted below, each beneficial owner's address is Medigus Ltd., Omer Industrial Park, No. 7A, P.O. Box 3030, Omer 8496500, Israel.

Our principal shareholders do not have different or special voting rights.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or greater shareholders		
Orbimed Israel GP Ltd.[(1)]	7,407,282	7.36%
Migdal Insurance & Financial Holdings Ltd.[(2)]	5,316,509	5.27%
Senvest Management LLC[(3)]	6,545,670	6.48%
Sabby Funds[(4)]	11,575,500	9.99%
Empery Asset Management LP[(5)]	10,529,750	9.99%
Directors and executive officers		
Christopher (Chris) Rowland	*	*
Minelu (Menashe) Sonnenschein	*	*
Aviel Roy-Shapira	*	*
Oded Yatzkan	*	*
Yaron Silberman	*	*
Dr. Nissim Darvish	-	-
Anat Naschitz	-	-
Efrat Venkert	-	-
Doron Birger	-	-
Eitan Machover	-	-
All directors and executive officers as a group (10 persons)[(6)]	1,813,072	1.81%

* less than 1%.

(1) Consists of 6,352,758 ordinary shares and warrants to purchase 1,054,524 ordinary shares exercisable within 60 days as of March 29, 2017. Based on a Schedule 13D/A filed with the SEC on December 8, 2016, by OrbiMed Israel GP Ltd., an Israeli limited liability company, or OrbiMed Israel, and OrbiMed Israel BioFund GP Limited Partnership, an Israeli limited partnership, or OrbiMed BioFund, OrbiMed Israel is the general partner of OrbiMed BioFund, which is the general partner of OrbiMed Israel Partners Limited Partnership, an Israeli limited partnership, which holds the securities. The address of the principal office of each OrbiMed Israel and OrbiMed BioFund is 89 Medinat HaYehudim St., Build E, 11th Floor, Herzliya 46766 Israel.

(2) Based on information provided to us, consists of 4,090,412 ordinary shares and warrants to purchase 1,226,097 ordinary shares exercisable within 60 days as of March 29, 2017. The principal business address of Migdal Insurance & Financial Holdings Ltd. is 4 Efal Street, Petach Tikva 49512, Israel, P.O. Box 3063.
(3) Based on a Schedule 13G/A filed with the SEC on February 13, 2017, as of December 31, 2016, Senvest Management LLC held shared voting power and shared dispositive power over 6,545,670 shares, including 1,363,049 Ordinary Shares issuable upon exercise of warrants. The address of each Senvest Management, LLC and Richard Mashaal is 540 Madison Avenue, 32nd Floor, New York, New York 10022.
(4) Based on information provided to us. Consists warrants to purchase ADSs currently exercisable or exercisable within 60 days of March 29, 2017 representing 11,0575,500 ordinary shares.
(5) Based on a Schedule 13G/A filed with the SEC on March 27, 2017 and information provided to us. Consists of 97,000 ADSs representing 4,850,000 ordinary shares and warrants to purchase up to 113,595 ADSs representing 5,679,750ordinary shares currently exercisable or exercisable within 60 days as of March 29, 2017.
(6) Consists of 1,261,072 ordinary shares and options to purchase 552,000 ordinary shares currently exercisable or exercisable within 60 days as of March 29, 2017.

Significant Changes in Percentage Ownership by Major Shareholders

To our knowledge, the significant changes in the percentage of ownership held by our major shareholders during the past three years have been:

(i) On March 24, 2017, we entered into securities purchase agreements with several investors as part of a public offering of our ADSs, Series A warrants and Series B warrants pursuant to our registration statement in the United States. In connection with the offering, Empery Asset Master, Ltd., Empery Tax Efficient, LP, and Empery Tax Efficient, II LP, or collectively Empery Asset Management LP, purchased an aggregate of 97,000 of our ADSs representing 4,850,000 of our ordinary shares, Series A warrants to purchase up to 571,429 ADSs representing 28,571,450 ordinary shares, and Series B warrants to purchase up to 474,429 ADSs representing 23,721,450 ordinary shares, and Sabby Healthcare Master Fund Ltd. and Sabby Volatility Warrant Master Fund, Ltd., or collectively Sabby Funds, purchased 97,000 of the ADSs representing 4,850,000 of our ordinary shares, Series A warrants to purchase up to 785,715 ADSs representing 39,285,750 ordinary shares, and Series B warrants to purchase up to 688,715 ADSs representing 34,435,750 ordinary shares.

(ii) On November 30, 2016, we entered into a securities purchase agreements as part of an offering of our ADSs pursuant to our shelf registration statement in the United States. In connection with the offering, CVI Investments, Inc., purchased 56,958 ADSs (representing 2,847,925 of our ordinary shares) and warrants to purchase up to 19,935 ADSs (representing 996,775 of our ordinary shares) and Empery Asset Management LP, purchased and aggregate of 56,958 of our ADSs representing 2,847,925 of our ordinary shares and warrants to purchase up to 19,935 ADSs.

(iii) On September 8, 2016, we entered into a securities purchase agreements as part of an offering of the ADSs pursuant to our shelf registration statement in the United States. As part of the offering, Senvest Management LLC purchased 15,000 ADSs (representing 750,000 of our ordinary shares) and Sabby Healthcare Master Fund Ltd. purchased 113,000 of the ADSs representing 5,650,000 of our ordinary shares.

(iv) On July 8, 2015, we completed a public offering of ordinary shares and warrants under a shelf offering report issued pursuant to our shelf prospectus in Israel. Subsequent to the offering, we were informed that OrbiMed Israel GP Ltd. purchased a total of 1,496,000 of our ordinary shares at a price of NIS 3.8 per share and 7,480,000 of our warrants, exercisable into additional 748,000 of our ordinary shares, affiliates of the Senvest Management LLC purchased an aggregate of 1,500,000 of our ordinary shares at a price of NIS 3.8 per share and 7,500,000 of our warrants, exercisable into additional 750,000 of our ordinary shares and affiliates of Migdal Insurance & Financial Holdings Ltd. purchased 842,000 of our ordinary shares at a price of NIS 3.8 per share and 4,210,000 of our warrants, exercisable into additional 421,000 of our ordinary shares.

(v) In June 2014 we entered into securities purchase agreements with affiliates of OrbiMed Israel GP Ltd., Sabby Healthcare Master Fund Ltd., Senvest Management LLC and Migdal Insurance & Financial Holdings Ltd. Under these securities purchase agreements, we issued affiliates of Orbimed Israel GP Ltd. an aggregate of 766,310 of our ordinary shares and a total of 3,065,244 warrants exercisable for 306,524 of our ordinary shares, Sabby Healthcare Master Fund Ltd. an aggregate of 1,247,200 of our ordinary shares and a total of 4,988,800 warrants exercisable for 498,880 of our ordinary shares, Senvest Management LLC an aggregate of 1,532,622 of our ordinary shares and a total of 6,130,487 warrants exercisable for 613,048 of our ordinary shares and Migdal Insurance & Financial Holdings Ltd. an aggregate of 3,065,244 of our ordinary shares and a total of 12,260,974 warrants exercisable for 1,226,097 of our ordinary shares.

(vi) We have been informed that Armistice Capital Master Fund Ltd. and Oren Dan have sold their holdings in the Company and are no longer beneficial owners of 5% or more of the share capital of the Company.

B. Related Party Transactions

Employment Agreements

We have entered into written employment agreements with each of our executive officers. All of these agreements contain customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. However, the enforceability of the noncompetition provisions may be limited under applicable law. In addition, we have entered into agreements with each executive officer and director pursuant to which we have agreed to indemnify each of them to the fullest extent permitted by law to the extent that these liabilities are not covered by directors and officers insurance.

Our office holders are generally eligible for bonuses each year. The bonuses are established and granted in accordance with our compensation policy and, and are generally payable upon meeting objectives and targets that are approved by our compensation committee and board of directors (and if required by our shareholders).

Directors and Officers Insurance Policy and Indemnification Agreements

Our articles of association permit us to exculpate, indemnify and insure our directors and officeholders to the fullest extent permitted by the Companies Law.

We have entered into agreements with each of our current director and officers exculpating them from a breach of their duty of care to us to the fullest extent permitted by law, subject to limited exceptions, and undertaking to indemnify them to the fullest extent permitted by law, to the extent that these liabilities are not covered by insurance. This indemnification is limited, with respect to any monetary liability imposed in favor of a third party, to events determined as foreseeable by the board of directors based on our activities. The maximum aggregate amount of indemnification that we may pay to our directors and officers based on such indemnification agreement is equal to 25% of our shareholders' equity pursuant to our latest audited or unaudited consolidated financial statements, as applicable, as of the date of the indemnification payment. Such indemnification amounts are in addition to any insurance amounts. Each director or officer who agrees to receive this letter of indemnification also gives his approval to the termination of all previous letters of indemnification that we have provided to him or her in the past, if any.

We currently have directors' and officers' liability insurance providing total coverage of $15 million for the benefit of all of our directors and officers, in respect of which we are charged a twelve-month premium of $ 67,000, and which includes a deductible of up to $50,000 per claim, other than securities related claims filed in the United States or Canada, for which the deductible shall not exceed $200,000. In connection with the March 2017 offering, we have expended our

In addition, at general meeting of our shareholders held on December 29, 2015, our shareholders approved our compensation policy, which determines, among others, that we may provide our directors and officers, including those serving in any of our subsidiaries from time or time and those who are controlling shareholders, with liability insurance policies provided that the engagement is in the ordinary course of business, in market terms and is not expected to materially influence our profits, properties and undertakings. The coverage limit shall be of up to $20 million per occurrence and for the insurance period (additional coverage for legal expenses not included), provided that the annual premium shall not exceed $80,000 and that the deductible (except for extraordinary matters as prescribed in the insurance policy, such as lawsuits against the Company pursuant to securities laws and/or lawsuits to be filed in the US/Canada) shall not exceed $50,000 per occurrence.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information.

See "Item 18. Financial Statements."

Export Sales

The following table presents total export sales for each of the fiscal years indicated (USD, in thousands):

	For the year ended December 31,		
	2014	**2015**	**2016**
Total export sales*	744	624	430
as a percentage of total revenues	100%	100%	78%

* Export sales, as presented, are defined as sales to customers located outside of Israel.

Legal Proceedings

From time to time we may assert or be subject to various asserted or unasserted legal proceedings and claims. Any such claims, regardless of merit, could be time-consuming and expensive to defend and could divert management's attention and resources from our operations. While management believes we have adequate insurance coverage and we accrue loss contingencies for all known matters that are probable and can be reasonably estimated, we cannot assure that the outcome of all current or future litigation will not have a material adverse effect on us and our results of operations.

On March 30, 2016, a former secretary and internal legal advisor filed a lawsuit against us and our chief executive officer. The lawsuit notes several claims, among which is that the employee was wrongfully terminated. Based on the assessment of our legal counsel we are of the opinion that the lawsuit should not have a material unfavorable effect on our results of operations.

On October 6 2016, following a withholding tax audit in Israel, we are deemed to be in debt of approximately NIS 5.3 million (which is approximately $1.46 million based on the exchange rate as of March 29, 2017) of additional withholding taxes, including penalties and interest. It is our management's opinion, based on the assessment of our legal counsel, that the chances for the claims being dismissed are more likely than not.

Dividends

We have never paid cash dividends on our ordinary shares and do not anticipate that we will pay any cash dividends on our ordinary shares or ADSs in the foreseeable future.

We intend to retain our earnings to finance the development and expenses of our business. Any future determination relating to our dividend policy will be at the discretion of our board of directors and will depend on a number of factors, including future earnings, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, applicable Israeli law and other factors our board of directors may deem relevant.

B. Significant Changes

No significant change, other than as otherwise described in this annual report, has occurred in our operations since the date of our consolidated financial statements included in this annual report.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our ordinary shares have been trading on the TASE under the symbol "MDGS" since February 2006. The ADSs are listed on the NASDAQ under the symbol "MDGS" with one ADS representing 50 ordinary shares.

The following table sets forth, for the periods indicated, the reported high and low sale prices of our ordinary shares on the TASE in NIS and U.S. dollars. U.S. dollar per ordinary share amounts are calculated using the U.S. dollar representative rate of exchange on the date for which the high or low market price is applicable, as reported by the Bank of Israel.

	NIS Price Per Ordinary Share*		U.S.$ Price Per Ordinary Share*	
	High	Low	High	Low
Annual:				
2017 (until March 29, 2017)	0.70	0.22	0.19	0.06
2016	2.23	0.47	0.58	0.12
2015	5.89	0.26	0.71	1.48
2014	6.73	1.50	1.93	0.39
2013	11.30	5.61	2.99	1.59
2012	13.60	5.66	3.55	1.41
Quarterly:				
First Quarter 2017 (until March 29, 2017)	0.70	0.19	0.19	0.06
Fourth Quarter 2016	1.19	0.47	0.31	0.12
Third Quarter 2016	2.23	0.65	0.58	0.17
Second Quarter 2016	1.42	0.74	0.38	0.19
First Quarter 2016	1.87	1.26	0.48	0.32
Fourth Quarter 2015	3.05	1.50	0.79	0.39
Third Quarter 2015	4.43	2.72	1.17	0.70
Second Quarter 2015	5.89	3.65	1.48	0.92
First Quarter 2015	3.90	2.59	0.98	0.67
Most Recent Six Months:				
March (until March 29, 2017)	0.70	0.19	0.19	0.06
February 2017	0.55	0.40	0.15	0.11
January 2017	0.58	0.40	0.11	0.15
December 2016	0.70	0.47	0.18	0.12
November 2016	1.19	0.70	0.31	0.18
October 2016	1.07	0.93	0.28	0.24
September 2016	1.41	0.97	0.37	0.26

On March 29, 2017, the last reported sale price of our ordinary shares on the TASE was NIS 0.23 per share, or approximately $0.06 per share (based on the exchange rate reported by the Bank of Israel for such date). On March 29, 2016, the exchange rate of the NIS to the dollar was $1.00 = NIS 3.625, as reported by the Bank of Israel.

ADSs

Our ADSs commenced trading on the NASDAQ under the symbol "MDGS" on August 5, 2015. Each ADR represents 50 ordinary shares.

The following table sets forth, for the periods indicated, the reported high and low closing sale prices of the ADSs on the NASDAQ in U.S. dollars.

	U.S. $ Price Per ADR*	
	High	**Low**
Yearly:		
2017 (until March 29, 2017)	10.7	2.95
2016	32.5	5.23
2015 (commencing August 5, 2015)	51.7	25.1
Quarterly:		
First Quarter 2017 (until March 29 17, 2017)	10.7	2.95
Fourth Quarter 2016	17.8	5.23
Third Quarter 2016	32.5	7.63
Second Quarter 2016	19.0	10.1
First Quarter 2016	26.80	15.0
Fourth Quarter 2015	44.8	25.7
Third Quarter 2015 (commencing August 5, 2015)	51.7	35.2
Most Recent Six Months:		
March 2017 (until March 29, 2017)	10.7	2.95
February 2017	8.3	4.15
January 2017	7.5	4.1
December 2016	8.80	5.2
November 2016	17.8	7.7
October 2016	13.4	11.6
September 2016	19.7	12.1

* price per ADS adjusted to reflect (i) the 10:1 reverse share split and the change in the ratio of ordinary shares per ADS to five deposited ordinary shares per ADS effected on November 6, 2015, and (ii) retroactively the change in the ratio of ordinary shares per ADS from five deposited ordinary shares per ADS to 50 deposited ordinary shares per ADS effected on March 15, 2017.

On March 29, 2017, the last reported sale price of the ADS on the NASDAQ was $3.08 per ADS.

For a description of the ADSs, see "Item 12. Description of Securities Other Than Equity Securities – D. American Depositary Shares."

B. Plan of Distribution

Not Applicable.

C. Markets

Our ordinary shares are listed and traded on the TASE. The ADSs, each representing 50 ordinary share and evidenced by an American depositary receipt, or ADR, are traded on the NASDAQ under the symbol "MDGS." The ADRs were issued pursuant to a Depositary Agreement entered into with The Bank of New York.

D. Selling Shareholders

Not Applicable.

E. Dilution

Not Applicable.

F. Expenses of the Issue

Not Applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

General

Our legal and commercial name is Medigus Ltd. We were incorporated in the State of Israel on December 9, 1999, as a private company pursuant to the Israeli Companies Ordinance (New Version), 1983. In February 2006, we completed our initial public offering in Israel, and our ordinary shares have since traded on the TASE, under the symbol "MDGS". In May 2015, we listed our ADSs on NASDAQ, and since August 2015 our ADSs have been traded on the NASDAQ under the symbol "MDGS". Each ADS represents 50 ordinary shares.

Our authorized share capital consists of 800,000,000 ordinary shares, par value NIS 0.10 per share. As of March 29, 2017, 99,628,584, ordinary shares were issued and outstanding. All of our outstanding ordinary shares have been fully paid and non-assessable. Holders of paid-up ordinary shares are entitled to participate equally in the payment of dividends and other distributions and, in the event of liquidation, in all distributions after the discharge of liabilities to creditors. Our ordinary shares are not redeemable.

Pursuant to the terms of the securities purchase agreements relating to an offering of our ADSs and warrants which closed on December 6, 2016, we granted the purchasers in such offering an eighteen month contractual preemptive right to participate in future financings, subject to certain exceptions, in an amount equal to up to 50% of the amount raised in such future financings. Other than the preemptive rights described herein, our ordinary shares are not subject to any other preemptive rights.

Options

As of March 29, 2017, options to purchase an aggregate of 1,344,464 ordinary shares have been granted under our share option plans. See "Item 4. Information on the Company - B. Business Overview – E. Share Ownership."

Warrants

As of March 29, 2017, the following warrants are outstanding:

- Warrants publicly traded on the TASE to purchase an aggregate of 3,526,250 ordinary shares at an exercise price per ordinary share of NIS 5.32, approximately $1.45. These warrants expire on July 8, 2018;
- Warrants publicly traded on the TASE to purchase an aggregate of 3,526,250 ordinary shares at an exercise price per ordinary share of NIS 5.32, approximately $1.45. These warrants expire on July 8, 2018;
- Unregistered warrants to purchase an aggregate of 3,410,861 ordinary shares at an exercise price per ordinary share of NIS 6.27, approximately $1.71. These warrants expire in August 2017.
- Unregistered warrants to purchase an aggregate of 3,955 ADSs at an exercise price per ADS of $14.375. These warrants expire on September 8, 2021.
- Unregistered warrants to purchase an aggregate of 41,864 ADSs at an exercise price per ADS of $9.0. These warrants expire on June 6, 2022.
- Unregistered warrants to purchase an aggregate of 3,987 ADSs at an exercise price per ADS of $7.37. These warrants expire on December 6, 2021.

- Warrants to purchase an aggregate of 2,142,858 ADSs at an exercise price per ADS of 3.50$. These warrants expire on March 29, 2022.
- Pre-funded warrants to purchase an aggregate of 1,033,144 ADSs at an exercise price per ADS of $0.01. until exercised in full.
- Warrants to purchase an aggregate of 150,000 ADSs at an exercise price per ADS of 4.375$. These warrants expire on March 29, 2022.

B. Memorandum and Articles of Association

Registration Number and Purposes of the Company

Our registration number with the Israeli Registrar of Companies is 51-286697-1. Our purpose as set forth in our articles of association is to engage in any lawful activity.

Transfer of shares

Our fully paid ordinary shares are issued in registered form and may be freely transferred under our articles of association, unless the transfer is restricted or prohibited by another instrument, applicable law or the rules of a stock exchange on which the shares are listed for trade. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our articles of association or the laws of the State of Israel, except for ownership by nationals of certain countries that are, or have been, in a state of war with Israel.

Liability to further capital calls

Our board of directors may make, from time to time, such calls as it may deem fit upon shareholders with respect to any sum unpaid with respect to shares held by such shareholders which is not payable at a fixed time. Such shareholder shall pay the amount of every call so made upon him or her.

Election of Directors

Our ordinary shares do not have cumulative voting rights for the election of directors. As a result, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect all of our directors, subject to the special approval requirements for external directors under the Israeli Companies Law, 5759-1999, or the Companies Law, under "Item 6. Directors, Senior Management and Employees—C. Board Practices–External directors."

Under our articles of association, our board of directors must consist of not less than three but no more than twelve directors, including two external directors as required by the Companies Law. Pursuant to our articles of association, other than the external directors, for whom special election requirements apply under the Companies Law, the vote required to appoint a director is a simple majority vote of holders of our voting shares participating and voting at the relevant meeting. In addition, our articles of association allow our board of directors to appoint new directors to fill vacancies on the board of directors to serve until the subsequent annual general meeting of our shareholders, provided, that the number of directors shall not exceed twelve directors. External directors are elected for an initial term of three years, may be elected for additional terms of three years each under certain circumstances, and may be removed from office pursuant to the terms of the Companies Law. For further information on the election and removal of external directors see "Item 6. Directors, Senior Management and Employees—C. Board Practices—External Directors."

Dividend and liquidation rights

We may declare a dividend to be paid to the holders of our ordinary shares in proportion to their respective shareholdings. Under the Companies Law, dividend distributions are determined by the board of directors and do not require the approval of the shareholders of a company unless the company's articles of association provide otherwise. Our articles of association do not require shareholder approval of a dividend distribution and provide that dividend distributions may be determined by our board of directors.

Pursuant to the Companies Law, the distribution amount is limited to the greater of retained earnings or earnings generated over the previous two years, according to our then last reviewed or audited consolidated financial statements, provided that the date of the financial statements is not more than six months prior to the date of the distribution, or we may distribute dividends that do not meet such criteria only with court approval. In each case, we are only permitted to distribute a dividend if our board of directors and the court, if applicable, determines that there is no reasonable concern that payment of the dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of our ordinary shares in proportion to their shareholdings. This right, as well as the right to receive dividends, may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

Exchange controls

There are currently no Israeli currency control restrictions on remittances of dividends on our ordinary shares, proceeds from the sale of the shares or interest or other payments to non-residents of Israel, except for shareholders who are subjects of certain countries that are, or have been, in a state of war with Israel.

Shareholder Meetings

Under the Companies Law, we are required to hold an annual general meeting of our shareholders once every calendar year that must be held no later than 15 months after the date of the previous annual general meeting. All general meetings other than the annual meeting of shareholders are referred to in our articles of association as extraordinary meetings. Our board of directors may call extraordinary meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Companies Law provides that our board of directors is required to convene a special meeting upon the written request of (i) any two of our directors or one-quarter of the members of our board of directors or (ii) one or more shareholders holding, in the aggregate, either (a) 5% or more of our outstanding issued shares and 1% or more of our outstanding voting power or (b) 5% or more of our outstanding voting power.

Under the Companies Law, one or more shareholders holding at least 1% of the voting rights at the general meeting may request that the board of directors include a matter in the agenda of a general meeting to be convened in the future, provided that it is appropriate to discuss such a matter at the general meeting.

Subject to the provisions of the Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors, which may be between four and 40 days prior to the date of the meeting. Furthermore, the Companies Law requires that resolutions regarding the following matters must be passed at a general meeting of our shareholders:

- amendments to our articles of association;
- appointment or termination of our auditors;
- appointment of external directors;
- approval of certain related party transactions;
- increases or reductions of our authorized share capital;
- mergers; and
- the exercise of our board of directors powers by a general meeting, if our board of directors is unable to exercise its powers and the exercise of any of its powers is required for our proper management.

Under our articles of association, we are not required to give notice to our registered shareholders pursuant to the Companies Law, unless otherwise required by law. The Companies Law requires that a notice of any annual general meeting or extraordinary general meeting be provided to shareholders at least 21 days prior to the meeting and if the agenda of the meeting includes the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, or an approval of a merger, or as otherwise required under applicable law, notice must be provided at least 35 days prior to the meeting.

Voting rights

Voting rights

All our ordinary shares have identical voting and other rights in all respects.

Quorum requirements

Pursuant to our articles of association, holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote before the shareholders at a general meeting. The quorum required for our general meetings of shareholders consists of at least two shareholders, present in person or by proxy, holding at least ten percent (10%) of the voting rights of the Company. A meeting adjourned for lack of a quorum will be adjourned to the same day of the following week at the same time and place, or to such other day, time or place if such is stated in the notice of the meeting. At the reconvened meeting, if a quorum is not present within an half an hour, any number of shareholders present in person or by proxy shall constitute a lawful quorum.

Vote requirements

Our articles of association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by the Companies Law or by our articles of association. Under the Companies Law, each of (i) the approval of an extraordinary transaction with a controlling shareholder and (ii) the terms of employment or other engagement of the controlling shareholder of the company or such controlling shareholder's relative (even if not extraordinary) requires the approval described under "Item 6. Directors, Senior Management and Employees—C.Board Practices—Fiduciary duties and approval of specified related party transactions and compensation under Israeli law—Disclosure of personal interests of a controlling shareholder and approval of transactions." Certain transactions with respect to remuneration of our office holders and directors require further approvals described under "Item 6. Directors, Senior Management and Employees—C. Board Practices—Fiduciary duties and approval of specified related party transactions and compensation under Israeli law—Approval of compensation of directors and executive officers." Another exception to the simple majority vote requirement is a resolution for the voluntary winding up, or an approval of a scheme of arrangement or reorganization, of the company pursuant to Section 350 of the Companies Law, which requires the approval of the majority of the shareholders voting their shares, other than abstainees, holding at least 75% of the voting rights represented at the meeting, in person, by proxy or by voting deed and voting on the resolution.

Access to corporate records

Under the Companies Law, shareholders are provided access to minutes of our general meetings, our shareholders register and principal shareholders register, our articles of association, our financial statements and any document that we are required by law to file publicly with the Israeli Companies Registrar or the Israel Securities Authority. In addition, shareholders may request to be provided with any document related to an action or transaction requiring shareholder approval under the related party transaction provisions of the Companies Law. We may deny this request if we believe it has not been made in good faith or if such denial is necessary to protect our interest or protect a trade secret or patent.

Modification of class rights

Under the Companies Law and our articles of association, the rights attached to any class of shares, such as voting, liquidation and dividend rights, may be amended by adoption of a resolution by the holders of a majority of the shares of that class present at a separate class meeting, or otherwise in accordance with the rights attached to such class of shares, as set forth in our articles of association.

Acquisitions under Israeli law

Full tender offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company. A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the relevant class for the purchase of all of the issued and outstanding shares of that class. If the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will also be accepted if the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of shares.

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition an Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may include in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If a tender offer is not accepted in accordance with the requirements set forth above, the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

Special tender offer

The Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the company. This requirement does not apply if there is already another holder of at least 25% of the voting rights in the company. Similarly, the Companies Law provides that an acquisition of shares in a public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company who holds more than 45% of the voting rights in the company, subject to certain exceptions.

A special tender offer must be extended to all shareholders of a company but the offeror is not required to purchase shares representing more than 5% of the voting power attached to the company's outstanding shares, regardless of how many shares are tendered by shareholders. A special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror and (ii) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer (excluding the purchaser and its controlling shareholder, holders of 25% or more of the voting rights in the company or any person having a personal interest in the acceptance of the tender offer or any other person acting on their behalf, including relatives and entities under such person's control). If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, by a majority vote of each party's shares, and, in the case of the target company, a majority vote of each class of its shares voted on the proposed merger at a shareholders meeting.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the votes of the shares represented at the shareholders meeting that are held by parties other than the other party to the merger, or by any person (or group of persons acting in concert) who holds (or hold, as the case may be) 25% or more of the voting rights or the right to appoint 25% or more of the directors of the other party, vote against the merger. If, however, the merger involves a merger with a company's own controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger is instead subject to the same special majority approval that governs all extraordinary transactions with controlling shareholders (as described under "Item 6. Directors, Senior Management and Employees—C. Board Practices—Fiduciary duties and approval of specified related party transactions and compensation under Israeli law—Disclosure of personal interests of a controlling shareholder and approval of transactions").

If the transaction would have been approved by the shareholders of a merging company but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the value to the parties to the merger and the consideration offered to the shareholders of the company.

Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of the merging entities, and may further give instructions to secure the rights of creditors.

In addition, a merger may not be consummated unless at least 50 days have passed from the date on which a proposal for approval of the merger was filed by each party with the Israeli Registrar of Companies and at least 30 days have passed from the date on which the merger was approved by the shareholders of each party.

Borrowing powers

Pursuant to the Companies Law and our articles of association, our board of directors may exercise all powers and take all actions that are not required under law or under our articles of association to be exercised or taken by a certain organ of the Company, including the power to borrow money for company purposes.

Changes in capital

Our articles of association enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Companies Law and must be approved by a resolution duly adopted by our shareholders at a general meeting. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings or profits, require the approval of both our board of directors and an Israeli court.

Transfer agent and registrar

Our transfer agent and registrar is the Depositary for the ADSs, Bank of New York Mellon, and its address is 101 Barclay Street, New York, NY.

Preemptive Rights

Pursuant to the terms of the securities purchase agreements relating to an offering of our ADSs and warrants which closed on December 6, 2016, we granted the purchasers in such offering an eighteen month contractual preemptive right to participate in future financings, subject to certain exceptions, in an amount equal to up to 50% of the amount raised in such future financings. Other than the preemptive rights described herein, our ordinary shares and ADSs are not subject to any other preemptive rights.

Listing

Our ordinary shares currently trade on the TASE in Israel under the symbol "MDGS," and our ADSs are listed on the NASDAQ under the symbol "MDGS." We have applied to list the Series A warrants on the NASDAQ under the symbol "MDGSW." No assurances can be given that our application will be approved. The Series B warrants are not and will not be listed for trading on any national securities exchange.

C. Material Contracts

Except as set forth below, we have not entered into any material contract within the three years prior to the date of this annual report filed on Form 20-F, other than contracts entered into in the ordinary course of business.

Securities Purchase Agreement, dated March 24, 2017

On March 24, 2017, we entered into a securities purchase agreements as part of an offering of our ADSs pursuant to a registration statement in the United States. As part of the offering we issued a total of 979,714 Class A Units at a purchase price per unit of $3.50 and of 1,163,144 Class B Units at a purchase price per unit of $3.49. Each Class A unit consists of (i) one American Depositary Share, or ADS, and (ii) one Series A warrant to purchase one ADS, and each Class B unit consists of (i) one pre-funded warrant to purchase one ADS, and (ii) one Series A warrant to purchase one ADS. The Series A warrants have a term of five years, and are exercisable immediately (or, at the election of the purchaser, six months following the issuance date) and have an exercise price of $3.50 per ADS. The pre-funded warrants are exercisable immediately until exercised in full and have an exercise price of $0.01 per ADS. As part of such offering, we issued to Rodman & Renshaw, a unit of H.C. Wainwright & Co., acting as placement agent in our offering, warrants to purchase up to an aggregate of 150,000 ADSs representing 7,500,000 ordinary shares, with an exercise price of $4.375 per ADS., who acted as the placement agent of the offering, Pursuant to the engagement letter executed with the placement agent, Rodman & Renshaw, relating to the offering, we agreed to provide the placement agent with the right of first refusal, expiring on the twelve month anniversary following the closing of the offering, if we or our subsidiaries decide to raise funds by means of a public offering or a private placement of equity or debt securities using an underwriter or placement agent in the United States.

Securities Purchase Agreement, November 30, 2016

On November 30, 2016, we entered into a securities purchase agreements as part of an offering of our ADSs pursuant to our shelf registration statement in the United States. As part of the offering we issued a total of 113,917 of our ADSs representing a total of 5,695,850 ordinary shares, at a purchase price of US$6.7 per ADS, and warrants to purchase up to a total of 39,871 ADSs representing 1,993,550 ordinary shares, at an initial exercise price of $9.00 per ADS, in a concurrent private placement. Pursuant to the engagement letter executed with the placement agent, Rodman & Renshaw, relating to the offering, we agreed to provide the placement agent with the right of first refusal, expiring on the twelve month anniversary following the closing of the offering, if we or our subsidiaries decide to raise funds by means of a public offering or a private placement of equity or debt securities using an underwriter or placement agent in the U.S.

Securities Purchase Agreement, dated September 8, 2016

On September 8, 2016, we entered into a securities purchase agreements as part of an offering of our ADSs pursuant to our shelf registration statement in the United States. As part of the offering we issued a total of 128,000 of our ADSs representing a total of 6,400,000 ordinary shares, at a purchase price of US$11.50 per ADS.

Securities Purchase Agreements, dated June 2014

In June 2014, we entered into securities purchase agreements with certain investors, including Sabby Healthcare Volatility Master Fund Ltd., Sabby Volatility Warrant Master Fund Ltd., Senvest Israel Partners LP, Senvest International LLC, Migdal Insurance Company Ltd., Capital Point Ltd. and OrbiMed. Under these securities purchase agreements, the investors invested an aggregate amount of approximately $11.1 million (approximately NIS 39 million). In connection with the securities purchase agreements, we issued an aggregate amount of 8,527,154 ordinary shares for a price per ordinary share of NIS 4.4786, and warrants, exercisable into an additional 3,410,861 ordinary shares for a period of 36 months from their date of issuance. Each ten warrants are exercisable into on ordinary share at a price per share of NIS 6.27. If at any time after the six-month anniversary of the closing date of the securities purchase agreements, the ordinary shares held by the investors have not been released from the applicable Israeli or U.S. transfer restrictions (i.e. via the filing of an Israeli prospectus or the registration of the securities in the United States), and subject to certain other conditions set forth in the warrants, then the warrants (other than those held by Migdal Insurance Company Ltd.) may also be exercised, in whole or in part, by means of a cashless exercise.

Shareholders' Undertaking to Orbimed

In January 2013, we entered into a share purchase agreement with OrbiMed pursuant to which we issued OrbiMed an aggregate amount of 3,994,547 ordinary shares and warrants to purchase 3,994,547 additional ordinary shares, for a total consideration of $8 million. The warrants have expired on March 3, 2016. In connection with the share purchase agreement, several of the Company's shareholders, including Menashe Sonnenschein and Aviel Shapira signed a letter of undertaking to OrbiMed, or the Shareholders' Undertaking, according to which each undertook, until the earlier of: (i) the three year anniversary of the closing date; or (ii) the date on which OrbiMed's voting rights exceed 45% of the aggregate voting rights of the Company, to vote their shares in accordance with OrbiMed's instructions in connection with certain matters such as the size of the board, to elect four directors nominated by OrbiMed (including the Chairman) and for any other matter in accordance with OrbiMed's instructions provided that such matter is not 'unreasonable'. The shareholders subject to the undertaking also agreed to certain transfer restrictions on their shares during the three year period. On March 3, 2016, the Shareholders' Undertaking has expired.

D. Exchange Controls

There are currently no Israeli currency control restrictions on payments of dividends or other distributions with respect to our securities or the proceeds from the sale of our securities, except or otherwise as set forth in this section and under "Item 10E. Additional Information — Taxation." However, legislation remains in effect pursuant to which currency controls can be imposed by administrative action at any time.

The ownership or voting of our ordinary shares by non-residents of Israel, except with respect to citizens of countries that are in a state of war with Israel, is not restricted in any way by our articles or by the laws of the State of Israel.

E. Taxation

The following description is not intended to constitute a complete analysis of all tax consequences relating to the acquisition, ownership and disposition of our ordinary shares. You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign or other taxing jurisdiction.

Israeli Tax Considerations and Government Programs

The following is a summary of the material Israeli tax laws applicable to us, and some Israeli Government programs benefiting us. This section also contains a discussion of some Israeli tax consequences to persons owning our ordinary shares. This summary does not discuss all the aspects of Israeli tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors subject to special treatment under Israeli law. Examples of this kind of investor include traders in securities or persons that own, directly or indirectly, 10% or more of our outstanding voting capital, all of whom are subject to special tax regimes not covered in this discussion. Some parts of this discussion are based on a new tax legislation which has not been subject to judicial or administrative interpretation. The discussion should not be construed as legal or professional tax advice and does not cover all possible tax considerations.

SHAREHOLDERS ARE URGED TO CONSULT THEIR OWN TAX ADVISORS AS TO THE ISRAELI OR OTHER TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES, INCLUDING, IN PARTICULAR, THE EFFECT OF ANY FOREIGN, STATE OR LOCAL TAXES.

General Corporate Tax Structure in Israel

Israeli resident companies are generally subject to corporate tax on their taxable income at the rate of 25% of a company's taxable income for 2016 tax year (to be reduced to 24% in 2017 and 23% in 2018. However, the effective tax rate payable by a company that derives income from a Benefited Enterprise or a Preferred Enterprise (as discussed below) may be considerably less. Capital gains derived by an Israeli resident company are subject to tax at the prevailing corporate tax rate.

Under Israeli tax legislation, a corporation will be considered as an "Israeli resident company" if it meets one of the following: (i) it was incorporated in Israel; or (ii) the control and management of its business are exercised in Israel.

Law for the Encouragement of Industry (Taxes), 5729-1969

The Law for the Encouragement of Industry (Taxes), 5729-1969, generally referred to as the Industry Encouragement Law, provides several tax benefits for "Industrial Companies."

The Industry Encouragement Law defines an "Industrial Company" as a company resident in Israel, of which 90% or more of its income in any tax year, other than income from defense loans, is derived from an "Industrial Enterprise" owned by it. An "Industrial Enterprise" is defined as an enterprise whose principal activity in a given tax year is industrial production.

The following corporate tax benefits, among others, are available to Industrial Companies:

- amortization over an eight-year period of the cost of purchased know-how and patents and rights to use a patent and know-how which are used for the development or advancement of the Industrial Enterprise;
- under limited conditions, an election to file consolidated tax returns with related Israeli Industrial Companies; and
- expenses related to a public offering are deductible in equal amounts over three years.

Although at the date of this annual report on Form 20-F, we still have no industrial production activities, we may qualify as an Industrial Company in the future and may be eligible for the benefits described above.

Tax Benefits and Grants for Research and Development

Israeli tax law allows, under certain conditions, a tax deduction for expenditures, including capital expenditures, for the year in which they are incurred. Expenditures are deemed related to scientific research and development projects, if:

- The expenditures are approved by the relevant Israeli government ministry, determined by the field of research;
- The research and development must be for the promotion of the company; and
- The research and development is carried out by or on behalf of the company seeking such tax deduction.

The amount of such deductible expenses is reduced by the sum of any funds received through government grants for the finance of such scientific research and development projects. No deduction under these research and development deduction rules is allowed if such deduction is related to an expense invested in an asset depreciable under the general depreciation rules of the income Tax Ordinance, 1961. Expenditures not so approved are deductible in equal amounts over three years.

From time to time we may apply the Office of the Chief Scientist for approval to allow a tax deduction for all research and development expenses during the year incurred. There can be no assurance that such application will be accepted.

Law for the Encouragement of Capital Investments, 5719-1959

The Law for the Encouragement of Capital Investments, 5719-1959, generally referred to as the Investment Law, provides certain incentives for capital investments in production facilities (or other eligible assets) by "Industrial Enterprises" (as defined under the Investment Law).

Tax Benefits Prior to the 2005 Amendment

An investment program that is implemented in accordance with the provisions of the Investment Law prior to the 2005 Amendment, referred to as an "Approved Enterprise," is entitled to certain benefits. A company that wished to receive benefits as an Approved Enterprise must have received approval from the Investment Center of the Israeli Ministry of Economy, or the Investment Center. Each certificate of approval for an Approved Enterprise relates to a specific investment program in the Approved Enterprise, delineated both by the financial scope of the investment and by the physical characteristics of the facility or the asset.

In general, an Approved Enterprise is entitled to receive a grant from the Government of Israel or an alternative package of tax benefits, known as the alternative benefits track. The tax benefits from any certificate of approval relate only to taxable profits attributable to the specific Approved Enterprise. Income derived from activity that is not integral to the activity of the Approved Enterprise does not enjoy tax benefits.

In addition, a company that has an Approved Enterprise program is eligible for further tax benefits if it qualifies as a Foreign Investors' Company, or FIC, which is a company with a level of foreign investment, as defined in the Investment Law, of more than 25%. The level of foreign investment is measured as the percentage of rights in the company (in terms of shares, rights to profits, voting and appointment of directors), and of combined share and loan capital, that are owned, directly or indirectly, by persons who are not residents of Israel. The determination as to whether a company qualifies as an FIC is made on an annual basis.

We are currently not entitled to tax benefits for Approved Enterprise.

Tax Benefits Subsequent to the 2005 Amendment

The 2005 Amendment applies to new investment programs and investment programs commencing after 2004, but does not apply to investment programs approved prior to April 1, 2005. The 2005 Amendment provides that terms and benefits included in any certificate of approval that was granted before the 2005 Amendment became effective (April 1, 2005) will remain subject to the provisions of the Investment Law as in effect on the date of such approval. Pursuant to the 2005 Amendment, the Investment Center will continue to grant Approved Enterprise status to qualifying investments. The 2005 Amendment, however, limits the scope of enterprises that may be approved by the Investment Center by setting criteria for the approval of a facility as an Approved Enterprise, such as provisions generally requiring that at least 25% of the Approved Enterprise's income be derived from exports.

The 2005 Amendment provides that Approved Enterprise status will only be necessary for receiving cash grants. As a result, it was no longer necessary for a company to obtain Approved Enterprise status in order to receive the tax benefits previously available under the alternative benefits track. Rather, a company may claim the tax benefits offered by the Investment Law directly in its tax returns, provided that its facilities meet the criteria for tax benefits set forth in the amendment. Companies are entitled to approach the Israeli Tax Authority for a pre-ruling regarding their eligibility for benefits under the Investment Law, as amended

In order to receive the tax benefits, the 2005 Amendment states that a company must make an investment which meets all of the conditions, including exceeding a minimum investment amount specified in the Investment Law. Such investment allows a company to receive "Benefited Enterprise" status, and may be made over a period of no more than three years from the end of the year in which the company requested to have the tax benefits apply to its Benefited Enterprise. Where the company requests to apply the tax benefits to an expansion of existing facilities, only the expansion will be considered to be a Benefited Enterprise and the company's effective tax rate will be the weighted average of the applicable rates. In this case, the minimum investment required in order to qualify as a Benefited Enterprise is required to exceed a certain percentage of the value of the company's production assets before the expansion.

The extent of the tax benefits available under the 2005 Amendment to qualifying income of a Benefited Enterprise depend on, among other things, the geographic location in Israel of the Benefited Enterprise. The location will also determine the period for which tax benefits are available. Such tax benefits include an exemption from corporate tax on undistributed income for a period of between two to ten years, depending on the geographic location of the Benefited Enterprise in Israel, and a reduced corporate tax rate of between 10% to the applicable corporate tax for the remainder of the benefits period, depending on the level of foreign investment in the company in each year. A company qualifying for tax benefits under the 2005 Amendment which pays a dividend out of income derived by its Benefited Enterprise during the tax exemption period will be subject to corporate tax in respect of the gross amount of the dividend at the otherwise applicable corporate tax rate, or a lower rate in the case of a qualified FIC which is at least 49% owned by non-Israeli residents. Dividends paid out of income attributed to a Benefited Enterprise are generally subject to withholding tax at source at the rate of 15% or such lower rate as may be provided in an applicable tax treaty.

The benefits available to a Benefited Enterprise are subject to the fulfillment of conditions stipulated in the Investment Law and its regulations. If a company does not meet these conditions, it may be required to refund the amount of tax benefits, as adjusted by the Israeli consumer price index, and interest, or other monetary penalties.

We applied for tax benefits as a "Benefited Enterprise" with 2012 as a "Year of Election." We may be entitled to tax benefits under this regime once we are profitable for tax purposes and subject to the fulfillment of all the relevant conditions. If we do not meet these conditions, the tax benefits may not be applicable which would result in adverse tax consequences to us. Alternatively, and subject to the fulfillment of all the relevant conditions, we may elect in the future to irrevocably waive the tax benefits available for Benefited Enterprise and claim the tax benefits available to Preferred Enterprise under the 2011 Amendment (as detailed below).

Tax Benefits under the 2011 Amendment

The Investment Law was significantly amended as of January 1, 2011 (the "2011 Amendment"). The 2011 Amendment introduced new benefits to replace those granted in accordance with the provisions of the Investment Law in effect prior to the 2011 Amendment.

The 2011 Amendment introduced new tax benefits for income generated by a "Preferred Company" through its "Preferred Enterprise," in accordance with the definition of such term in the Investments Law, which generally means that a "Preferred Company" is an industrial company meeting certain conditions (including a minimum threshold of 25% export).

A Preferred Company is entitled to a reduced flat tax rate with respect to the income attributed to the Preferred Enterprise, at the following rates:

Tax Year	Development Region "A"	Other Areas within Israel
2011 – 2012	10%	15%
2013	7%	12.5%
2014	9%	16%
2017 onwards[(1)]	7.5%	16%

(1) In December 2016, the Israeli Parliament (the Knesset) approved an amendment to the Investment Law pursuant to which the tax rate applicable to Preferred Enterprises in Development Region "A" would be reduced to 7.5% as of 2017.

Dividends distributed from income which is attributed to a "Preferred Enterprise" will be subject to withholding tax at source at the following rates: (i) Israeli resident corporations — 0%, (ii) Israeli resident individuals — 20% in 2016 (iii) non-Israeli residents — 20% in 2016, subject to a reduced tax rate under the provisions of an applicable double tax treaty.

Under the 2011 Amendment, a company located in Development Region "A" may be entitled to cash grants and the provision of loans under certain conditions, if approved. The rates for grants and loans shall not be fixed, but up to 20% of the amount of the approved investment (may be increased with additional 4%). In addition, a company owning a Preferred Enterprise under the Grant Track may be entitled also to the tax benefits which are prescribed for a Preferred Company.

The termination or substantial reduction of any of the benefits available under the Investment Law could materially increase our tax liabilities.

We are currently not entitled to tax benefits for Preferred Enterprise.

Taxation of Our Shareholders

Capital Gains

Capital gain tax is imposed on the disposition of capital assets by an Israeli resident, and on the disposition of such assets by a non-Israeli resident if those assets are either (i) located in Israel; (ii) are shares or a right to a share in an Israeli resident corporation, or (iii) represent, directly or indirectly, rights to assets located in Israel. The Israeli Income Tax Ordinance of 1961 (New Version) (the "Ordinance") distinguishes between "Real Gain" and the "Inflationary Surplus." Real Gain is the excess of the total capital gain over Inflationary Surplus computed generally on the basis of the increase in the Israeli CPI between the date of purchase and the date of disposition. Inflationary Surplus is not subject to tax in Israel.

Real Gain accrued by individuals on the sale of our ordinary shares will be taxed at the rate of 25%. However, if the individual shareholder is a "Controlling Shareholder" (i.e., a person who holds, directly or indirectly, alone or together with another, 10% or more of one of the Israeli resident company's means of control) at the time of sale or at any time during the preceding 12 months period, such gain will be taxed at the rate of 30%.

Real Gain derived by corporations will be generally subject to a corporate tax rate of 25% in 2016 (to be reduced to 24% in 2017 and 23% in 2018 and thereafter).

Individual and corporate shareholder dealing in securities in Israel are taxed at the tax rates applicable to business income — 25% for corporations in 2016 (to be reduced to 24% in 2017 and 23% in 2018 and thereafter) and a marginal tax rate of up to 50% in 2016 for individuals, including an excess tax which is levied on individuals whose taxable income in Israel exceeds certain threshold (NIS 810,720 in 2016 and NIS 640,000 in 2017 and thereafter, as discussed below).

Notwithstanding the foregoing, capital gain derived from the sale of our ordinary shares by a non-Israeli shareholder may be exempt under the Ordinance from Israeli taxation provided that the following cumulative conditions are met: (i) the shares were purchased upon or after the registration of the securities on the stock exchange (this condition will not apply to shares purchased on or after January 1, 2009), (ii) the seller does not have a permanent establishment in Israel to which the derived capital gain is attributed, (iii) if the seller is a corporation, no more than 25% of its means of control are held, directly and indirectly, by an Israeli resident shareholders, and (iv) if the seller is a corporation, there is no Israeli Resident that is entitled to 25% or more of the revenues or profits of the corporation directly or indirectly. In addition, such exemption would not be available to a person whose gains from selling or otherwise disposing of the securities are deemed to be business income.

In addition, the sale of shares may be exempt from Israeli capital gain tax under the provisions of an applicable tax treaty. For example, the U.S.-Israel Double Tax Treaty exempts U.S. resident from Israeli capital gain tax in connection with such sale, provided (i) the U.S. resident owned, directly or indirectly, less than 10% of an Israeli resident company's voting power at any time within the 12 month period preceding such sale; (ii) the seller, being an individual, is present in Israel for a period or periods of less than 183 days at the taxable year; and (iii) the capital gain from the sale was not derived through a permanent establishment of the U.S. resident in Israel.

Either the purchaser, the Israeli stockbrokers or financial institution through which the shares are held is obliged, subject to the above mentioned exemptions, to withhold tax upon the sale of securities from the Real Gain at the rate of 25%.

At the sale of securities traded on a stock exchange a detailed return, including a computation of the tax due, must be filed and an advanced payment must be paid on January 31 and June 30 of every tax year in respect of sales of securities made within the previous six months. However, if all tax due was withheld at source according to applicable provisions of the Ordinance and regulations promulgated thereunder the aforementioned return need not be filed and no advance payment must be paid. Capital gain is also reportable on the annual income tax return.

Dividends

We have never paid cash dividends. A distribution of dividend by our company from income attributed to a Benefited Enterprise will generally be subject to withholding tax in Israel at a rate of 15% unless a reduced tax rate is provided under an applicable tax treaty. A distribution of dividend by our company from income attributed to a Preferred Enterprise will generally be subject to withholding tax in Israel at the following tax rates: Israeli resident individuals — 20% with respect to dividends to be distributed as of 2016; Israeli resident companies — 0% for a Preferred Enterprise; Non-Israeli residents — 20% with respect to dividends to be distributed as of 2016, subject to a reduced rate under the provisions of any applicable double tax treaty. A distribution of dividends from income, which is not attributed to a Preferred Enterprise to an Israeli resident individual, will generally be subject to income tax at a rate of 25%. However, a 30% tax rate will apply if the dividend recipient is a "Controlling Shareholder" (as defined above) at the time of distribution or at any time during the preceding 12 months period. If the recipient of the dividend is an Israeli resident corporation, such dividend will be exempt from income tax provided the income from which such dividend is distributed was derived or accrued within Israel.

The Ordinance provides that a non-Israeli resident (either individual or corporation) is generally subject to an Israeli income tax on the receipt of dividends at the rate of 25% (30% if the dividends recipient is a "Controlling Shareholder" (as defined above), at the time of distribution or at any time during the preceding 12 months period); those rates are subject to a reduced tax rate under the provisions of an applicable double tax treaty. Thus, under the U.S.-Israel Double Tax Treaty the following rates will apply in respect of dividends distributed by an Israeli resident company to a U.S. resident: (i) if the U.S. resident is a corporation which holds during that portion of the taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any), at least 10% of the outstanding shares of the voting share capital of the Israeli resident paying corporation and not more than 25% of the gross income of the Israeli resident paying corporation for such prior taxable year (if any) consists of certain type of interest or dividends — the tax rate is 12.5%, (ii) if both the conditions mentioned in section (i) above are met and the dividend is paid from an Israeli resident company's income which was entitled to a reduced tax rate applicable to an Approved Enterprise — the tax rate is 15% and (iii) in all other cases, the tax rate is 25%. The aforementioned rates under the Israel U.S. Double Tax Treaty will not apply if the dividend income was derived through a permanent establishment of the U.S. resident in Israel.

A non-Israeli resident who receives dividends from which tax was withheld is generally exempt from the obligation to file tax returns in Israel with respect to such income, provided that (i) such income was not generated from business conducted in Israel by the taxpayer, and (ii) the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed.

Payers of dividends on our ordinary shares, including the Israeli stockbroker effectuating the transaction, or the financial institution through which the securities are held, are generally required, subject to any of the foregoing exemptions, reduced tax rates and the demonstration of a shareholder regarding his, her or its foreign residency, to withhold tax upon the distribution of dividend at the rate of 25%, so long as the shares are registered with a nominee company.

Excess Tax

Individuals who are subject to tax in Israel are also subject to an additional tax at a rate of 2% in 2016 (to be increased to 3% in 2017 and thereafter) on annual income exceeding a certain threshold (NIS 810,720 for 2016 and NIS 640,000 for 2017 and thereafter, linked to the annual change in the Israeli Consumer Price Index), including, but not limited to income derived from, dividends, interest and capital gains.

Foreign Exchange Regulations

Non-residents of Israel who hold our ordinary shares are able to receive any dividends, and any amounts payable upon the dissolution, liquidation and winding up of our affairs, repayable in non-Israeli currency at the rate of exchange prevailing at the time of conversion. However, Israeli income tax is generally required to have been paid or withheld on these amounts. In addition, the statutory framework for the potential imposition of currency exchange control has not been eliminated, and may be restored at any time by administrative action.

Estate and Gift Tax

Israeli law presently does not impose estate or gift taxes.

U.S. Federal Income Tax Consequences

The following discussion describes certain material U.S. federal income tax consequences to U.S. Holders (as defined below) under present law of an investment in our ordinary shares. This discussion applies only to U.S. Holders that hold our ordinary shares as capital assets within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended (the "Code"), that have acquired their ordinary shares or ADSs and that have the U.S. dollar as their functional currency.

This discussion is based on the tax laws of the United States, including the Code, as in effect on the date hereof and on U.S. Treasury regulations as in effect or, in some cases, as proposed, on the date hereof, as well as judicial and administrative interpretations thereof available on or before such date. All of the foregoing authorities are subject to change, which change could apply retroactively and could affect the tax consequences described below. This summary does not address any estate or gift tax consequences, the alternative minimum tax, the Medicare tax on net investment income or any state, local, or non-U.S. tax consequences.

The following discussion neither deals with the tax consequences to any particular investor nor describes all of the tax consequences applicable to persons in special tax situations such as:

- banks;
- certain financial institutions;
- insurance companies;
- regulated investment companies;
- real estate investment trusts;
- broker-dealers;
- traders that elect to mark to market;
- U.S. expatriates;
- tax-exempt entities;
- persons holding our ordinary shares as part of a straddle, hedging, constructive sale, conversion or integrated transaction;
- persons that actually or constructively own 10% or more of the total combined voting power of all classes of our voting share capital;
- persons that are resident or ordinarily resident in or have a permanent establishment in a jurisdiction outside the United States;
- persons who acquired our ordinary shares pursuant to the exercise of any employee share option or otherwise as compensation; or
- pass-through entities, or persons holding our ordinary shares through pass-through entities.

INVESTORS ARE URGED TO CONSULT THEIR TAX ADVISORS ABOUT THE APPLICATION OF THE U.S. FEDERAL TAX RULES TO THEIR PARTICULAR CIRCUMSTANCES AS WELL AS THE STATE, LOCAL, NON-U.S. AND OTHER TAX CONSEQUENCES TO THEM OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES.

The discussion below of the U.S. federal income tax consequences to "U.S. Holders" will apply to you if you are the beneficial owner of our ordinary shares and you are, for U.S. federal income tax purposes,

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized in the United States or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust that (1) is subject to the primary supervision of a court within the United States and the control of one or more U.S. persons for all substantial decisions or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

If an entity or other arrangement treated as a partnership for U.S. federal income tax purposes holds our ordinary shares, the tax treatment of a partner will generally depend upon the status of the partner and the activities of the partnership. A person that would be a U.S. Holder if it held our ordinary shares directly and that is a partner of a partnership holding our ordinary shares is urged to consult its own tax advisor.

Passive Foreign Investment Company

Based on our anticipated income and the composition of our income and assets, there is a significant risk that we will be a passive foreign investment company ("PFIC") for U.S. federal income tax purposes at least until we start generating a substantial amount of active revenue. However, because PFIC status is a factual determination based on actual results for the entire taxable year, our U.S. counsel expresses no opinion with respect to our PFIC status. A non-U.S. entity treated as a corporation for U.S. federal income tax purposes will generally be a PFIC for U.S. federal income tax purposes for any taxable year if either:

- at least 75% of its gross income for such year is passive income (such as interest income); or
- at least 50% of the value of its assets (based on an average of the quarterly values of the assets) during such year is attributable to assets that produce passive income or are held for the production of passive income.

For this purpose, we will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of any other entity treated as a corporation for U.S. federal income tax purposes in which we own, directly or indirectly, 25% or more (by value) of the stock.

A separate determination must be made after the close of each taxable year as to whether we were a PFIC for that year. Because the value of our assets for purposes of the PFIC test will generally be determined by reference to the market price of our ordinary shares, our PFIC status may depend in part on the market price of our ordinary shares, which may fluctuate significantly. In addition, there may be certain ambiguities in applying the PFIC test to us. No rulings from the U.S. Internal Revenue Service (the "IRS"), however, have been or will be sought with respect to our status as a PFIC.

If we are a PFIC for any taxable year during which you hold our ordinary shares, we generally will continue to be treated as a PFIC with respect to your investment in our ordinary shares for all succeeding years during which you hold our ordinary shares, unless we cease to be a PFIC and you make a "deemed sale" election with respect to our ordinary shares. If such election is made, you will be deemed to have sold our ordinary shares you hold at their fair market value on the last day of the last taxable year in which we were a PFIC, and any gain from such deemed sale would be subject to the consequences described below. After the deemed sale election, your ordinary shares with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC.

For each taxable year that we are treated as a PFIC with respect to you, you will be subject to special tax rules with respect to any "excess distribution" (as defined below) you receive and any gain you realize from a sale or other disposition (including a pledge) of our ordinary shares, unless you make a valid "mark-to-market" election as discussed below. Distributions you receive in a taxable year that are greater than 125% of the average annual distributions you received during the shorter of the three preceding taxable years or your holding period for our ordinary shares will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over your holding period for our ordinary shares;
- the amount allocated to the current taxable year, and any taxable years in your holding period prior to the first taxable year in which we were a PFIC, will be treated as ordinary income; and
- the amount allocated to each other taxable year will be subject to the highest tax rate in effect for individuals or corporations, as applicable, for each such year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to taxable years prior to the year of disposition or excess distribution cannot be offset by any net operating losses, and gains (but not losses) realized on the sale of our ordinary shares cannot be treated as capital gains, even if you hold our ordinary shares as capital assets.

If we are treated as a PFIC with respect to you for any taxable year, to the extent any of our subsidiaries are also PFICs, you may be deemed to own shares in such lower-tier PFICs that are directly or indirectly owned by us in that proportion which the value of our ordinary shares you own bears to the value of all of our ordinary shares, and you may be subject to the adverse tax consequences described above with respect to the shares of such lower-tier PFICs you would be deemed to own. As a result, you may incur liability for any excess distribution described above if we receive a distribution from our lower-tier PFICs or if any shares in such lower-tier PFICs are disposed of (or deemed disposed of). You should consult your tax advisor regarding the application of the PFIC rules to any of our subsidiaries.

A U.S. Holder of "marketable stock" (as defined below) in a PFIC may make a mark-to-market election for such stock to elect out of the tax treatment discussed above. If you make a valid mark-to-market election for our ordinary shares, you will include in income for each year that we are treated as a PFIC with respect to you an amount equal to the excess, if any, of the fair market value of our ordinary shares as of the close of your taxable year over your adjusted basis in such ordinary shares. You will be allowed a deduction for the excess, if any, of the adjusted basis of our ordinary shares over their fair market value as of the close of the taxable year. However, deductions will be allowable only to the extent of any net mark-to-market gains on our ordinary shares included in your income for prior taxable years. Amounts included in your income under a mark-to-market election, as well as gain on the actual sale or other disposition of our ordinary shares, will be treated as ordinary income. Ordinary loss treatment will also apply to the deductible portion of any mark-to-market loss on our ordinary shares, as well as to any loss realized on the actual sale or disposition of our ordinary shares, to the extent the amount of such loss does not exceed the net mark-to-market gains for such ordinary shares previously included in income. Your basis in our ordinary shares will be adjusted to reflect any such income or loss amounts. If you make a mark-to-market election, any distributions we make would generally be subject to the rules discussed below under "— Taxation of dividends and other distributions on our ordinary shares," except the lower rates applicable to qualified dividend income would not apply.

The mark-to-market election is available only for "marketable stock," which is stock that is regularly traded on a qualified exchange or other market, as defined in applicable U.S. Treasury regulations. We expect our ordinary shares will be listed on NASDAQ. Because a mark-to-market election cannot be made for equity interests in any lower-tier PFICs we own, you generally will continue to be subject to the PFIC rules with respect to your indirect interest in any investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. The NASDAQ is a qualified exchange, but there can be no assurance that the trading in our ordinary shares will be sufficiently regular to qualify our ordinary shares as marketable stock. You should consult your tax advisor as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs. Alternatively, if a non-U.S. entity treated as a corporation is a PFIC, a holder of shares in that entity may avoid taxation under the PFIC rules described above regarding excess distributions and recognized gains by making a "qualified electing fund" election to include in income its share of the entity's income on a current basis. However, you may make a qualified electing fund election with respect to your ordinary shares only if we furnish you annually with certain tax information, and we currently do not intend to prepare or provide such information.

A U.S. Holder of a PFIC may be required to file an IRS Form 8621. If we are a PFIC, you should consult your tax advisor regarding any reporting requirements that may apply to you. You are urged to consult your tax advisor regarding the application of the PFIC rules to the acquisition, ownership and disposition of our ordinary shares.

YOU ARE STRONGLY URGED TO CONSULT YOUR TAX ADVISOR REGARDING THE IMPACT OF OUR BEING A PFIC ON YOUR INVESTMENT IN OUR ORDINARY SHARES AS WELL AS THE APPLICATION OF THE PFIC RULES AND THE POSSIBILITY OF MAKING A MARK-TO-MARKET ELECTION.

Taxation of Dividends and Other Distributions on our Ordinary Shares

Subject to the PFIC rules discussed above, the gross amount of any distributions we make to you (including the amount of any tax withheld) with respect to our ordinary shares generally will be includible in your gross income as dividend income on the date of receipt by the holder, but only to the extent the distribution is paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). The dividends will not be eligible for the dividends-received deduction allowed to corporations in respect of dividends received from other U.S. corporations. To the extent the amount of the distribution exceeds our current and accumulated earnings and profits (as determined under U.S. federal income tax principles), such excess amount will be treated first as a tax-free return of your tax basis in your ordinary shares, and then, to the extent such excess amount exceeds your tax basis in your ordinary shares, as capital gain. We currently do not, and we do not intend to, calculate our earnings and profits under U.S. federal income tax principles. Therefore, you should expect that a distribution will generally be reported as a dividend even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above.

With respect to certain non-corporate U.S. Holders, including individual U.S. Holders, dividends may be taxed at the lower capital gain rates applicable to "qualified dividend income," provided (1) our ordinary shares are readily tradable on an established securities market in the United States (such as NASDAQ), (2) we are neither a PFIC nor treated as such with respect to you (as discussed above) for either the taxable year in which the dividend was paid or the preceding taxable year, (3) certain holding period requirements are met and (4) you are not under an obligation to make related payments with respect to positions in substantially similar or related property. As discussed above under "Passive foreign investment company," there is a significant risk that we will be a PFIC for U.S. federal income tax purposes, and, as a result, the qualified dividend rate may be unavailable with respect to dividends we pay.

The amount of any distribution paid in a currency other than U.S. dollars will be equal to the U.S. dollar value of such currency on the date such distribution is includible in your income, regardless of whether the payment is in fact converted into U.S. dollars at that time. The amount of any distribution of property other than cash will be the fair market value of such property on the date of distribution.

Any dividends will constitute foreign source income for foreign tax credit limitation purposes. If the dividends are taxed as qualified dividend income (as discussed above), the amount of the dividend taken into account for purposes of calculating the foreign tax credit limitation will in general be limited to the gross amount of the dividend, multiplied by the reduced tax rate applicable to qualified dividend income and divided by the highest tax rate normally applicable to dividends. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends distributed by us with respect to our ordinary shares will generally constitute "passive category income" but could, in the case of certain U.S. Holders, constitute "general category income."

If Israeli withholding taxes apply to any dividends paid to you with respect to our ordinary shares, subject to certain conditions and limitations, such withholding taxes may be treated as foreign taxes eligible for credit against your U.S. federal income tax liability. Instead of claiming a credit, you may elect to deduct such taxes in computing taxable income, subject to applicable limitations. If a refund of the tax withheld is available under the applicable laws of Israel or under the Israel-U.S. income tax treaty (the "Treaty"), the amount of tax withheld that is refundable will not be eligible for such credit against your U.S. federal income tax liability (and will not be eligible for the deduction against your U.S. federal taxable income). The rules relating to the determination of the foreign tax credit are complex, and you should consult your tax advisor regarding the availability of a foreign tax credit in your particular circumstances, including the effects of the Treaty.

Taxation of Disposition of Ordinary Shares

Subject to the PFIC rules discussed above, upon a sale or other disposition of ordinary shares, you will generally recognize capital gain or loss for U.S. federal income tax purposes in an amount equal to the difference between the amount realized (including the amount of any tax withheld) and your tax basis in such ordinary shares. If the consideration you receive for our ordinary shares is not paid in U.S. dollars, the amount realized will be the U.S. dollar value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition. However, if our ordinary shares are treated as traded on an "established securities market" and you are either a cash basis taxpayer or an accrual basis taxpayer that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), you will determine the U.S. dollar value of the amount realized in a non-U.S. dollar currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If you are an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, you will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of sale or disposition and the U.S. dollar value of the currency received at the spot rate on the settlement date.

Your tax basis in our ordinary shares generally will equal the cost of such ordinary shares. Any gain or loss on the sale or other disposition of our ordinary shares will generally be treated as U.S. source income or loss, and treated as long-term capital gain or loss if your holding period in our ordinary shares at the time of the disposition exceeds one year. Accordingly, in the event any Israeli tax (including withholding tax) is imposed upon the sale or other disposition, you may not be able to utilize foreign tax credit unless you have foreign source income or gain in the same category from other sources. Long-term capital gain of non-corporate U.S. Holders generally will be subject to U.S. federal income tax at reduced tax rates. The deductibility of capital losses is subject to significant limitations.

Information Reporting and Backup Withholding

Dividend payments with respect to ordinary shares and proceeds from the sale, exchange or redemption of ordinary shares may be subject to information reporting to the IRS and possible U.S. backup withholding. Backup withholding will not apply, however, to a U.S. Holder that furnishes a correct taxpayer identification number and makes any other required certification or that is otherwise exempt from backup withholding. U.S. Holders that are required to establish their exempt status generally must provide such certification on IRS Form W-9. You should consult your tax advisor regarding the application of the U.S. information reporting and backup withholding rules.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against your U.S. federal income tax liability, and you may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the IRS and furnishing any required information in a timely manner.

Information with respect to Foreign Financial Assets

Certain U.S. Holders may be required to report information relating to an interest in our ordinary shares, subject to certain exceptions (including an exception for ordinary shares held in accounts maintained by certain U.S. financial institutions). Penalties can apply if U.S. Holders fail to satisfy such reporting requirements. You should consult your tax advisor regarding the effect, if any, of this requirement on your ownership and disposition of our ordinary shares.

THE SUMMARY OF U.S. FEDERAL INCOME TAX CONSEQUENCES SET OUT ABOVE IS FOR GENERAL INFORMATIONAL PURPOSES ONLY. INVESTORS ARE URGED TO CONSULT THEIR TAX ADVISORS ABOUT THE APPLICATION OF THE U.S. FEDERAL TAX RULES TO THEIR PARTICULAR CIRCUMSTANCES AS WELL AS THE STATE, LOCAL, NON-U.S. AND OTHER TAX CONSEQUENCES TO THEM OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES.

B. Dividends and Paying Agents

Not applicable.

C. Statement by Experts

Not applicable.

D. Documents on Display

We are subject to the informational requirements of the United States Securities Exchange Act of 1934, as amended, and in accordance therewith file annual and special reports with, and furnish other information to, the SEC. You may read and copy the registration statement and any other documents we have filed at the SEC, including any exhibits and schedules, at the SEC's public reference room at 100 F Street N.E., Washington, D.C. 20549. You may call the SEC at 1-800-SEC-0330 for further information on this public reference room. In addition, the SEC maintains a web site that contains reports and other information regarding issuers that file electronically with the SEC. You may access the SEC's website at http://www.sec.gov. These SEC filings are also available to the public on the Israel Securities Authority's Magna website at www.magna.isa.gov.il and from commercial document retrieval services.

As a foreign private issuer, we will be exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. However, we will be required to comply with the informational requirements of the Securities Exchange Act of 1934, as amended, applicable to foreign private issuers, and, accordingly, will file current reports on Form 6-K, annual reports on Form 20-F and other information with the Securities and Exchange Commission.

In addition, because our ordinary shares are traded on the TASE, we have filed Hebrew language periodic and immediate reports with, and furnish information to, the TASE and the ISA, as required under Chapter Six of the Israeli Securities Law, 5768-1968. Copies of our filings with the ISA can be retrieved electronically through the MAGNA distribution site of the ISA (www.magna.isa.gov.il) and the TASE website (www.maya.isa.gov.il). We maintain a corporate website at www.medigus.com. Information contained on, or that can be accessed through, our website does not constitute a part of this annual report on Form 20-F.

E. Subsidiary Information

Not applicable**.**

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk is the risk of loss related to changes in market prices, including interest rates and foreign exchange rates, of financial instruments that may adversely impact our consolidated financial position, results of operations or cash flows.

Risk of Interest Rate Fluctuation

Currently, our investments consist primarily of cash and cash equivalents, short-term bank deposits and tradable short term Israeli government loans that can be sold in the securities markets of Israel. We follow an investment policy that was set by the investment committee of our board of directors, pursuant to which we currently invest in tradable short term Israeli government loans or bank deposits. Our investments are exposed to market risk due to fluctuation in interest rates, which may affect our interest income and the fair market value of our investments. However, given the low levels of interest rates worldwide, our interest income is not material and a further reduction in interest rates would not cause us a significant reduction in the absolute amounts of interest income to us. We manage this exposure by performing ongoing evaluations of our investments. Due to the short-term maturities of our investments to date, their carrying value has always approximated their fair value. It is be our current policy to hold investments to maturity in order to limit our exposure to interest rate fluctuations.

Foreign Currency Exchange Risk

Our reporting and functional currency is the U.S. dollar. Our revenues are currently primarily payable in U.S. dollars and Euros and we expect our future revenues to be denominated primarily in U.S. dollars and Euros. However, certain amount of our expenses are in NIS and as a result, we are exposed to the currency fluctuation risks relating to the recording of our expenses in U.S. dollars. We may, in the future, decide to enter into currency hedging transactions. These measures, however, may not adequately protect us from material adverse effects.

To date, we have not engaged in hedging transactions, however we hold our investments in both NIS and US dollars. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

Our interest rate risk exposure is in respect to bank deposits, which expose us to risk due to change in fair value interest rates. As of December 31, 2016, these deposits carried low interest rates and under these low interest rates, reasonable changes in interest rates are expected have negligible impact on the fair value of these assets.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities.

Not applicable.

B. Warrants and rights.

Not applicable.

C. Other Securities.

Not applicable.

D. American Depositary Shares

General

The following is a summary description of the ADSs and does not purport to be complete. Each ADS represents 50 ordinary shares (or a right to receive 50 ordinary shares) deposited with the principal Tel Aviv office of either of Bank Hapoalim or Bank Leumi, as custodian for the Bank of New York Mellon as the Depositary. Each ADS also represents any other securities, cash or other property which may be held by the Depositary. The Depositary's office at which the ADSs will be administered is located at 101 Barclay Street, New York, New York 10286. The Bank of New York Mellon's principal executive office is located at 225 Liberty Street, New York, New York 10286.

You may hold ADSs either (A) directly (i) by having an American Depositary Receipt, or ADR, which is a certificate evidencing a specific number of ADSs, registered in your name, or (ii) by having uncertificated ADSs registered in your name, or (B) indirectly by holding a security entitlement in ADSs through your broker or other financial institution. If you hold ADSs directly, you are a registered ADS holder, also referred to as an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs will receive statements from the Depositary confirming their holdings. As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. Israeli law governs shareholder rights. The Depositary will be the holder of the shares underlying your ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the Depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the Depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR.

Dividends and Other Distributions

How will you receive dividends and other distributions on the shares?

The Depositary has agreed to pay to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. You will receive these distributions in proportion to the number of shares your ADSs represent.

Cash. The Depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the Depositary to distribute the NIS only to those ADS holders to whom it is possible to do so. It will hold the NIS it cannot convert for the account of the ADS holders who have not been paid. It will not invest the NIS and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. For more information see "Item 10. Addition Information—E. Taxation." The Depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the Depositary cannot convert the NIS, you may lose some or all of the value of the distribution.*

Shares. The Depositary may distribute additional ADSs representing any shares we distribute as a dividend or free distribution. The Depositary will only distribute whole ADSs. It will sell shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the Depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The Depositary may sell a portion of the distributed shares sufficient to pay its fees and expenses in connection with that distribution (or ADSs representing those shares).

Rights to purchase additional shares. If we offer holders of our securities any rights to subscribe for additional ordinary shares or any other rights, the Depositary may make these rights available to ADS holders. If the Depositary decides it is not legal and practical to make the rights available but that it is practical to sell the rights, the Depositary will use reasonable efforts to sell the rights and distribute the proceeds in the same way as it does with cash. The Depositary will allow rights that are not distributed or sold to lapse. *In that case, you will receive no value for them.*

If the Depositary makes rights available to ADS holders, it will exercise the rights and purchase the shares on your behalf. The Depositary will then deposit the shares and deliver ADSs to the persons entitled to them. It will only exercise rights if you pay it the exercise price and any other charges the rights require you to pay.

U.S. securities laws may restrict transfers and cancellation of the ADSs represented by shares purchased upon exercise of rights. For example, you may not be able to trade these ADSs freely in the United States. In this case, the Depositary may deliver restricted depositary shares that have the same terms as the ADSs described in this section except for changes needed to put the necessary restrictions in place.

Other Distributions. The Depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the Depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the Depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The Depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution.

The Depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. *This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you*.

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The Depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the Depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

You may surrender your ADSs at the Depositary's office. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the Depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the Depositary will deliver the deposited securities at its office, if feasible.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

You may surrender your ADR to the Depositary for the purpose of exchanging your ADR for uncertificated ADSs. The Depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Alternatively, upon receipt by the Depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the Depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

Voting Rights

How do you vote?

ADS holders may instruct the Depositary how to vote the number of deposited shares their ADSs represent. The Depositary will notify ADS holders of shareholders' meetings and arrange to deliver our voting materials to them if we ask it to. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the Depositary how to vote. For instructions to be valid, they much reach the Depositary by a date set by the Depositary. *Otherwise, you won't be able to exercise your right to vote unless you withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares.*

The Depositary will try, as far as practical, subject to the laws of Israel, and of our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. The Depositary will only vote or attempt to vote as instructed.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the Depositary to vote your shares. In addition, the Depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that you may not be able to exercise your right to vote and there may be nothing you can do if your shares are not voted as you requested.*

In order to give you a reasonable opportunity to instruct the Depositary as to the exercise of voting rights relating to deposited securities, if we request the Depositary to act, we agree to give the Depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

Each of our American Depositary Shares, or ADSs, represents 50 of our ordinary shares. The ADSs trade on the NASDAQ Capital Market.

The form of the deposit agreement for the ADSs and the form of American Depositary Receipt (ADR) that represents an ADS as filed as exhibits to the Company's registration statement on Form F-6 with the SEC on May 7, 2015. Copies of the deposit agreement are available for inspection at the principal office of the Bank of New York Mellon, located at 101 Barclay Street, New York, New York 10286, and at the principal office of our custodians Bank Hapoalim B.M., 104 Hayarkon Street, Tel Aviv 63432, Israel.

Fees and Expenses

***Persons depositing or withdrawing shares or ADS holders must pay*:**	***For*:**
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	● Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property ● Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$.05 (or less) per ADS	● Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs	● Distribution of securities distributed to holders of deposited securities which are distributed by the Depositary to ADS holders
$.05 (or less) per ADS per calendar year	● Depositary services
Registration or transfer fees	● Transfer and registration of shares on our share register to or from the name of the Depositary or its agent when you deposit or withdraw shares
Expenses of the Depositary	● Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement) ● converting foreign currency to U.S. dollars
Taxes and other governmental charges the Depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	● As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	● As necessary

The Depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The Depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The Depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The Depositary may collect any of its fees by deduction from any cash distribution payable to ADS holders that are obligated to pay those fees. The Depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the Depositary may make payments to us to reimburse and/or share revenue from the fees collected from ADS holders, or waive fees and expenses for services provided, generally relating to costs and expenses arising out of establishment and maintenance of the ADS program. In performing its duties under the deposit agreement, the Depositary may use brokers, dealers or other service providers that are affiliates of the Depositary and that may earn or share fees or commissions.

Payment of Taxes

You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The Depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until such taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the Depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

Reclassifications, Recapitalizations and Mergers

If we:	***Then:***
● Change the nominal or par value of our shares ● Reclassify, split up or consolidate any of the deposited securities ● Distribute securities on the shares that are not distributed to you ● Recapitalize, reorganize, merge, liquidate, sell all or substantially all of our assets, or take any similar action	The cash, shares or other securities received by the Depositary will become deposited securities. Each ADS will automatically represent its equal share of the new deposited securities. The Depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the Depositary to amend the deposit agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the Depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the Depositary notifies ADS holders of the amendment. *At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended*.

How may the deposit agreement be terminated?

The Depositary will terminate the deposit agreement at our direction by mailing notice of termination to the ADS holders then outstanding at least 30 days prior to the date fixed in such notice for such termination. The Depositary may also terminate the deposit agreement by mailing notice of termination to us and the ADS holders if 60 days have passed since the Depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment.

After termination, the Depositary and its agents will do the following under the deposit agreement but nothing else: collect distributions on the deposited securities, sell rights and other property, and deliver shares and other deposited securities upon cancellation of ADSs. Four months after termination, the Depositary may sell any remaining deposited securities by public or private sale. After that, the Depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement for the pro rata benefit of the ADS holders that have not surrendered their ADSs. It will not invest the money and has no liability for interest. The Depositary's only obligations will be to account for the money and other cash. After termination our only obligations will be to indemnify the Depositary and to pay fees and expenses of the Depositary that we agreed to pay.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the Depositary. It also limits our liability and the liability of the Depositary. We and the Depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith;
- are not liable if we are or it is prevented or delayed by law or circumstances beyond our or its control from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person.

In the deposit agreement, we and the Depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the Depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the Depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The Depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the Depositary or our transfer books are closed or at any time if the Depositary or we think it advisable to do so.

Right to Receive the Shares Underlying your ADSs

ADS holders have the right to cancel their ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because: (i) the Depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our shares;
- when you owe money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Pre-release of ADSs

The deposit agreement permits the Depositary to deliver ADSs before deposit of the underlying shares. This is called a pre-release of the ADSs. The Depositary may also deliver shares upon cancellation of pre-released ADSs (even if the ADSs are canceled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying shares are delivered to the Depositary. The Depositary may receive ADSs instead of shares to close out a pre-release. The Depositary may pre-release ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made represents to the Depositary in writing that it or its customer owns the shares or ADSs to be deposited; (2) the pre-release is fully collateralized with cash or other collateral that the Depositary considers appropriate; and (3) the Depositary must be able to close out the pre-release on not more than five business days' notice. In addition, the Depositary will limit the number of ADSs that may be outstanding at any time as a result of pre-release, although the Depositary may disregard the limit from time to time if it thinks it is appropriate to do so.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, or DRS, and Profile Modification System, or Profile, will apply to uncertificated ADSs upon acceptance thereof to DRS by the Depository Trust Company, or DTC. DRS is the system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is a required feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of ADSs, to direct the Depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the Depositary of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the Depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the Depositary's reliance on and compliance with instructions received by the Depositary through the DRS/Profile System and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the Depositary.

Shareholder communications; inspection of register of holders of ADSs

The Depositary will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The Depositary will send you copies of those communications if we ask it to. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

There are no defaults, dividend arrangements or delinquencies that are required to be disclosed.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

(a) Disclosure controls and procedures

We performed an evaluation of the effectiveness of our disclosure controls and procedures that are designed to ensure that information required to be disclosed on Form 20-F and filed with the Securities and Exchange Commission is recorded, processed, summarized and reported timely within the time period 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 an issuer in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. There can be no assurance that our disclosure controls and procedures will detect or uncover all failures of persons within the company to disclose information otherwise required to be set forth in our reports. Nevertheless, our disclosure controls and procedures are designed to provide reasonable assurance of achieving the desired control objectives. Based on our evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15(d) - 15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this annual report on Form 20-F are effective at such reasonable assurance level.

(b) Management report on internal control over financial reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Based principally on the framework in Internal Control - Integrated Framework (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management has concluded that our internal control over financial reporting was effective as of December 31, 2016.

Attestation Report of the Registered Public Accounting Firm

Not applicable.

(c) Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that Mr. Birger and Mr. Machover qualifies as an "audit committee financial expert" and that he is independent under the applicable SEC and Nasdaq Marketplace rules.

ITEM 16B. CODE OF ETHICS

In March 2016, we adopted a code of ethics, which applies to all our directors, officers and employees, including without limitation our, Chief Executive Officer, Chief Financial Officer, and controller, or persons performing similar functions. This code of ethics is posted on our website, www.medigus.com.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees and services

The table below summarizes the total amounts that we were billed by our independent accountants, Kesselman & Kesselman, an independent registered public accounting firm, a member firm of PricewaterhouseCoopers International Limited, related to the following periods.

	Year Ended December 31, 2015	Year Ended December 31, 2016
	(USD in thousands)	
Audit fees[1]	120	128
Tax Fees[2]		10
Total	120	138

(1) Includes professional services rendered in connection with the audit of our annual financial statements and the review of our interim financial statements. Includes professional fees related to annual tax returns.
(2) Represents fees paid for tax consulting services.

Audit committee's pre-approval policies and procedures

Our audit committee's specific responsibilities in carrying out its oversight of the quality and integrity of the accounting, auditing and reporting practices of the Company include the approval of audit and non-audit services to be provided by the external auditor. The audit committee approves in advance the particular services or categories of services to be provided to the Company during the following yearly period and also sets forth a specific budget for such audit and non-audit services. Additional non-audit services may be pre-approved by the audit committee.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

None.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

Nasdaq Stock Market Listing Rules and Home Country Practices

As a foreign private issuer, we are permitted to follow Israeli corporate governance practices instead of Nasdaq Marketplace rules, provided that we disclose which requirements we are not following and the equivalent Israeli requirement. We rely on this "foreign private issuer exemption" with respect to the following items:

- *Distribution of Annual and Quarterly Reports to Shareholders*. Under Israeli law, as a public company whose shares are traded on the TASE, we are not required to distribute annual and quarterly reports directly to shareholders and the generally accepted business practice in Israel is not to distribute such reports to shareholders but to make such reports publicly available through the website of the Israeli Securities Authority and the TASE. In addition, we make our audited financial statements available to our shareholders at our offices. As a foreign private issuer, we are generally exempt from the SEC's proxy solicitation rules.

- *Quorum*. While the Marketplace Rules of the Nasdaq Stock Market require that the quorum for purposes of any meeting of the holders of a listed company's common voting stock, as specified in the company's bylaws, be no less than 33 1/3% of the company's outstanding common voting stock, under Israeli law, a company is entitled to determine in its articles of association the number of shareholders and percentage of holdings required for a quorum at a shareholders meeting. Our Articles of Association provide that a quorum of two or more shareholders holding at least 10% of the voting rights in person or by proxy is required for commencement of business at a general meeting. However, the quorum set forth in our Articles of Association with respect to an adjourned meeting consists of any number of shareholders present in person or by proxy.

- *Independent Directors*. Our board of directors presently includes two external directors who were appointed in accordance with the Companies and one independent director pursuant to the definitions of the Companies Law, as determined by our board of directors, rather than a majority of external, or independent, directors. Israeli law does not require, nor do our independent directors conduct, regularly scheduled meetings at which only they are present. We are required, however, to ensure that all members of our Audit Committee are "independent" under the applicable Nasdaq and SEC criteria for independence, and we must also ensure that a majority of the members of our Audit Committee are unaffiliated directors as defined in the Companies Law.

- *Audit Committee*. Israeli law, and our Articles of Association, do not require that the Company adopt and file an audit committee charter. Consistent with Israeli law, the independent auditors are elected at a meeting of shareholders instead of being appointed by the Audit Committee.

- *Nomination of our Directors*. With the exception of our external directors and directors elected by our board of directors due to vacancy, our directors are elected by a general or special meeting of our shareholders. Other than external directors, our directors are appointed to hold office until the subsequent annual general meeting or they are removed from office by the majority of our shareholders at a general or special meeting of our shareholders. The nominations for directors, which are presented to our shareholders, are generally made by our directors, but nominations may be made by one or more of our shareholders as provided in our Articles of Association, under the Companies Law or in an agreement between us and our shareholders. In accordance with our Articles of Association, under the Companies Law, any one or more shareholders holding, in the aggregate, either (1) 5% of our outstanding shares and 1% of our outstanding voting power or (2) 5% of our outstanding voting power, may nominate one or more persons for election as directors at a general or special meeting by delivering a written notice of such shareholder's intent to make such nomination or nominations to our registered office. Each such notice must set forth all of the details and information as required to be provided by our Articles of Association.

- *Compensation Committee and Compensation of Officers*. Israeli law, and our Articles of Association, do not require that the Company adopt and file a compensation committee charter. Our compensation committee has been established and conducts itself in accordance with provisions governing the composition of and the responsibilities of a compensation committee as set forth in the Companies Law. Additionally, we comply with the requirements set forth under the Companies Law, pursuant to which transactions with office holders regarding their terms of office and employment, and transactions with a controlling shareholder in a company regarding his or her employment and/or his or her terms of office with the company, may require the approval of the compensation committee, the board of directors and under certain circumstances the shareholders, either in accordance with our previously approved compensation policy or, in special circumstances in deviation therefrom, taking into account certain considerations set forth in the Companies Law. The requirements for shareholder approval of any office holder compensation, and the relevant majority or special majority for such approval, are all as set forth in the Companies Law. Thus, we will seek shareholder approval for all corporate actions with respect to office holder compensation requiring such approval under the requirements of the Companies Law, including seeking prior approval of the shareholders for the compensation policy and for certain office holder compensation, rather than seeking approval for such corporate actions in accordance with Nasdaq Listing Rules.

- *Approval of Related Party Transactions*. All related party transactions are approved in accordance with the requirements and procedures for approval of interested party acts and transactions, set forth in sections 268 to 275 of the Companies Law, and the regulations promulgated thereunder, which require the approval of the audit committee, the compensation committee, the board of directors and shareholders, as may be applicable, for specified transactions, rather than approval by the audit committee or other independent body of our board of directors as required under the Marketplace Rules of the Nasdaq Stock Market.

- *Equity Compensation Plans.* We do not necessarily seek shareholder approval for the establishment of, and amendments to, stock option or equity compensation plans (as set forth in NASDAQ Listing Rule 5635(c)), as such matters are not subject to shareholder approval under Israeli law. We will attempt to seek shareholder approval for our stock option or equity compensation plans (and the relevant annexes thereto) to the extent required in order to ensure they are tax qualified for our employees in the United States. However, even if such approval is not received, then the stock option or equity compensation plans will continue to be in effect, but we will not be able to grant options to our U.S. employees that qualify as Incentive Stock Options for U.S. federal tax purpose. Our stock option or other equity compensation plans are also available to our non-U.S. employees, and provide features necessary to comply with applicable non-U.S. tax laws.

Otherwise, we comply with the rules generally applicable to U.S. domestic companies listed on the Nasdaq Stock Market. We may in the future decide to use the foreign private issuer exemption with respect to some or all of the other Nasdaq Marketplace Rules related to corporate governance. We also comply with Israeli corporate governance requirements under the Israeli Companies Law applicable to public companies.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS

Not applicable.

ITEM 18. FINANCIAL STATEMENTS

The consolidated financial statements and the related notes required by this Item are included in this annual report on Form 20-F beginning on page F-1.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders of

MEDIGUS Ltd.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of loss and other comprehensive loss, changes in equity and cash flows present fairly, in all material respects, the financial position of Medigus Ltd. and its subsidiary as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2016 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board. These financial statements are the responsibility of the Company's Board of Directors and management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by the Board of Directors and management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1c to the financial statements, the Company has suffered recurring losses from operations and negative cash flows from operating activities. These factors, among others, raise substantial doubt about its ability to continue as a going concern. Management's plans in regards to these matters are also described in Note 1c. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 1b to the consolidated financial statements, the Company changed its functional and reporting currency from New Israel Shekels to US dollars as of January 1, 2016.

Tel-Aviv, Israel
March 30, 2017

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel,
P.O Box 50005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il

MEDIGUS LTD.
CONSOLIDATED BALANCE SHEETS

	Note	December 31, 2016	December 31, 2015	January 1, 2015
		USD in thousands		
Assets				
CURRENT ASSETS:				
Cash and cash equivalents	5	3,001	10,312	10,817
Financial assets at fair value through profit or loss				2,105
Accounts receivable, net:	6			
Trade		21	254	132
Other		366	1,006	446
Inventory	2 (h),7	198	304	361
		3,586	11,876	13,861
NON-CURRENT ASSETS:				
Inventory	2 (h),7	934		139
Property and equipment	8	178	226	243
Intangible assets		26	39	48
		1,138	265	430
TOTAL ASSETS		4,724	12,141	14,291

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

MEDIGUS LTD.
CONSOLIDATED BALANCE SHEETS

	Note	December 31 2016	December 31 2015	January 1, 2015
		USD in thousands		
Liabilities and equity				
CURRENT LIABILITIES -				
Accounts payable and accruals:	10			
Trade		367	358	204
Other		967	1,495	829
		1,334	1,853	1,033
NON-CURRENT LIABILITIES:				
Long-term advanced payments		149		
Warrants at fair value	4	237	9	110
Retirement benefit obligation, net		77	98	98
		463	107	208
COMMITMENTS AND CONTINGENT LIABILITIES	11			
TOTAL LIABILITIES		1,797	1,960	1,241
EQUITY:	12			
Ordinary share capital		1,189	870	683
Share premium		53,817	51,990	46,066
Other capital reserves		200	118	296
Warrants		1,057	1,532	802
Accumulated deficit		(53,336)	(44,329)	(34,797)
TOTAL EQUITY		2,927	10,181	13,050
TOTAL LIABILITIES AND EQUITY		4,724	12,141	14,291

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

MEDIGUS LTD.
CONSOLIDATED STATEMENTS OF LOSS AND OTHER COMPREHENSIVE LOSS

	Note	Year Ended December 31		
		2016	2015	2014
		USD in thousands		
REVENUES	17	549	624	744
COST OF REVENUES	13	176	277	351
GROSS PROFIT		373	347	393
RESEARCH AND DEVELOPMENT EXPENSES	13	3,655	4,384	4,025
SELLING AND MARKETING EXPENSES	13	2,125	2,680	2,341
ADMINISTRATIVE AND GENERAL EXPENSES	13	3,684	2,842	2,280
OTHER INCOME, NET	14		3	269
OPERATING LOSS		(9,091)	(9,556)	(7,984)
PROFIT FROM CHANGES IN FAIR VALUE OF WARRANTS ISSUED TO INVESTORS	4	25	106	980
FINANCING INCOME IN RESPECT OF DEPOSITS AND EXCHANGE DIFFERENCES		99	19	685
FINANCING EXPENSES IN RESPECT OF BANK COMMISSIONS		(12)	(33)	(35)
FINANCING INCOME (EXPENSES), NET		87	(14)	650
LOSS BEFORE TAXES ON INCOME		(8,979)	(9,464)	(6,354)
TAXES ON INCOME	9	(28)	(68)	(4)
LOSS FOR THE YEAR		(9,007)	(9,532)	(6,358)
OTHER COMPREHENSIVE LOSS:				
Amounts which will not be reclassified to profit or loss -				
re-measurement of net liabilities for employee benefits				(27)
Currency translation differences			(211)	(1,546)
OTHER COMPREHENSIVE LOSS FOR THE YEAR, net of tax			(211)	(1,573)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		(9,007)	(9,743)	(7,931)
		USD		
BASIC AND DILUTED LOSS PER SHARE	15	(0.26)	(0.34)	(0.33)
WEIGHTED AVERAGE ORDINARY SHARES OUTSTANDING (IN THOUSANDS)		34,397	28,415	19,500

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

MEDIGUS LTD.
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

		Equity attributed to the owners of the company							
	Note	Ordinary shares	Share premium	Capital reserves from options granted	Capital reserves from transactions with controlling shareholders	Currency translation differences	Warrants	Accumulated deficit	Total equity
		USD in thousands							
BALANCE AS OF DECEMBER 31, 2013		442	36,927	553	538	640	475	(28,412)	11,163
TOTAL COMPREHENSIVE LOSS FOR THE YEAR						(1,546)		(6,385)	(7,931)
TRANSACTIONS WITH SHAREHOLDERS:									
Proceeds from issuance of shares and warrants, net	12B	241	8,939				327		9,507
Options granted to employees and service providers	12C			311					311
Forfeiture and expiration of options	12C		200	(200)					-,-
TOTAL TRANSACTIONS WITH SHAREHOLDERS		241	9,139	111			327		9,818
BALANCE AS OF DECEMBER 31, 2014		683	46,066	664	538	(906)	802	(34,797)	13,050

MEDIGUS LTD.
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

		Equity attributed to the owners of the company							
	Note	Ordinary shares	Share premium	Capital reserves from options granted	Capital reserves from transactions with controlling shareholders	Currency translation differences	Warrants	Accumulated deficit	Total equity
		USD in thousands							
BALANCE AS OF DECEMBER 31, 2014		683	46,066	664	538	(906)	802	(34,797)	13,050
TOTAL COMPREHENSIVE LOSS FOR THE YEAR						(211)		(9,532)	(9,743)
TRANSACTIONS WITH SHAREHOLDERS:									
Proceeds from issuance of shares and warrants, net	12B	187	5,841				730		6,758
Options granted to employees and service providers	12C			116					116
Forfeiture of options	12C		83	(83)					-,-
TOTAL TRANSACTIONS WITH SHAREHOLDERS		187	5,924	33			730		6,874
BALANCE AS OF DECEMBER 31, 2015		870	51,990	697	538	(1,117)	1,532	(44,329)	10,181

MEDIGUS LTD.
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

		Equity attributed to the owners of the company							
	Note	Ordinary shares	Share premium	Capital reserves from options granted	Capital reserves from transactions with controlling shareholders	Currency translation differences	Warrants	Accumulated deficit	Total equity
		USD in thousands							
BALANCE AS OF DECEMBER 31, 2015		870	51,990	697	538	(1,117)	1,532	(44,329)	10,181
TOTAL COMPREHENSIVE LOSS FOR THE YEAR								(9,007)	(9,007)
TRANSACTIONS WITH SHAREHOLDERS:									
Proceeds from issuance of shares and warrants, net	12B	319	1,260	70					1,649
Options granted to employees and service providers	12C			104					104
Forfeiture and expiration of options and warrants	12C		567	(92)			(475)		-,-
TOTAL TRANSACTIONS WITH SHAREHOLDERS		319	1,827	82			(475)		1,753
BALANCE AS OF DECEMBER 31, 2016		1,189	53,817	779	538	(1,117)	1,057	(53,336)	2,927

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

MEDIGUS LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the year ended December 31		
	2016	2015	2014
	USD in thousands		
CASH FLOWS FROM OPERATING ACTIVITIES:			
CASH FLOWS USED IN OPERATIONS (see Appendix)	(9,255)	(6,969)	(7,780)
Income tax paid	(14)	(45)	(4)
Interest received	4	33	27
NET CASH USED IN OPERATING ACTIVITIES	(9,265)	(6,981)	(7,757)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(32)	(84)	(68)
Purchase of intangible assets	(6)	(12)	(43)
Withdrawal of short-term deposits			2,290
Net cash generated from (used in) investing activities	(38)	(96)	2,179
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of shares and warrants, net	1,902	6,758	9,299
Net cash generated from financing activities	1,902	6,758	9,299
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(7,401)	(319)	3,721
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	10,312	10,817	6,893
GAINS (LOSSES) FROM EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	90	(186)	203
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF YEAR	3,001	10,312	10,817

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

MEDIGUS LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS

APPENDIX TO THE STATEMENTS OF CASH FLOWS:

	For the year ended December 31		
	2016	2015	2014
	USD in thousands		
NET CASH USED IN OPERATIONS:			
Loss for the year before taxes on income	(8,979)	(9,464)	(6,354)
Adjustment in respect of:			
Profit on change in the fair value of warrants issued to investors	(25)	(106)	(980)
Losses (gains) from exchange differences on cash and cash equivalents	(90)	4	(652)
Retirement benefit obligation, net	(21)		41
Gains on change in the fair value of financial instruments at fair value through profit or loss		(3)	(17)
Revaluation of and exchange differences on short-term deposits			(4)
Interest received	(4)	(33)	(27)
Depreciation	80	100	126
Amortization of intangible assets	19	22	84
Options granted to employees and service providers	104	116	311
CHANGES IN OPERATING ASSET AND LIABILITY ITEMS:			
Decrease (increase) in accounts receivable:			
Trade	233	(126)	(70)
Other	640	(425)	(46)
Increase (decrease) in accounts payable and accruals:			
Trade	9	155	70
Other	(393)	657	(198)
Decrease (increase) in inventory	(828)	56	(20)
Net sales (purchases) of financial assets at fair value through profit or loss		2,078	(44)
NET CASH USED IN OPERATIONS	(9,255)	(6,969)	(7,780)

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

NOTE 1 - GENERAL:

a. Medigus Ltd. (the "Company") was incorporated in Israel on December 9, 1999 and is resident in Israel. The address of its registered office is P.O. Box 3030, Omer, 8496500.

On July 22, 2007 the Company established a wholly owned subsidiary, MEDIGUS USA LLC, in the USA (hereinafter - the "Subsidiary").

The Subsidiary has not engage in any business activities until October 2013.

On October 1, 2013, the Company and the Subsidiary entered into an agreement whereby the Subsidiary provides services to the Company in consideration for reimbursement of direct costs plus a reasonable premium.

The Company together with its subsidiary (hereinafter – the "Group") is a medical device group specializing in developing innovative endoscopic procedures and devices. To date most of the Group's research and development activities have been focused in developing and manufacturing of the MUSE endoscopy system (hereinafter - "MUSE"), a FDA approved system, for the treatment of gastroesophageal reflux disease (GERD). In addition, the Group uses the technological platform it developed for the purpose of additional special systems and products that are suitable for both medical and industrial applications.

To date, the Company continues negotiations to market the MUSE endoscopy system, together with marketing and selling miniature cameras and related equipment.

The Company's shares are listed on the Tel Aviv Stock Exchange Ltd. ("TASE") and as of May 20, 2015, the Company's American Depository Shares (ADSs) evidenced by American Depositary Receipts (ADRs) are listed on the NASDAQ Capital Market. As of December 31, 2016, each ADR represents 5 ordinary shares of the Company. The Company's depositary agent for the ADR program is The Bank of New York Mellon.

On March 15, 2017, the Group effected a change in the ratio of ordinary shares per ADS from 5 ordinary shares per ADS to 50 ordinary shares per ADS. The change in the ordinary shares ratio for the ADSs had the same effect as a 1-for-10 reverse stock split of the ADSs.

b. Effective January 1, 2016, the Company changed its functional currency to the U.S. dollar ("dollar" or "USD") from the New Israeli Shekel ("NIS"). This change was based on management's assessment that the dollar is the primary currency of the economic environment in which the Company operates. Accordingly, the functional and reporting currency of the Company in these financial statements is the USD.

In determining the appropriate functional currency to be used, the Company followed the guidance in International Accounting Standard (IAS) 21, which states that economic factors relating to sales, costs and expenses, financing activities and cash flows, as well as other potential factors, should be considered both individually and collectively. The Company recently incurred a significant increase in expenses denominated in dollars relating to the marketing of its products in the US, which is reflected primarily by recruitment of additional human resources in the US. The Company expects an additional increase in expenses denominated in dollars related to these activities. These changes, as well as the fact that all of the Company's budgeting and planning is conducted solely in dollars, led to the decision to make the change in functional currency as of January 1, 2016, as indicated above.

The effect of the change in the functional currency is accounted for prospectively. All items were translated into the new functional currency using the exchange rate at the date of the change. The resulting translated amounts for non-monetary items are treated as their historical cost.

Due to the change in its functional currency as above and concurrently with it, the Company decided to change its presentation currency from NIS to USD.

The change in presentation currency was applied retrospectively to all comparative figures presented.

NOTE 1 - GENERAL (continued)**:**

In effecting the change in presentation currency to the dollar, with respect to comparative figures: (1) all assets and liabilities of the Company were translated using the dollar exchange rate as of each balance sheet presented; (2) equity items were translated using historical exchange rates at the relevant transaction dates; (3) the statements of comprehensive loss items have been translated at the average exchange rates for the relevant reporting periods; and (4) the resulting translation differences have been reported as "currency translation differences" within other comprehensive loss. In accordance with paragraph 40 of IAS 1, due to the aforementioned change in functional currency, an additional balance sheet as of January 1, 2015 has been presented in the financial statements. IAS 1 does not require such additional information in the detailed financial statement notes.

c. During the year ended December 31, 2016, the Group incurred a total comprehensive loss of USD 9 million and negative cash flows from operating activities of USD 9.2 million. As of December 31, 2016, the Group had accumulated losses of USD 54 million. Based on the projected cash flows and its cash balances as of December 31, 2016, the Group's Management is of the opinion that without further fund raising it will not have sufficient resources to enable it to continue its operating activities including the development, manufacturing and marketing of its products for a period of at least 12 months from the date of approval of these financial statements. As a result, there are substantial doubt about the Group's ability to continue as a going concern.

Management's plans include the continued commercialization of their products and securing sufficient financing through the sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances however, that the Group will be successful in obtaining the level of financing needed for its operations. If the Group is unsuccessful in commercializing its products and securing sufficient financing, it may need to reduce activities, curtail or cease operations.

The financial statements do not include any adjustments relating to the recoverability and classification of recorded assets and the amounts and classification of liabilities that might be necessary should the Group be unable to continue as a going concern.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES:

a. Basis for preparation of the financial statements:

The Group's financial statements as of December 31, 2016 and 2015 and for each of the three years in the period ended December 31, 2016, are in compliance with International Financial Reporting Standards, which are standards and interpretations thereto issued by the International Accounting Standard Board (hereinafter "IFRS").

In connection with the presentation of these financial statements it is noted as follows:

1) The significant accounting policies applied in the preparation of these financial statements are set out below. These policies have been consistently applied to all years presented, unless otherwise stated.

2) These financial statements have been prepared under the historical cost convention, as modified by the revaluation of plan assets related to the retirement benefit obligation, and financial assets and financial liabilities (including derivative instruments) measured at fair value through profit or loss.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)**:**

3) The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Group's accounting policies. Areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in note 3. Actual results may differ materially from estimates and assumptions used by management.

4) The Group analyzes the expenses recognized in the consolidated statement of loss using a classification method based on the expenses' function.

b. Consolidation

Inter-company transactions and balances eliminated as part of the consolidation.

Accounting policies of the Subsidiary are those of the Group and have been consistently applied.

c. Translation of foreign currency balances and transactions:

1) The functional currency and the presentation currency

Items included in the financial statements of each of the companies in the Group have been prepared in the currency of the principal economic environment in which it operates (hereinafter – "the functional currency"). The consolidated financial statements are presented in US Dollar, which is the Group's functional and presentation currency, and rounded to the nearest thousand.

2) Transactions and balances

Transactions made in a currency which is different from the functional currency ("foreign currency") are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at the end-of-year exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in income or loss.

Gains and losses from changes in exchange rates are presented in the statement of comprehensive loss among "Financing income (expenses) in respect of deposits and exchange differences."

d. Property and equipment

Property and equipment are initially recognized at purchased cost. Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. The carrying amount of replaced items is derecognized. All other repairs and maintenance are charged to income or loss during the financial period in which they are incurred.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)**:**

Property and equipment is recognized at cost less accumulated depreciation.

Depreciation is calculated using the straight line method over the estimated useful life of the asset as follows:

Machinery and equipment	6 – 10 years (primarily 10)
Furniture	7 – 14 years
Computers	3 years

Leasehold improvements are depreciated using the straight line method over the shorter of the term of the lease or the estimated useful lives of the assets.

The assets' residual values, their useful lives and the depreciation method are reviewed, and adjusted if appropriate, at the end of each year.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposals are determined by comparing the net proceeds with the carrying amount and are recognized within 'Other income – net' in the statement of comprehensive loss.

e. Intangible assets:

Computer programs

Licenses to use purchased computer programs are capitalized on the basis of the costs incurred in their purchase and preparation for use of the specific program. These costs are depreciated using the straight line method over the estimated useful life of the assets (usually three years).

Costs related to the maintenance of computer programs are recognized as expenses when incurred.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)**:**

f. Impairment of non-monetary assets

Non-monetary assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less selling costs and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels of identifiable cash flows (cash-generating units). Non-monetary assets that were impaired are reviewed for possible reversal of the impairment recognized at each balance sheet date.

g. Financial instruments:

1) Classification

The Group classifies its financial assets to the following categories: financial assets at fair value through profit or loss, receivables and financial assets available for sale. The classification depends, among other things, on the purpose for which the financial assets were purchased. Management determines the classification of financial assets upon initial recognition.

a) Financial assets at fair value through profit or loss

This category includes financial assets held for trading. A financial asset is classified to this category if it is purchased primarily for the purpose of selling in the short-term.

Instruments included in this category are marketable securities which are denominated in NIS.

Changes in financial assets at fair value through profit or loss are presented among "operating activities" as part of the changes in working capital in the statement of cash flows.

Changes in the fair values of financial assets at fair value through profit or loss are recorded to "other income, net" in the statement of comprehensive loss (see Note 14).

The fair value of marketable securities is based on their quoted price in an active market.

b) Receivables

Receivables are non-derivative financial assets with fixed or determinable payments that are not quoted on an active market. These assets are classified as current assets, except for maturities longer than 12 months after the date of the balance sheet which are classified as non-current assets. The Group's receivables are included in "accounts receivable", "short-term deposits" and "cash and cash equivalents" in the balance sheet (see also sections l and j below).

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)**:**

The Group classifies its financial liabilities to the following categories: financial liabilities at fair value through profit or loss and financial liabilities at amortized cost. The Group's management determines the classification of financial liabilities upon initial recognition.

a) Financial liabilities at fair value through profit or loss.

Warrants allotted to investors with a cashless exercise mechanism. In accordance with International Accounting Standard 32: "Financial Instruments: Presentation", these warrants are a "financial liability". As the aforementioned liability is a non-equity derivative financial instrument, it is classified in accordance with IAS 39 as a financial liability at fair value through profit or loss, which is measured at its fair value at each date of the balance sheet, with changes in the fair value carried to "profit from changes in fair value of warrants issued to investors" in the statement of comprehensive loss.

b) Financial liabilities at amortized cost

Trade payables and financial liabilities included in "other liabilities" are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method.

2) Recognition and measurement

Regular purchases and sales of financial assets are recorded at the date of the settlement which is the date on which the asset was delivered to the Group or delivered from the Group.

Investments are initially recognized at fair value plus transaction costs for all financial assets not carried at fair value through profit or loss. Financial assets measured at fair value through profit or loss are initially recognized at fair value and transaction costs are charged to income or loss. Financial assets are derecognized when the rights to receive cash flows from the investments have expired or have been transferred and the Group has transferred substantially all risks and rewards of ownership associated with these assets. Available for sale financial assets and financial assets at fair value through profit or loss are measured in subsequent periods at fair value. Receivables are subsequently carried at amortized cost using the effective interest method.

Gains or losses arising from the changes in the fair value of financial assets at fair value through profit or loss are presented in the statement of comprehensive loss among "other income - net" in the period in which they were incurred.

As to methods for measurement of the Company's financial instruments, see note 4.

3) Impairment of financial assets

The Group assesses at each date of the balance sheet whether there is objective evidence that a financial asset or group of financial assets measured at depreciated cost is impaired. A financial asset or a group of financial assets is impaired and impairment losses are incurred only if there is objective evidence of impairment as a result of one or more events that occurred after the initial recognition of the asset (a 'loss event') and that loss event (or events) has an impact on the estimated future cash flows of the financial asset or group of financial assets that can be reliably estimated.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)**:**

h. Inventory

Inventory is measured at the lower of cost or net realizable value.

The cost is determined on the basis of "first in-first out" basis. Cost of purchased products and inventory in process includes costs of design, raw materials, direct labor, other direct costs and fixed production overheads.

Net realizable value is an estimated selling price in the ordinary course of business less applicable variable selling expenses.

Provisions for potentially obsolete or slow-moving inventory are made based on management's analysis of inventory levels and historical obsolescence.

The Company periodically analyzes anticipated product sales based on historical results, current backlog and marketing plans. Based on these analyses, the Company anticipates that certain products will not be sold during the next twelve months. Inventories that are not anticipated to be sold in the next twelve months, have been classified as non-current.

i. Trade receivables

The balance of trade receivables includes amounts due from customers for products sold or services rendered in the ordinary course of business. If collection is expected in one year or less, they are classified as current assets. If not, they are presented as noncurrent assets.

Trade receivables are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method, less provision for doubtful accounts.

j. Cash and cash equivalents

The consolidated statements of financial position and the consolidated statements of cash flows include cash and cash equivalents, which are short-term bank deposits with original maturities dates of three months or less.

k. Current and deferred taxes

Tax expenses for the reported years include current and deferred taxes. The taxes are recognized in the Statements of Loss and Other Comprehensive Loss.

The amount that was recorded as current taxes, is calculated based on the tax laws that have been enacted or substantively enacted at the balance sheet date, in countries in which the Company and its subsidiary operate and generate taxable income. The Group's management periodically evaluates the tax implications applicable to the taxable income, in accordance with the relevant tax laws, and creates provisions in accordance with the amounts expected to be paid to the tax authorities.

The Group recognizes deferred taxes using the liability method, for temporary differences between the amounts of assets and liabilities included in the financial statements, and the amounts for tax purposes. Deferred taxes are not recognized, if the temporary differences arise at the initial recognition of the asset or liability which at the time of the transaction has no effect on profit or loss, whether for accounting or tax reporting. The amount of deferred taxes is determined using the tax rates (and laws) which are expected to apply when the related deferred tax assets is realized or the deferred tax liabilities will be settled.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued)**:**

Deferred tax assets are recognized for temporary differences that are tax deductible, up to the amount of the differences that are expected to be utilized in the future, against taxable income.

No deferred tax assets have been recorded in the Group's books of accounts for current losses carried forward since it is not probable that the Group will be able to utilize those losses in the foreseeable future against taxable income.

Deferred tax assets and liabilities are offset only if:

- There is a legally enforceable right to offset current tax assets against current tax liabilities; and
- Deferred income tax assets and liabilities relate to income taxes imposed by the same taxation authority on the same taxable entity.

In the event of a dividend distribution originating from tax exempted "benefited enterprises", tax will be levied on the amount distributed using the tax rate that would have been applicable to Company had it not been exempted from tax. In the event of such a distribution, the amount of tax will be recognized as an expense in the statement of comprehensive loss.

l. Employee benefits

1) Retirement benefit obligation

A defined contribution plan is a post-employment employee benefit plan, to which Company pays fixed deposits to a separate and independent entity, so that the Group has no legal or constructive obligation to pay further contributions if the fund does not hold sufficient assets to pay all employees the benefits relating to employee service in the current and prior periods.

According to Israeli labor laws and work agreements, and as customary in the Company, the Company is obligated to pay severance pay to employees who are terminated or leave their employment in certain circumstances.

The obligation of the Company to the employees which is in the framework of a defined contribution plan, is to make fixed deposits to a separate and independent entity, so that the Group has no obligation, legal or otherwise, to make additional deposits, when assets of this fund are insufficient to pay to all of the employees their benefits for their current and past employment services.

2) Vacation and recreation pay

Under the Israeli law each employee is legally entitled to vacation and recreation benefits, both calculated on an annual basis. The entitlement is based on term of employment. The Group records the obligation and expense for vacation and recreation pay based on the benefits that have been accumulated for each employee.

3) Bonus plans

The Company recognizes the obligation and expense for bonuses when a contractual or constructive obligation exists. The obligation is recognized in the amount expected to be paid, to the extent that the Company can reliably estimate the amount expected to be paid.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

m. Share based payments

The Group operates several equity-settled share based compensation plans to employees and other service providers, under which the Group receives services from employees and service providers in return for equity instruments (options) of the Company. The fair value of the services received from employees and service providers in return for granting the options is recognized as an expense in the statement of comprehensive loss. The total amount charged as an expense is determined taking into consideration the fair value of the options granted:

— Without considering service and performance conditions, which are non-market vesting conditions (e.g. meeting profit and sales targets and continued employment in the Company for a certain period).

— Non-market vesting conditions are included among the assumptions used to estimate the number of options expected to vest. The total expense is recognized during the vesting period, which is the period over which all of the specified vesting conditions of the share-based payment are to be satisfied.

At each date of the balance sheet, the Group revises the estimates of the number of options that are expected to vest, based on non-market vesting conditions. It recognizes the impact of the revision to original estimates, if any, in profit or loss, with a corresponding adjustment to equity.

When the options are exercised, the Company issues new shares. The proceeds, less directly related transaction costs, are reflected in the share capital (at par value) and in share premium.

n. Revenue recognition

Revenues are measured in accordance with the fair value of the consideration received or receivable in respect of sales supplied in the ordinary course of business. Revenues are presented net of V.A.T. returns, rebates and discounts.

1) Sales of goods:

Revenue from the sale of goods is recognized when all of the following conditions are met:

- The Group transferred the significant risks and rewards of ownership of the goods to the purchaser;
- The Group does not retain continuing managerial involvement to the degree usually associated with ownership nor effective control over the goods sold;
- The amount of the revenues can be measured reliably. The amount of the revenue is not considered as being reliably measured until all the conditions relating to the transaction are met. The Group bases its estimates on past experience, considering the type of customer, type of transaction and special details of each arrangement.
- It is probable that the economic benefits that are associated with the transaction will flow to the Group; and
- The costs incurred or to be incurred in respect of the transaction can be measured reliably.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

2) Construction contracts:

A construction contract is defined by IAS 11, "Construction contracts", as a contract specifically negotiated for the construction of an asset.

When the outcome of a construction contract can be estimated reliably and it is probable that the contract will be profitable, contract revenue is recognized over the period of the contract by reference to the stage of completion. Contract costs are recognised as expenses by reference to the stage of completion of the contract activity at the end of the reporting period. When it is probable that total contract costs will exceed total contract revenue, the Group recognizes the expected loss as an expense immediately.

When the outcome of a construction contract cannot be estimated reliably, the Group recognizes revenue only to the extent of contract costs incurred that it is probable will be recoverable.

Variations in contract work, claims and incentive payments are included in contract revenue to the extent that may have been agreed with the customer and are capable of being reliably measured.

The Group uses the "percentage-of-completion method" to determine the appropriate amount to recognize in a given period. The stage of completion is measured by reference to the contract costs incurred up to the end of the reporting period as a percentage of total estimated costs for each contract. Costs incurred in the year in connection with the future activities on a contract are excluded from contract costs in determining the stage of completion.

On the balance sheet, the Group reports the net contract position for each contract as either an asset or a liability. A contract represents an asset where costs incurred plus recognized profits (less recognized losses) exceed progress billings; a contract represents a liability when the opposite is the case.

o. Leases

Lease agreements in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made in connection with operating leases are recognized in profit or loss using the straight-line basis over the term of the lease.

p. Loss per share

Loss per share is based on the loss that is attributed to the shareholders holding ordinary shares, divided by the weighted average number of ordinary shares in issue during the period.

For purposes of the calculation of the diluted loss per share, the Group adjusts the loss that is attributed to the holders of the Company's ordinary shares, and the weighted average number of ordinary shares in issue, to assume conversion of all of the dilutive potential shares.

The potential shares are taken into account only if their effect is dilutive (increases loss per share).

NOTE 2 -SIGNIFICANT ACCOUNTING POLICIES (continued):

q. New international financial reporting standards, amendments to standards and new interpretations:

Standards, amendments and interpretations to existing standards which are not yet effective and have not been early adopted by the Group:

a) International Financial Reporting Standard 9 "Financial Instruments" (hereinafter – "IFRS 9" or "the Standard"):

IFRS 9 deals with the classification, measurement and recognition of financial assets and financial liabilities. The full version of IFRS 9 was published in July 2014. This Standard replaces the present existing directives in International Accounting Standard 39 "Financial Instruments: Recognition and Measurement" (hereinafter IAS 39) regarding the classification and measurement of financial instruments. IFRS 9 leaves the measurement model connected with measuring financial assets, but simplifies it and sets forth three main categories: amortized cost, fair value through other comprehensive income and fair value through profit or loss. The classification is based on the business model of the entity and on characteristics of the contractual cash flows of the financial asset. Investments in capital instruments will be measured at fair value through profit or loss. Nevertheless, the entity's management can choose, on the date of initial recognition, irrevocably, to present the changes in fair value of an investment in a capital instrument in other comprehensive income, without recycling them to profit or loss.

The Standard presents a new model for an impairment of financial instruments, based on the Expected Credit Loss Model. This model replaces the existing model in IAS 39, which is based on the Incurred Loss Model. The new impairment model requires the recognition of impairment provisions based on expected credit losses (ECL) rather than only incurred credit losses as is the case under IAS 39. It applies to financial assets classified at amortised cost, debt instruments measured at fair value in other comprehensive income and contract assets under IFRS 15 Revenue from Contracts with Customers. While the group has not yet undertaken a detailed assessment of how its impairment provisions would be affected by the new model, it may result in an earlier recognition of credit losses.

Regarding classification and measurement of financial liabilities, there were no changes, excluding the recognition of changes in the fair value of liabilities designated to the fair value through "profit or loss" category, resulting from the entity's own credit risk, in other comprehensive income.

The Standard will be implemented retrospectively as from annual periods starting January 1, 2018. According to the provisions of IFRS 9 it may be implemented earlier. The Group is examining the expected effect of IFRS 9 on its financial statements.

b) International Financial Reporting Standard 15 "Revenues from Contracts with Customers" (hereinafter – IFRS 15).

IFRS 15 will replace, on its first implementation, the directives on the subject of recognizing revenues existing today under International Financial Reporting Standards.

The core principle of IFRS 15 is that revenues from contracts with customers must be recognized in a way that reflects the transfer of control of goods or services supplied to customers in the framework of the contracts by amounts which reflect the proceeds that the entity expects that it will be entitled to receive for those goods or services.

NOTE 2 -SIGNIFICANT ACCOUNTING POLICIES (continued):

IFRS 15 sets forth a single model for recognizing revenues, according to which the entity will recognize revenues according to the said core principle by implementing five stages:

(1) Identifying the contract(s) with the customer.

(2) Identifying the separate performance obligations in the contract.

(3) Determining the transaction price.

(4) Allocating the transaction price to separate performance obligations in the contract.

(5) Recognizing revenue when (or as) each of the performance obligations is satisfied.

The Standard will be implemented retrospectively as from annual periods starting January 1, 2018. According to the provisions of IFRS 15 it may be implemented earlier. The Company is still assessing the impact of the adoption of the new revenue standards on its consolidated financial statements.

c) International Financial Reporting Standard 16 "Leases" (hereafter - IFRS 16)

IFRS16, *Leases*, which replaces the current guidance in IAS 17. IFRS 16 requires lessees, with certain exceptions, to recognize a lease liability reflecting future lease payments and a 'right-of-use asset' for lease contracts. The standard is effective for annual periods beginning on or after January 1, 2019, with earlier application permitted if IFRS 15, *Revenue from Contracts with Customer*, is also applied. The Group is yet to assess IFRS 16's full impact.

NOTE 3 - SIGNIFICANT JUDGMENTS:

Judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

a. Government grants

As of December 31, 2016 Israeli National Authority for Technological Innovation of the Israeli Ministry of Economy and Industry (formerly known as the Office of the Chief Scientist, or the OCS), or NATI grants received by the Group and for which there is an obligation to pay royalties totaled approximately to USD 0.2 million. Over all of the reporting periods presented, the Company has concluded that, with respect to all of the grants received from the Chief Scientist, there is reasonable assurance that the grants received will not be repaid, therefore the grants were recorded to income as reduction of research and development expenses.

b. Deferred tax assets

Based on management's judgment, no deferred tax assets have been recorded in the Group's books of accounts for current losses carried forward for tax purposes since it is not probable that the Group will be able to utilize those losses in the foreseeable future against taxable income as of December 31, 2016. Had the Group recorded a deferred tax asset for all of the accumulated losses carried forward for tax purposes the accumulated deficit of the Group would have been decreased by approximately USD 13 million.

NOTE 3 - SIGNIFICANT JUDGMENTS (continued)**:**

c. Fair value measurement of share-based payment transactions

The Group grants share based payment to employees and consultants. The fair value of the share options is measured at grant date on the basis of accepted valuation models and assumptions regarding unobservable inputs used in the valuation models. The value of the transactions, measured as described above, is recognized as an expense over the vesting period. Concurrently with the periodic recognition of an expense, an increase is recognized in a capital reserve, within the Group's equity.

d. Considering the likelihood of contingent losses and quantifying possible settlements:

Provisions are recorded when a loss is considered probable and can be reasonably estimated. Judgment is necessary in assessing the likelihood that a pending claim or litigation against the Group will succeed, or a liability will arise, quantifying the possible range of final settlement. These judgments are made by management with the support of internal specialists, or with the support of outside consultants such as legal counsel. Because of the inherent uncertainties in this evaluation process, actual results may be different from these estimates.

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT:

Financial risk management:

1) Financial risk factors

The Group's activities expose it to a variety of financial risks: market risks (including currency risks, fair value interest rate risk, cash flow interest rate risk and price risk), credit risks and liquidity risks. The Group's overall risk management plan focuses on the unpredictability of financial markets and seeks to minimize the potential adverse effects on the Group's financial performance.

Risk management is performed by the finance department according to the policy authorized by the board of directors.

a) Market risk:

Foreign exchange risk

The Company operates internationally and is exposed to foreign exchange risks due to exposure to foreign currencies, primarily the NIS. Foreign exchange risk arises from future commercial transactions, assets or liabilities denominated in foreign currency.

The Group's policy to reduce the exposure to changes in exchange rates is based on maintaining, where possible, the balances of current monetary assets, according to the currency of the current liabilities.

As of December 31, 2016, if the functional currency of the Company (USD) had weakened/strengthened by 10% against the NIS, with all other variables held constant, the loss for the year would decrease/increase by USD 39 thousand (2015- USD 308 thousand), primarily as a result of foreign exchange gains/losses on cash and cash equivalents.

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (continued)**:**

As of December 31, 2015, if the functional currency of the Company (NIS) had weakened/strengthened by 10% against the USD, with all other variables held constant, the loss for the year would decrease/increase by USD 308 thousand (2014- USD 562 thousand), primarily as a result of foreign exchange gains/losses on cash and cash equivalents.

b) Credit risks

Credit risks are treated at the Group level. Credit risks arise from cash and cash equivalents, bank deposits and from credit exposures in connection with outstanding receivables and committed transactions.

The Group's cash and cash equivalents as of December 31, 2016 and 2015 are held with large established banks.

No credit limits were exceeded during the reported periods and Group's management does not expect any losses from non-performance of these parties.

c) Liquidity risk

Cash flow forecasting is performed by the Group's finance department. The finance department monitors rolling forecasts of the Company's liquidity requirements to ensure that it has sufficient cash to meet operational needs, while maintaining sufficient headroom on its undrawn committed borrowing facilities, so that the Group does not breach any of its credit facilities.

The Group invests cash surpluses in interest bearing investments such as time deposits and short-term government debentures, choosing instruments with appropriate maturities or sufficient liquidity to provide sufficient headroom as determined by the above-mentioned forecasts.

Liquidity risk arises from financial liabilities due to payable balances (except for institutions and advanced payments) and amounted to USD 1,009 thousands on December 31, 2016 (2015 - USD 1,277 thousands).

These liabilities are classified as current liabilities, and are expected to mature within 12 months from the date of the balance sheet.

2) Estimates of fair value

The following is an analysis of the financial instruments measured at fair value, according to valuation methods. Inputs for the asset or liability that are not based on observable market data (unobservable inputs) (Level 3).

The following table presents the group's financial assets and liabilities that are measured at fair value December 31, 2016 and December 31, 2015:

	December 31			
	2016		2015	
	Level 3	Total	Level 3	Total
	USD in thousands			
Financial liabilities at fair value through profit or loss -				
Warrants at fair value	237	237	9	9

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (continued)**:**

Financial instruments in level 3

The Company's financial liability at fair value through profit or loss is the obligation for warrants (Orbimed), warrants (series E) (see Note 12 (b)(1)) and warrants (series I) (see Note 12(b)(6)).

	December 31					
	2016			2015		
	Standard deviation	Risk-free interest	Fair value (USD thousands)	Standard deviation	Risk-free interest	Fair value (USD thousands)
Warrants (Series I) (*)	155.39%	1.26%	237			
Warrants (Series E) (*)	155.39%	0.00%	-	48%	0.4%	9
Warrants (Orbimed) (**)				45%	0.001%	-

(*) In calculating the value of warrants (Series E and Series I) a Black and Scholes model was used. If the change in standard deviation for that warrants shifted +/- 5%, the impact on profit or loss would be USD 4 thousand. The higher the standard deviation, the higher the fair value. The expected volatility is based on fluctuations in the price of the Company's share.

(**) In calculating the value of warrants (Orbimed) a binomial model was used. The risk-free interest rate between the periods is derived from a curve of "Shachar" type Israel government bond for a period which corresponds to the term of the warrants at the time of the calculation was made. The expected volatility is based on fluctuations in the price of the Company's share.

On March 3, 2016 the warrants (Orbimed) expired as the exercise period was ended.

The following table presents the changes in Level 3 instruments for the year ended December 31, 2016:

	Warrants
	USD in thousands
Opening balance at January 1	9
Issue of warrants (see note 12(b)(6))	253
Gains recognized in profit or loss	(25)
Closing balance at December 31	237
Total unrealized profits for the period included in profit or loss for liabilities held at the end of the reporting period	25

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (continued)**:**

The following table presents the changes in Level 3 instruments for the year ended December 31, 2015:

	Warrants
	USD in thousands
Opening balance at January 1	110
Gains recognized in profit or loss	(106)
Currency translation differences	5
Closing balance at December 31	9
Total unrealized profits for the period included in profit or loss for liabilities held at the end of the reporting period	106

NOTE 5 - CASH AND CASH EQUIVALENTS:

	As of December 31	
	2016	2015
	USD in thousands	
Cash in banks	1,944	1,812
Short-term bank deposits	1,057	8,500
	3,001	10,312

The currencies in which the cash and cash equivalents are denominated or to which they are linked are as follows:

	December 31	
	2016	2015
	USD in thousands	
NIS	880	6,823
US Dollar	2,040	3,427
Other currencies	81	62
	3,001	10,312

The carrying amount of the cash and cash equivalents approximates their fair value.

NOTE 6 - ACCOUNTS RECEIVABLE:

a. Trade receivables:

	December 31, 2016		
	NIS unlinked	Denominated in US Dollars	Total
	USD in thousands		
Outstanding accounts	2	41	43
Credit cards	8		8
Provision of doubtful debts		(30)	(30)
	10	11	21

NOTE 6 - ACCOUNTS RECEIVABLE (continued)**:**

	December 31, 2015			
	NIS unlinked	Denominated in US Dollars	Denominated in Euro	Total
	USD in thousands			
Outstanding accounts		193	53	246
Credit cards	8			8
	8	193	53	254

b. Other receivables:

	December 31	
	2016	2015
	USD in thousands	
Institutions	70	73
Prepaid expenses	277*	811*
Advances to suppliers	17	95
Other	2	27
	366	1,006

* Including USD 214 thousand (December 31, 2015: USD 652 thousand) materials used to manufacture MUSE systems which will be used, for testing, training, demonstrations and promotional activities. The cost of these materials will be recorded to research and development expenses or selling and marketing expenses depending on actual use.

c. The carrying amounts of other receivables (except for the non-monetary balances from institutions, prepaid expenses, and advances to suppliers) approximate their fair value.

The maximum exposure to credit risks as of the balance sheet date in respect of other receivable is the carrying amount of all the aforementioned receivables net of the non-monetary balances (institutions, prepaid expenses and advances to suppliers), amounting to USD 23 thousand (December 31, 2015 - USD 281 thousand). The Group does not hold any collateral in respect of these balances.

NOTE 7 - INVENTORY:

Composed as follows:

	December 31	
	2016	2015
	USD in thousands	
Current assets:		
Raw materials and supplies		199
Work in progress	128	20
Finished goods	70	85
	198	304
Non-current assets:		
Raw materials and supplies	829	
Work in progress	66	
Finished goods	39	
	934	

NOTE 8 - PROPERTY AND EQUIPMENT:

a. Composition of property and equipment and accumulated depreciation thereon, grouped by major classifications and changes therein, and their movements during 2016:

	Cost			Accumulated Depreciation			Depreciated balance December 31	
	Balance at beginning of year	Additions during the year	Balance at end of year	Balance at beginning of year	Additions during the year	Balance at end of year	2016	2015
Property and equipment:	USD in thousands			USD in thousands			USD in thousands	
Machinery and equipment	712	24	736	557	52	609	127	155
Leasehold improvements	47		47	36	5	41	6	11
Office furniture and equipment (including computers)	383	8	391	323	23	346	45	60
	1,142	32	1,174	916	80	996	178	226

b. Composition of property and equipment and accumulated depreciation thereon, grouped by major classifications and changes therein, and their movements during 2015:

	Cost			Accumulated Depreciation			Depreciated balance December 31, 2015
	Balance at beginning of year	Additions during the year	Balance at end of year	Balance at beginning of year	Additions during the year	Balance at end of year	
Property and equipment:	USD in thousands			USD in thousands			USD in thousands
Machinery and equipment	675	37	712	481	76	557	155
Leasehold improvements	33	14	47	33	3	36	11
Office furniture and equipment (including computers)	350	33	383	302	21	323	60
	1,058	84	1,142	816	100	916	226

NOTE 9 - TAXES ON INCOME:

a. Corporate taxation in Israel:

1) Measurement of results for tax purposes:

Commencing with tax year 2008 the results of the Company for tax purposes are measured in nominal values. Through the end of tax year 2007 the results of the Company for tax purposes were measured having regard to the changes in the Israeli consumer price index ("CPI"), in accordance with the Income Tax Law (Inflationary Adjustments), 1985 (hereinafter-the the "Inflationary Adjustments Law"). The transitional provisions regarding the discontinuation of the application of the Inflationary Adjustments Law stipulate that losses carried forward for tax purposes, deduction for depreciation, and real loss from sale of a depreciable asset or security will be linked to the CPI until the end of tax year 2007 and linkage shall be discontinued as of this date.

2) Tax rates

The income of the Company (other than income which is eligible for reduced tax rates in accordance with encouragement laws in Israel, see C below) is subject to corporate tax at the regular corporate tax rates.

According to the Law for the Amendment of National Priorities (Legislative Amendments for Achieving the Budgetary Goals for 2013-2014), 2013 (hereinafter - the Law), which was published in the official gazette on August 2015, stipulated that the corporate tax rate will be 26.5% for 2014 and thereafter. (As to the tax rates on the income of a Preferred Enterprise as set out in the Law for the Encouragement of Capital Investments-1959, see C below).

In January 2016, published the Amendment of the Income Tax Ordinance (No. 216), 2016, which stipulated a reduction of the corporate tax, commencing 2016 and thereafter from 26.5% to 25%.

In January 2016, the Law for the Amendment of the Income Tax Ordinance (No. 216) was published, enacting a reduction of corporate tax rate in 2016 and thereafter, from 26.5% to 25%. In December 2016, the Economic Efficiency Law (Legislative Amendments for Implementing the Economic Policy for the 2017 and 2018 Budget Year), 2016 was published, introducing a gradual reduction in corporate tax rate from 25% to 23%. However, the law also included a temporary provision setting the corporate tax rate in 2017 at 24%. As a result, the corporate tax rate will be 24% in 2017 and 23% in 2018 and thereafter.

The Company's capital gains are subject to tax at the regular corporate tax rates.

b. Taxation of a subsidiary outside Israel

The Subsidiary incorporated in the U.S. is assessed according to U.S. tax law.

c. Encouragement laws in Israel:

Tax benefits under the Law for the Encouragement of Capital Investments-1959 (hereinafter- the "Law for the Encouragement of Capital Investments"):

a) General

Under the Law for the Encouragement of Capital Investments, companies are entitled to various tax benefits by virtue of their "approved enterprise" or "benefited enterprise" status subject to the fulfillment of certain conditions. In addition, companies may be entitled to additional tax benefits as "foreign investors' companies," as defined by the Law for the Encouragement of Capital Investments.

NOTE 9 - TAXES ON INCOME (continued):

According to the Economic Policy Law for 2011 and 2012 (Legislative Amendments), 2011, which was published in December 2010 also amended the Capital Investment Encouragement Law (hereinafter – the amendment).

The amendement sets alternative benefit tracks to the ones that were in place under the provisions of the Law for the Encouragement of Capital Investments, as follows: investment grants track designed for enterprises located in national development zone A and two new tax benefits tracks (preferred enterprise and a special preferred enterprise), which provide for application of a unified tax rate to all preferred income of the company, as defined in the law.

Under the amended law, a company which qualifies for benefits under the encouragement law prior to the amendment thereof may opt for application of the amendment on each year, commencing with the first year in which the amendment became effective (2011) thereby making available to itself the tax benefits in accordance with the tracks set in the amendment subject to the fulfillment of certain conditions. A company's election for application of the amendment is irrevocable and once it opts for application thereof, it will no longer be entitled to the tax benefits available to it under the pre-amendment regime of the Law for the Encouragement of Capital Investments. A company will be allowed to continue and enjoy the tax benefits available under the law prior to its amendment until the end of the period of benefits, as defined in the law.

In December 2016, published in the Economic Efficiency Law (Legislative Amendments to Achieving the Budget Goals for 2017 and -2018), 2016. Under this law, added two new benefit programs for high-tech industries " benefited technology enterprise "and "special benefited technology enterprise ".

b) Tax benefits

The Company has not decided at this stage whether and when to elect the application of the amendment of the law. Once the Company generates taxable income, it is currently scheduled to be eligible for tax benefits available under the Law for the Encouragement of Capital Investments before it was amended in accordance with the provisions of the benefited enterprise regime, as follows:

Reduced tax rates

During the period of benefits - 10 years commencing in the first year in which the Company earns taxable income from the benefited enterprises (provided the maximum period to which it is restricted by law has not elapsed) - the income from the benefited enterprises owned by the Company is tax exempt so long as it is not distributed or deemed to be distributed. The portion of income which qualifies for tax exemption as above is based on the ratio between the turnover relating to the "benefited enterprise" and the total turnover of the Company.

In the event of a dividend distribution or deemed dividend distribution from income which was previously exempt, the Company will be subject to tax on the grossed-up amount of the (deemed) dividend, according to the tax rate which would have applied to the income were it not eligible for the exemption.

The Company has not yet utilized the tax benefits for the main plant, nor for the expansion of the plant.

NOTE 9 - TAXES ON INCOME (continued):

c) Conditions to receive the benefits

The entitlement to the above benefits is conditional upon the Company's fulfillment of the conditions stipulated by the Law for the Encouragement of Capital Investments, and the regulations promulgated thereunder. In the event of failure to comply with these conditions, the benefits may be cancelled and the Company may be required to refund the amount of the benefits, in whole or in part, with the addition of interest. As of the date of approval of these financial statements, the Company has met the aforementioned conditions.

d. Carry forward tax losses

Carry forward tax losses aggregate NIS 204 million (approximately USD 53 million) and NIS 167 million (approximately USD 43 million) as of December 31, 2016 and 2015, respectively. The Company did not record deferred taxes in respect of these losses, as the utilization thereof is not expected in the foreseeable future.

e. Tax advances for certain employee benefits expenses

Tax advances for certain employee benefits expenses that are not deductable for tax purposes paid to the tax authorities are charged to income on a current basis; the Company does not record these advances as a tax asset in its books of accounts, as utilization thereof is not expected in the foreseeable future.

The total said tax advances paid which have not yet been offset is approximately NIS 174 thousand (approximately – USD 45 thousand) as of December 31, 2016 (December 31, 2015- NIS 162 thousand (approximately – USD 42 thousand).

f. Tax assessments

On October 6 2016, following a withholding tax audit in Israel for years 2011-2014, the Company is deemed to be in debt of approximately NIS 5.3 million, (which is approximately USD 1.46 million) additional withholding taxes. It is the management's opinion, based on legal opinion, that it's more likely than not that the claim will be dismissed. Accordingly, no provision was recorded in these financial statements.

In accordance with Israeli tax regulations, the tax returns filed by the Company through the 2010 tax year are considered final.

g. Taxes on income included in the Statements of Loss and Other Comprehensive Loss for the periods presented:

The following is reconciliation between the "theoretical" tax, which would apply to the Company if all of its income were taxed at the regular rate applicable to the Company in Israel (see a2 above) and the amount of tax reflected in the Statements of Loss for the reported year:

	2016	2015	2014
	USD in thousands		
Loss before taxes on income as reported in the Statements of Loss	(8,979)	(9,464)	(6,354)
Theoretical tax savings	(2,245)	(2,508)	(1,589)
Increase in taxes arising from tax losses created in the reported year for which deferred taxes were not recorded	2,273	2,576	1,593
Taxes on income reported in the Statement of Loss	28	68	4

NOTE 10 - ACCOUNTS PAYABLE AND ACCRUALS:

a. Trade payables are denominated in the following currencies:

	December 31	
	2016	2015
	USD in thousands	
NIS unlinked	108	184
US Dollar	252	174
Euro	7	
	367	358

b. Other:

	December 31	
	2016	2015
	USD in thousands	
Payroll and related expenses	150	367
Wages and fees of related parties and related expenses	90	164
Institutions	132	183
Provision for vacations and recreation pay	170	182
Advanced payments from customers	193	393
Accrued expenses	232	206
	967	1,495

Other payable balances (except for institutions and advances from customers) are denominated in the following currencies:

	As of December 31	
	2016	2015
	USD in thousands	
NIS unlinked	378	517
US Dollar	235	369
Euro	29	33
	642	919

The balances of the financial instruments included within the trade payables and other payables approximate their fair value as the effect of the discounting is immaterial.

NOTE 11 - COMMITMENTS AND CONTINGENT LIABILITIES:

a. Commitments:

Lease agreements:

1) The Company and the subsidiary have operating lease agreements with respect to the buildings they use. The lease periods end in December 31, 2017 and June 30, 2017, respectively.

   The lease payments of the Company are linked to the Israeli CPI and for subsidiary are stated at the US dollar.

   The annual lease payments amounted to approximately USD 120 thousands in 2016.

   The minimum annual lease payments under the agreements for 2017 are USD 124 thousands.

2) The Company leases vehicles under operating lease agreements for a period of 36 months. With regards to these agreements, the Company has deposited amounts as security for the future lease payments. As of the balance sheet date the balance of such deposits is approximately USD 24 thousands. The minimum annual lease payments according to the agreements are as follows:

	December 31, 2016
	USD in thousands
2017	82
2018	38
2019	2
	122

b. Contingent liabilities:

1) On June 16, 2015, the Company filed a claim in the District Court of Delaware against EndoChoice, Inc. ("EndoChoice") for its patent infringement, seeking an injunctive order and damages. On October 6, 2015, the Company filed claims against EndoChoice's trademark applications with the Israeli Patent Office. On December 29, 2015, EndoChoice filed a separate trademark and unfair competition action against the Company and its U.S. Subsidiary. In addition, on January 27, 2016, EndoChoice commenced an opposition procedure with the Israeli Patent Office against the Company's trademark application in Israel.

   On October 28, 2016, the Group and EndoChoice settled all litigation and administrative proceedings between themselves, including those actions pending in the U.S. District Court for the District of Delaware C.A. Nos. 15-505-LPS-CJB and C.A. No. 15-1215-LPS-CJB and the trademark opposition proceedings in the State of Israel involving Trademark Application Nos. 257172, 260433 and 262423. Under the settlement agreement, Medigus was granted a covenant not to sue with respect to EndoChoice FUSE-related trademarks and EndoChoice was granted a non-exclusive license to Medigus' U.S. Patent No. 6,997,871 and related patents. Each party has agreed to bear its own costs and fees associated with the Litigations.

2) On March 30, 2016, a former Company secretary and internal legal advisor (the "Employee") filed a lawsuit against the Company at the amount of $219 thousands. The lawsuit notes several claims, among which is that the Employee was wrongfully terminated. According to the Company's management and based on the advice of its legal advisors, the lawsuit should not have a material unfavorable effect on the Company's financial statements. Accordingly, no provision was recorded in these financial statements.

3) Refer to Note 9f regarding withholding tax audit.

NOTE 12 - EQUITY:

a. Share capital:

1) Composed as follows:

	Number of shares				Amount			
	Authorized		Issued and paid		Authorized		Issued and paid	
	December 31		December 31		December 31		December 31	
	2016	2015	2016	2015	2016	2015	2016	2015
	In thousands				NIS in thousands		USD in thousands	
Ordinary shares of NIS 0.1 par value*	150,000	150,000	44,143	32,047	15,000	15,000	1,189	870

* Traded on the Tel Aviv Stock exchange at NIS 0.5030 per ordinary share of NIS 0.1 par value on December 31, 2016. Traded on the NASDAQ at USD 0.565 per ADS on December 31, 2016.

2) The ordinary shares confer upon their holders voting rights and the right to participate in shareholders' meetings, the right to receive dividends and the right to participate in surplus assets in the event of liquidation of the Company.

b. Share offering to the public and existing shareholders:

1) On August 21, 2014 and August 26, 2014, the Company allotted in a private issue, a total of 8,527,154 ordinary shares of the Company, and also a total of 34,108,614 warrants (Series E) for the purchase of an additional 3,410,861 shares for total cash consideration of approximately USD 11 million. Each 10 warrants (Series E) is exercisable into 1 ordinary share of the Company at an exercise price of NIS 6.27 per share during the 36 months following the allotment.

21,847,610 warrants (Series E) of the warrants which were issued may, under certain circumstances, also be exercised via a cashless exercise mechanism, whereby the number of shares the value of which equals the exercise premium in cash will be deducted from the number of shares to be issued upon exercise of the warrant. In addition, the number of warrants outstanding will be adjusted to certain events specified in the warrant agreement (such as: dividends, distribution bonus shares, etc.)

In accordance with International Accounting Standard 32: "Financial Instruments: Presentation", these warrants are a "financial liability", which was classified in the balance sheet as a non-current liability among "warrants at fair value".

The remainder of the warrants which do not have a cashless exercise mechanism were classified as an equity instrument.

Net proceeds from the issuance, net of cash issuance expenses, amounted to approximately USD 10 million.

NOTE 12 - EQUITY (continued)**:**

The fair value of 12,260,974 warrants which were allotted on August 21, 2014 was approximately USD 365 thousands. Calculation of fair value was made based on the following assumptions: quoted share price on August 21, 2014 of NIS 4.34, standard deviation of 51.8%, risk-free interest rate of 1.06%, no dividend expectation, and expected period to exercise of 3 years.

The fair value of 21,847,640 warrants which were allotted on August 26, 2014 was approximately USD 680 thousand. Calculation of fair value was made based on the following assumptions: quoted share price on August 26, 2014 of NIS 4.46, standard deviation of 51.8%, risk-free interest rate of 0.96%, no dividend expectation, and expected period to exercise of 3 years.

As to the fair value of the said warrants as of December 31, 2016 and 2015 see note 4(2).

The changes in the fair value of the warrants over the period from the allotment date until the date of the balance sheet was recorded in the Statements of Loss and Other Comprehensive Loss among "Profit from change in fair value of warrants issued to investors". For further details of the measurement and classification of warrants, see Note 4.

The gross proceeds were attributed as follows: first to the fair value of the warrants classified as financial liabilities at fair value through profit or loss and the remainder was attributed between shares and warrants classified as equity in accordance with their relative fair values.

Issuance expenses were attributed to equity and liability in proportion with the allocation of the proceeds, as detailed below:

	Equity		Liabilities	
	Ordinary share capital and share premium	Warrants	Warrants	Total
	USD in thousands			
Proceeds gross	9,984	355	663	11,002
Issuance expenses	(777)	(27)	*(52)	(856)
Proceeds net	9,207	328	611	10,146

* The issuance expenses in the amount of USD 52 thousand which were attributed to the warrants classified as a financial liability were charged directly to profit or loss.

2) On July 8, 2015, the Company issued a shelf offering report in Israel in accordance with a shelf prospectus of the Company dated August 28, 2013.

In accordance with results of the offering to the public the Company issued 70,525 units at the price of NIS 380 per unit. Each unit was comprised of 100 ordinary shares (and 500 warrants (Series 9).

Each 10 warrants (Series 9) is exercisable into 1 share in consideration for an exercise price of NIS 5.32 until July 8, 2018.

The immediate proceeds (gross) from the issuance of all securities offered amounted to approximately NIS 26.8 million (approximately USD 7 million).

NOTE 12 - EQUITY (continued)**:**

Net proceeds from the issuance, net of issuance expenses, amounted to approximately USD 6.8 million (NIS 25.5 million) of which a total of USD 6 million were allocated to shares, and a total of USD 0.8 million to warrants (Series 9) in accordance to the fair value ratios of the instruments.

3) On March 3, 2016 warrants (Orbimed) expired as the exercise period was ended.

4) On September 12, 2016, the Company closed a registered direct offering, pursuant to which the Company issued a total of 1,280,000 American depositary shares (ADS) representing a total of 6,400,000 ordinary shares, at a purchase price per ADS of $1.15.

   The immediate proceeds (gross) from the issuance of securities offered amounted to approximately USD 1.47 million.

   Net proceeds from the issuance, net of issuance expenses, amounted to approximately USD 1.3 million.

   To the co-placement agent on this offering the Company issued 197,750 warrants (Series H). Each warrant (Series H) is exercisable into 1 share in consideration for an exercise price of USD 0.23 per share per share during the 5 years following the allotment. The warrants may, under certain circumstances, also be exercised via a cashless exercise mechanism.

   The fair value of warrants (Series H) which was allocated to co-placement agent amounted to USD 38 thousand were deducted from the issue proceeds and charged to profit or loss.

5) On October 17, 2016 warrants (Series 8) expired as the exercise period was ended.

6) On December 6, 2016, the Company closed a registered direct offering, pursuant to which the Company issued a total of a total of 1,139,170 ADSs representing a total of 5,695,850 ordinary shares, at a purchase price of US$0.67 per ADS, and warrants (Series I) to purchase up to a total of 398,710 ADSs representing 1,993,550 ordinary shares.

   The immediate proceeds (gross) from the issuance of securities offered amounted to approximately USD 0.8 million.

   Net proceeds from the issuance, net of issuance expenses, amounted to approximately USD 0.6 million.

   Each warrant (Series I) is exercisable into 1 ordinary share of the Company at an exercise price of USD 0.18 per share during the 5.5 years following the allotment.

   In accordance with International Accounting Standard 32: “Financial Instruments: Presentation”, these warrants (Series I) are a “financial liability”, which was classified in the balance sheet as a non-current liability among “warrants at fair value”.

   As to the fair value of the said warrants as of December 31, 2016 see note 4(2).

   To the placement agent on this offering the Company issued 199,355 warrants (Series J). Each warrant (Series J) is exercisable into 1 share in consideration for an exercise price of USD 0.1474 per share during the 5 years following the allotment. The warrants may, under certain circumstances, also be exercised via a cashless exercise mechanism.

NOTE 12 - EQUITY (continued)**:**

To Roth Capital Partners and Maxim Group LLC the company issued 99,675 warrants (Series J Each warrant (Series J) is exercisable into 1 share in consideration for an exercise price of USD 0.18 per share during the 5.5 years following the allotment. The warrants may, under certain circumstances, also be exercised via a cashless exercise mechanism.

The fair value of warrants (Series J) amounted to USD 32 thousand were deducted from the issue proceeds and charged to profit or loss.

c. Share based payments (not include warrants (Series H and Series J) as described above)**:**

1) The following are the grants of options to employees and other service providers:

Date of grant	Plan	Number of options granted	exercise price per option (NIS)	Fair value on grant date-NIS in thousands	Number of options outstanding-December 31, 2016	Number of options exercisable at 31 December 2016	Expiration date
September 2011	Series A	(*)695,000	(**)0.91	279	125,000	125,000	November 2, 2017
November 2011	Series A	1,420,000	(**)0.91	536	885,000	885,000	November 2, 2017
April 2012	Series A	230,000	(**)0.91	117	150,000	150,000	April 23, 2018
April 2012	Series B	1,150,000	(**)0.68	659	820,000	820,000	April 23, 2018
October 2013	Series C	(***)4,500,000	(**)0.83	1,357	3,850,000	3,850,000	September 30, 2018
July 2014	Series D	(*)310,000	(**)0.537	56	60,000	60,000	July 17, 2020
July 2014	Series D	3,070,000	(**)0.537	554	1,995,000	1,080,000	July 17, 2020
December 2015	Series F	(*)157,500	2.05	116	157,500	39,375	December 29, 2021
December 2015	Series F	664,800	2.05	491	330,000	82,500	December 29, 2021
December 2015	Series G	350,000	2.05	259	350,000	116,667	December 29, 2021
Total		12,547,300			8,722,500	7,208,542	

(*) Granted to related parties.
(**) Linked to the CPI as set out in the option allotment plan.
(***) The board of directors meeting dated August 12, 2013, and the general meeting of the Company's shareholders dated September 29, 2013 authorized the allotment of 4,500,000 options (Series C), to the CEO of the Company. The options (Series C) are subject to the conditions of the option allotment plan, for the allotment of non-marketable options to officers, employees and advisors of the Group. Each 10 options is exercisable into one ordinary Company share of NIS 0.1 par value at the exercise price of NIS 8.3.

NOTE 12 - EQUITY (continued)**:**

The right to exercise options is vested as follows:

(1) 3,200,000 options will vest in 24 equal monthly batches, on the first day of each month, for a period of 24 months, commencing one year following the date employment started according to the agreement, i.e., commencing October 1, 2014.

(2) 650,000 options will vest on June 30, 2014, provided that a target is met which was set by the Company's board of directors and which is related to clinical activities of the MUSE system in the USA through this date. These options were vested as of June 30, 2014.

(3) 650,000 options will vest on February 1, 2015 provided that a sales revenues target is met in 2014, as set by the Company's board of directors. In accordance with the decision of the Company's board, these options expired on March 31, 2015 due to failure to meet the target.

Vesting conditions of all of the above options, except for the 1,300,000 options (Series C) as detailed in (2) and (3) above are service conditions.

Each 10 options (Series 6, Series A, Series B, Series C and Series D) is exercisable into 1 ordinary share.
Each 1 option (Series F and Series G) is exercisable into 1 ordinary share.

The fair value of all of the options was calculated using the Black and Scholes options pricing model, and based on the following assumptions:

Date of grant	Fair value on grant date-NIS in thousands	Share price on date of grant (NIS)	Expected dividend	Expected volatility	Risk free interest	Vesting conditions	Expected term
July 2014	610	0.482	None	40%	1.90%	four equal batches, following one, two, three and four years from their grant date	6 years
December 2015	607	1.627	None	54%	1.39%	four equal batches, following one, two, three and four years from their grant date	6 years
December 2015	259	1.627	None	54%	1.39%	will vest in 36 equal monthly equal batches commencing January 29, 2016.	6 years

NOTE 12 - EQUITY (continued)**:**

1) The changes in the number of share options and the weighted averages of their exercise prices are as follows:

	For the year ended December 31					
	2016		2015		2014	
	Number of options	Weighted average of exercise price per 1 ordinary share-(NIS)	Number of options	Weighted average of exercise price per 1 ordinary share-(NIS)	Number of options	Weighted average of exercise price per 1 ordinary share-(NIS)
Outstanding at the beginning of year	10,459,800	7.58	11,110,000	8.4	9,150,000	10.7
Granted			1,172,300	2.05	3,380,000	5.37
Forfeited	(302,500)	6.45	(485,833)	15.6	(644,667)	16.1
Expired	(1,434,800)	3.39	(1,336,667)	6.98	(775,333)	15.9
Outstanding at year end	8,722,500	6.97	10,459,800	7.58	11,110,000	8.4
Exercisable at year end	7,208,542	7.59	6,034,999	9.23	3,547,498	11.6

2) The amounts of expenses that were recorded for options to employees and other service providers in the reported years are USD 104 thousand, USD 116 thousand and USD 311 thousand for the years ended December 31, 2016, 2015 and 2014, respectively.

3) The plans are intended to be governed by the terms stipulated by Section 102 to the Israeli Income Tax Ordinance (except for the options to controlling shareholders).

In accordance with these general rules and the track chosen by the Company pursuant to the terms thereof, in respect of options granted to employees under the option allotment plan, the Company is not allowed to claim as an expense for tax purposes the amounts credited to employees as a benefit, including amounts recorded as salary benefits in the Company's books, with the exception of the salary-benefit component, if exists, determined on the grant date.

NOTE 13 - EXPENSES BY NATURE:

	Year ended December 31		
	2016	2015	2014
	USD in thousands		
Payroll and related expenses	4,104	4,575	4,030
Professional fees	2,129	1,222	934
Materials used and subcontracted work	1,566	2,120	1,525
Travel	605	710	607
Advertising and participation in exhibitions	403	648	652
Rent and office maintenance	212	238	297
Vehicle maintenance	202	177	189
Preparation of patents	110	114	146
Depreciation and amortization	99	122	178
Management fees			248
Other	210	257	191
TOTAL COST OF REVENUES, ADMINISTRATIVE AND GENERAL, SELLING AND MARKETING AND RESEARCH AND DEVELOPMENT EXPENSES, NET	9,640	10,183	8,997

NOTE 14 - OTHER INCOME, NET:

	Year ended December 31	
	2015	2014
	USD in thousands	
In respect of financial assets at fair value through profit or loss - Profit from changes in fair value	3	19
	3	19
In respect of cancellation of an agreement with a customer (*)		250
Total	3	269

(*) Supply agreement

On January 10, 2010 the Company and Voyage Medical Inc. (a US medical device company, hereinafter – the "Customer") entered into a multi-year supply agreement (hereinafter – the "Agreement") for the supply of disposable miniature video cameras and control systems which were developed by the Company.

On February 12, 2014, after suitable assurances were not received from the Customer, in accordance with the terms of the Agreement, the Company terminated the said agreement. As a result of the termination of the Agreement the Company recognized the remaining deferred revenue balance (of the initial USD 300 thousands) amounting to USD 106 thousand. In addition, since almost all of the products relating to the remaining additional advance payments received in 2010 and 2011 totaling USD 250 thousand were never delivered to the Customer (excluding a few units relating to an immaterial advance payment), the said advance payments were recorded to Other Income, net.

NOTE 15 - LOSS PER SHARE:

a. Basic loss per share

The basic loss per share is calculated by dividing the loss attributable to equity holders of the Company by the weighted average number of shares in issue.

	Year ended on December 31		
	2016	2015	2014
	USD in thousands		
Loss attributed to shareholders	(9,007)	(9,532)	(6,358)
Weighted average of the number of ordinary shares issued	34,397	28,415	19,500
Basic loss per share (USD)	(0.26)	(0.34)	(0. 33)

NOTE 15 - LOSS PER SHARE (continued)**:**

b. Diluted loss per share

The diluted loss per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares. A calculation is done to determine the number of shares which could have been acquired at fair value (determined as the average annual market share price of the Company's shares) based on the monetary value and according to the conditions attached to the outstanding options and warrants. The number of shares calculated as above is compared to the number of shares which would have been issued assuming the exercise of the share options and warrants.

However, in calculating the diluted loss per share for the years reported, share options granted to employees and others and warrants, were not taken into account – as their impact in the event of full dilution is anti-dilutive. Therefore, the diluted loss per share is equal to the basic loss per share.

NOTE 16 -TRANSACTIONS AND BALANCES WITH RELATED PARTIES

On March 3, 2013, as a result of the completion of the transaction with Orbimed (see Note 12 B), Elazar Sonnenschein, Menashe Sonnenschein, Aviel Roy Shapira, Esther and Kfir Luzzatto and Yair Rabinowitch have signed a letter of undertaking to OrbiMed, or the Shareholders' Undertaking, according to which each undertook, until the earlier of: (i) the three year anniversary of the closing date; or (ii) the date on which OrbiMed's voting rights exceed 45% of the aggregate voting rights of the Company, to vote their shares in accordance with OrbiMed's instructions in connection with certain matters such as the size of the board, to elect four directors nominated by OrbiMed (including the chairman of the board of directors) and for any other matter in accordance with OrbiMed's instructions provided that such matter is not 'unreasonable'. On March 3, 2016, the Shareholders' Undertaking has expired.

"Related Parties" – As defined in IAS 24 – 'Related Party Disclosures" (hereinafter- "IAS 24")

Key management personnel of the Company - included together with other entities, in the said definition of "Related Parties" mentioned in IAS 24, include some members of senior management.

a. Transactions with related parties:

1):

	Year ended on December 31		
	2016	2015	2014
	USD in thousands		
Preparation of patents	18	114	146
Benefits to related parties:			
Payroll and related expenses to related parties employed by the Company* (3 recipients)	377	716	938
Compensation to directors not employed by the Company (2016:4 recipients, 2015: 3 recipients, 2014: 4 recipients,)	52	58	62
Management fees to a related party			286
Compensation to a director employed by the Company	14	13	12
Directors' insurance	61	48	21

* Includes an amount of USD 20 thousand (2015: USD 71 thousand, 2014: USD 204 thousand) representing the value of the benefit in respect of options granted. As for the method used to determine the said value and the assumptions used in calculation thereof, see Note 12 C.

NOTE 16 - TRANSACTIONS AND BALANCES WITH RELATED PARTIES (continued):

2) Compensation to key management personnel

The compensation to key management personnel for employment services they provide to the Company is as follows:

	Year ended on December 31		
	2016	2015	2014
	USD in thousands		
For employment services:			
Payroll and other short-term benefits	330	*456	526
Share based payments	19	62	192
	349	518	718

* Including provision for bonus of approximately USD 86 thousand.

3) Indemnification, exemption and insurance for directors and officers of the Company

a. The Company provides its directors and officers with an obligation for indemnification and exemption.

b. The Company has a directors and officers' liability insurance policy covering all Company's directors and officers. We currently have directors' and officers' liability insurance providing total coverage of $15 million for the benefit of all of our directors and officers, in respect of which we are charged a twelve-month premium of $ 67 thousand, and which includes a deductible of up to $50,000 per claim, other than securities related claims filed in the United States or Canada, for which the deductible shall not exceed $200,000.

b. Balances with related parties:

	December 31	
	2016	2015
	USD in thousands	
Current liabilities, presented in the balance sheets among "accounts payable and accruals"	90	164

c. As to options granted to related parties, see Note 12 C.

NOTE 17 - ENTITY LEVEL DISCLOSURES:

a. Revenues by product:

	Year ended on December 31		
	2016	**2015**	**2014**
	USD in thousands		
Miniature camera and related equipment	449	558	653
MUSE and related equipment	100	66	91
	549	624	744

b. Revenues by geographical area (based on the location of customers):

	Year ended on December 31		
	2016	**2015**	**2014**
	USD in thousands		
USA	345	446	460
Israel	119		
Japan		33	104
Other	85	145	180
	549	624	744

c. All of the Group's long-lived assets are located in Israel.

d. Major customers

Set forth below is a breakdown of Company's revenue by major customers (major customer –revenues from this customer constitute at least 10% of total revenues in a certain year):

	Year ended on December 31		
	2016	**2015**	**2014**
	USD in thousands		
Customer A	239	261	
Customer B	118		
Customer C (see also Note 14)			106
Customer D			114

NOTE 18 - SUBSEQUENT EVENTS:

1. Refer to Note 1a regarding a change in the ratio of ordinary shares per ADS.

2. On March 20, 2017 a general meeting of the Company's shareholders approved an increase of the authorized share capital of the Company by an additional NIS 65,000,000 such that the authorized share capital of the Company following such increase shall be NIS 80,000,000, consisting of 800,000,000 ordinary shares, NIS 0.10 par value per share.

3. On March 24, 2017, the Company entered into a securities purchase agreement as part of an offering of its ADSs pursuant to a registration statement in the United States. As part of the offering, the Company issued a total of 979,714 Class A Units at a purchase price per unit of $3.50 and of 1,163,144 Class B Units at a purchase price per unit of $3.49. Each Class A unit consists of (i) one American Depositary Share, or ADS, and (ii) one Series A warrant to purchase one ADS, and each Class B unit consists of (i) one pre-funded warrant to purchase one ADS, and (ii) one Series A warrant to purchase one ADS. The Series A warrants have a term of five years, and are exercisable immediately (or, at the election of the purchaser, six months following the issuance date) and have an exercise price of $3.50 per ADS. The pre-funded warrants are exercisable immediately until exercised in full and have an exercise price of $0.01 per ADS. As part of such offering, the Company issued to the placement agent of the offering, warrants to purchase up to an aggregate of 150,000 ADSs representing 7,500,000 ordinary shares, with an exercise price of $4.375 per ADS.

   The immediate proceeds (gross) from the issuance of securities offered amounted to approximately USD 7.5 million.

   Net proceeds from the issuance, net of issuance expenses, amounted to approximately USD 6.5 million.

ITEM 19. EXHIBITS

Exhibit Number	Exhibit Description
1.1	Articles of Association of Medigus Ltd., as amended.[(1)∞]
2.1	Form of Deposit Agreement between Medigus Ltd., The Bank of New York Mellon as Depositary, and owners and holders from time to time of ADSs issued thereunder, including the Form of American Depositary Shares.[(1)]
2.2	Form of Ordinary Shares Purchase Warrant issued in connection with the June 2014 Securities Purchase Agreements to non-Israeli investors.[(1)]
2.3	Form of Ordinary Shares Purchase Warrant issued in connection with the June 2014 Securities Purchase Agreements to Israeli investors (other than Migdal).[(1)]
2.4	Form of Ordinary Shares Purchase Warrant issued in connection with the June 2014 Securities Purchase Agreements to Migdal.[(1)∞]
2.5	Form of Series A Warrant to purchase Ordinary Shares Represented by American Depositary Shares issued in connection with the March 2017 Securities Purchase Agreements.[(2)]
2.6	Form of Pre-Funded Series B Warrant to purchase Ordinary Shares Represented by American Depositary Shares issued in connection with the March 2017 Securities Purchase Agreements.[(2)]
2.7	Form of Placement Agent Warrant to purchase Ordinary Shares Represented by American Depositary Shares issued in connection with the March 2017 Securities Purchase Agreements.[(2)]
4.1	Securities Purchase Agreement by and among Medigus Ltd. and OrbiMed Israel Partners Limited Partnership dated June 29, 2014.[(1)]
4.2	Securities Purchase Agreement by and among Medigus Ltd., Sabby Volatility Warrant Master Fund Ltd., Sabby Healthcare Volatility Master Fund Ltd., Armistice Capital Master Fund Ltd., Senvest Israel Partners LP and Senvest International LLC dated June 29, 2014.[(1)]
4.3	Securities Purchase Agreement by and among Medigus Ltd. and Capital Point Ltd. dated June 29, 2014. [(1)]
4.4	Securities Purchase Agreement by and among Medigus Ltd. and Migdal Insurance Company Ltd. dated June 29, 2014.[(1)∞]
4.5	2013 Share Option and Incentive Plan.[(1)]
4.8	Series A Option Plan.[(1)∞]
4.9	Series B Option Plan.[(1)∞]
4.10	Compensation Policy of Medigus Ltd.[(3)]
4.11	Lease Agreement between Medigus USA LLC and Regus Plc dated December 4, 2013.[(1)]
4.12	Lease Agreement between Medigus Ltd. and Sky-City Office Center for HiTech Industries Ltd. dated June 15, 2014.[(1)∞]
4.13	Lease Agreement Tefen Yazamut Ltd. regarding main offices in Omer Industrial Park dated December 10, 2013.[(1)∞]
4.14	Form of Indemnification and Exculpation Undertaking.[(1)]
4.15	Securities Purchase Agreement by and Securities Purchase Agreement by and between the Registrant and the purchasers in the registered direct offering dated September 8, 2016.[(4)]
4.16	Securities Purchase Agreement by and between the Registrant and the purchasers in the registered direct offering dated December 1, 2016. [(5)]
4.17	Form of Warrant to purchase Ordinary Shares Represented by American Depositary Shares issued in connection with the December 2016 Securities Purchase Agreements.[(5)]
4.18	Form of Securities Purchase Agreement, dated March 24, 2017.[(2)]
8.1	List of Subsidiaries[(1)]
12.1	Certification of Chief Executive Officer as required by rule 13a-14(a).[(6)]
12.2	Certification of Chief Financial Officer as required by rule 13a-14(a).[(6)]
13.1	Certification of Chief Executive Officer as required by rule 13a-14(a) and Section 1350 of Chapter 63 of Title 18 of the United States Code.[(6)]
13.2	Certification of Chief Financial Officer as required by rule 13a-14(a) and Section 1350 of Chapter 63 of Title 18 of the United States Code.[(6)]
15.1	Consent of Kesselman & Kesselman, Certified Public Accountant (Isr.), a member of PricewaterhouseCoopers International Limited, independent registered public accounting firm for the Medigus Ltd.[(6)]

(1) Previously filed with the Securities and Exchange Commission on May 7, 2015, as an exhibit to the Registrant's registration statement on Form 20-F (File No 001-37381) and incorporated by reference herein.
(2) Previously filed with the Securities and Exchange Commission on March 23, 2017, as an exhibit to the Registrant's registration statement on Form F-1 (File 333-216155) and incorporated by reference herein.
(3) Previously filed with the Securities and Exchange Commission on March 30, 2016, as an exhibit to the Registrant's annual report on Form 20-F (File No 001-37381) and incorporated by reference herein.
(4) Previously filed with the Securities and Exchange Commission on September 8, 2016, as an exhibit to the Registrant's report on Form 6-K (File No 001-37381) and incorporated by reference herein.
(5) Previously filed with the Securities and Exchange Commission on December 1, 2016, as an exhibit to the Registrant's report on Form 6-K (File No 001-37381) and incorporated by reference herein.
(6) Furnished herewith.
∞ English translation of original Hebrew document.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this registration statement on its behalf.

Medigus Ltd.

By: /s/ Christopher (Chris) Rowland
Christopher (Chris) Rowland
Chief Executive Officer

By: /s/ Oded Yatzkan
Oded Yatzkan
Chief Financial Officer

Date: March 30, 2017

Exhibit 12.1

CERTIFICATION

I, Christopher (Chris) Rowland, certify that:

1. I have reviewed this annual report on Form 20-F of Medigus Ltd.;

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 company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company 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 company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company'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 company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting.

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company'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 company'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 company's internal control over financial reporting.

Date: March 30, 2017

By: /s/ Christopher (Chris) Rowland
Christopher (Chris) Rowland,
Chief Executive Officer

Exhibit 12.2

CERTIFICATION

I, Oded Yatzkan, certify that:

1. I have reviewed this annual report on Form 20-F of Medigus Ltd.;

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 company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company 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 company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company'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 company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting.

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company'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 company'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 company's internal control over financial reporting.

Date: March 30, 2017

By: /s/ Oded Yatzkan
Oded Yatzkan,
Chief Financial Officer

Exhibit 13.1

CERTIFICATION

PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(SUBSECTIONS (a) AND (b) OF SECTION 1350, CHAPTER 63 OF
TITLE 18, UNITED STATES CODE)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code), the undersigned officer of Medigus Ltd., a company organized under the laws of the State of Israel (the "Company"), does hereby certify that, to his knowledge:

1. This Annual Report on Form 20-F for the year ended December 31, 2016 (the "Form 20-F") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Form 20-F fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 30, 2017

By: /s/ Christopher (Chris) Rowland
Christopher (Chris) Rowland
Chief Executive Officer

This certification accompanies this annual report on Form 20-F pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

Exhibit 13.2

CERTIFICATION

PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(SUBSECTIONS (a) AND (b) OF SECTION 1350, CHAPTER 63 OF
TITLE 18, UNITED STATES CODE)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code), the undersigned officer of Medigus Ltd., a company organized under the laws of the State of Israel (the "Company"), does hereby certify that, to his knowledge:

1. This Annual Report on Form 20-F for the year ended December 31, 2016 (the "Form 20-F") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Form 20-F fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 30, 2017

By: /s/ Oded Yatzkan
Oded Yatzkan
Chief Financial Officer

This certification accompanies this annual report on Form 20-F pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Forms F-3 (No. 333-213280) and S-8 (No. 333-206803) of Medigus Ltd. of our report dated March 30, 2017 relating to the financial statements, which appears in this Form 20-F.

Tel-Aviv, Israel
March 30, 2017

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

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