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, 2015

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)

Gilad Mamlok
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, eachrepresenting five (5) 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, 2015: **32,047,034 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.

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;
- projected capital expenditures and liquidity;
- changes in our strategy;
- government regulations and approvals;
- changes in customers' budgeting priorities;
- litigation and regulatory proceedings; 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 selected consolidated financial data as of December 31, 2015 and 2014 and for the years ended December 31, 2015, 2014 and 2013 have been derived from our audited consolidated financial statements included elsewhere in this annual report. These audited financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS"), as set forth by the International Accounting Standard Board. The audited consolidated selected financial data as of December 31, 2013, 2012 and 2011 and for the years ended December 31, 2012 and December 31, 2011, have been 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.

Consolidated Statements of Operations Data

	As of December 31,					
	2011	2012	2013	2014	2015	2015
			NIS (thousands)			U.S.$ [1]
Revenues	1,796	2,999	2,498	2,664	2,416	619
Cost of revenues	808	1,161	1,126	1,252	1,073	275
Gross Profit	988	1,838	1,372	1,412	1,343	344
Research and development, expenses net	9,031	7,752	8,180	14,401	17,020	4,362
Sales and marketing expenses	1,179	1,784	3,234	8,353	10,391	2,663
General and administrative expenses	4,802	4,694	6,877	8,206	11,028	2,826
Other income, net	221	214	666	941	10	3
Operating loss	(13,803)	(12,178)	(16,253)	(28,607)	(37,086)	(9,504)
Gain on adjusting warrants to fair value	-	-	11,544	3,605	394	101
Finance income (expenses) – net	(120)	(161)	(395)	2,386	(49)	(13)
Loss before income tax	(13,923)	(12,339)	(5,104)	(22,616)	(36,741)	(9,416)
Income taxes	-	85	(85)	(13)	(264)	(68)
Net loss	(13,923)	(12,254)	(5,189)	(22,629)	(37,005)	(9,484)
Basic and diluted loss per ordinary share[2]	(1.8)	(1.4)	(.4)	(1.2)	(1.3)	(0.33)
Number of ordinary shares used in computing basic and diluted loss per ordinary share[2]	7,515,131	8,698,359	13,019,916	19,499,715	28,414,514	28,414,514

(1) Calculated using the exchange rate reported by the Bank of Israel for December 31, 2015, at the rate of one U.S. dollar per NIS 3.902.

(2) 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. For more information see "Item 4. Information on the Company A. History and Development of the Company."

	As of December 31,					
	2011	2012	2013	2014	2015	2015
	NIS (thousands)					$ U.S.(1)
Balance Sheet Data:						
Cash and cash equivalents	1,183	13,412	23,926	42,067	40,239	10,312
Short-term investments			8,073			
Financial assets at fair value through profit or loss	7,355	1,080	7,958	8,187		
Total assets	11,797	6,679	45,200	55,579	47,374	12,141
Total non-current liabilities	953	1,578	3,070	809	415	106
Accumulated deficit	(89,666)	(101,887)	(107,076)	(129,810)	(166,815)	(42,751)
Total shareholders' equity	7,326	2,938	38,750	50,756	39,728	10,181

(1) Calculated using the exchange rate reported by the Bank of Israel for December 31, 2015 at the rate of one U.S. dollar per NIS 3.902.

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
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
2011	3.821	3.395	3.582	3.821

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 2016(1)	3.912	3.875	3.895	3.891
February 2016	3.964	3.871	3.908	3.91
January 2016	3.983	3.913	3.951	3.951
December 2015	3.905	3.855	3.881	3.902
November 2015	3.921	3.868	3.889	3.877
October 2015	3.923	3.816	3.863	3.867
September 2015	3.949	3.863	3.913	3.923

(1) Through March 15, 2016.

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

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

We have sustained losses in recent years, including an operating net loss of NIS 37,086 thousand for the year ended December 31, 2015. 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 our commercialization of our MUSE™ system, expand its 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.

We will need additional funding. If we are unable to raise capital when needed, we may be forced to delay, reduce or eliminate our research, development and commercialization efforts.

During the year ended December 31, 2015, the Company had a total comprehensive loss of NIS 37 million. As of December 31, 2015 the Company had accumulated losses of NIS 167 million and a positive working capital of NIS 39 million.

Based on the projected cash flows and its cash balances as of December 31, 2015, the Company's Management is of the opinion that without further fund raising it will not have sufficient resources to enable the Company 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 these financial statements. As a result, there are substantial doubts about our ability to continue as a going concern. Management's plans include the continued commercialization of our products, taking cost reduction steps 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 its operations.

If we are unable to obtain additional financing, which, as a result, may require us to reduce the scope of, or delay or eliminate, some or all of our current and planned research, development and commercialization activities. We also may have to reduce marketing, customer service or other resources devoted to our products. Any of these factors could materially harm our business and results of 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 or 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.

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, and mainly the MUSE™ system, depends significantly on the availability of coverage and reimbursement for endoscopic procedures from third-party insurers, 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. We have a CPT category 1 code for the procedure since January 1, 2016.

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

Though we have plans for the development of additional natural orifice surgical products based on our technology including miniature cameras, flexible stapling and ultrasound, and while we currently derive most of our revenue from the sale of miniature cameras and related imaging equipment, we plan to derive most of our revenue from product sales of our imaging equipment and our flagship MUSE ™ system and its future applications, and 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 our flagship product.

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 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 failure in mechanical components, which could result in difficulties in operation, or opening or releasing the products, 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 users of our products do not follow the instructions for use and/or the available product training or instructions, which appear on the screen during the performance of the procedure, the foregoing may cause injury and in certain cases, could even cause death. A result of this kind could reduce the rate of progress, or even prevent, of marketing for the MUSE ™ product 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 to 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 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) clinical and economic value. The collection of clinical and economic data and the process of generating peer review publications in support of our product and procedure 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, 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.

As a result of the concerns relating to the current economic situation or related to ongoing 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, the continued negative worldwide economic conditions and market instability makes it increasingly difficult for us, our customers, our distributors and our suppliers to accurately forecast future product demand trends, which could cause us to order or produce excess products that can increase our inventory carrying costs and result 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 resulting 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 sensors which are suitable for our Complementary Metal Oxide Semiconductor (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 either of these suppliers, there is no contractual commitment on the part of either supplier for any set quantity of such sensors.

Modifications to our current regulator-cleared products or the introduction of new products may require new regulatory clearances or approvals or require us to recall or cease marketing our current products until clearances or approvals are obtained.

Our MUSE™ system has received marketing clearance from the U.S. Food and Drug Administration ("FDA") based on 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 license to market the product in Canada, Turkey and Israel.

Modifications to our products may require new regulatory approvals or 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 cleared devices that would constitute a major change in its intended use, or any change that could significantly affect the safety or effectiveness of the device would require us to obtain a new 510(k) marketing clearance and may even, in some circumstances, require the submission of a premarket approval ("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 in the future 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 products as modified, which could require us to 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, Medigus started the process for receiving a regulator clearance in China by the CFDA, 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 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 specific cleared 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
- 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. 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.

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 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, Centers for Medicare & Medicaid Services, or 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 2013 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 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 recently enacted legislation reforming the U.S. healthcare system, 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. This could materially adversely affect our business and results of operations.

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.

We may attempt to acquire new products or technologies, and if we are unable to successfully complete these acquisitions or to integrate acquired businesses, products, technologies or employees, we may fail to realize expected growth.

Our success depends, in part, on our ability to expand our product offerings and continue to offer advanced medical equipment for endoscopic procedures and grow our business in response to changing technologies, customer demands and competitive pressures. In some circumstances, we may determine to do so through the acquisition of complementary businesses, products or technologies rather than through internal development. Successful acquisitions depends on, among other items, identification of suitable acquisition candidates and the integration of the acquisitions, with which can be difficult, time consuming and costly. In addition, acquisitions could result in potentially dilutive issuances of equity securities or the incurrence of debt, contingent liabilities or expenses, or other charges such as amortization of intangible assets, any of which could harm our business and materially adversely affect our financial results or cause a reduction in the price of our ordinary shares.

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 use 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 that may ultimately issue 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.

We are currently litigating a claim against EndoChoice, Inc., or EndoChoice, for its patent infringement. In response, EndoChoice filed a separate trademark and unfair competition action against us and our U.S. Subsidiary. In addition, EndoChoice commenced an opposition procedure with the Israeli Patent Office against us in connection with our trademark application in Israel. We believe we will fend off EndoChoice's claims but we cannot provide any assurance we will be successful in doing so. Failure to fend off these claims may adversely affect our business in the Israeli or the U.S. market, as applicable. For more information see "Item 8. Financial Information—A. Consolidated Statements and Other Financial Information—Legal Proceedings."

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, including clinical trials requirements and complex evaluation process, both processes 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 much more costly 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, which is responsible for the registration of medical devices in Israel, issuance of import licenses and monitoring marketing of medical equipment. we have received PMDA 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 in the future be subject to product actions 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 a death or a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under FDA regulations, we are required to report to the FDA any incident in which our product 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. In addition, all manufacturers placing medical devices in European Union 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. Any adverse event involving our products could result in future voluntary corrective actions, such as product actions or customer notifications, or agency actions, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

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. 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 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 countries 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 – 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 the foreign currencies and the NIS may negatively affect our earnings.

Our reporting and functional currency is the NIS. However, 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. As a result, we are exposed to the currency fluctuation risks relating to the recording of our revenues in NIS. For example, if the NIS strengthens against either the U.S. dollar or the Euro, our reported revenues in NIS may be lower than anticipated. The Israeli rate of inflation has generally not offset or compounded the effects caused by fluctuations between the NIS and the U.S. dollar or the Euro. Although the Israeli rate of inflation has not had a material adverse effect on our financial condition during 2013, 2014 or 2015, 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 is set at 26.5% for 2015 and 25% for 2016 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. We may be required to pay penalties in addition to repayment of the grants, which may also 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 NIS 0.8 million that we received from the Office of the Chief Scientist of the Israeli Ministry of Economic and Industry , or the OCS. We have received royalty-bearing grants from the government of Israel through the OCS, for the financing of a portion of our research and development expenditures in Israel. When know-how is developed using OCS grants, the Encouragement of Industrial Research and Development Law 5744-1984, or the R&D Law, as well as the terms of these grants restrict our ability to manufacture products and transfer technology and know-how, developed as a result of OCS funded R&D, outside of Israel.

A recipient of the OCS grants is required to return the grants by the payment of royalties on the revenues generated from the sale of products (and related services) developed (in all or in part) as a result of a research and development program funded by the OCS (at rates which are determined under the R&D Law up to the aggregate amount of the total grants received by the OCS, plus annual interest (as detailed in the R&D Law).

Transfer of know-how outside of Israel 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 impose certain conditions, including, in certain circumstances, requirement of payment of a redemption fee (referred to in the law as the "Base Amount") calculated according to the formula provided in the R&D Law which takes into account the consideration for such know-how paid to us in the transaction in which the technology is transferred. Regulations promulgated in 2012 established a maximum payment of the redemption fee paid to the OCS under the formulas provided in the R&D Law and differentiates between certain situations, as further detailed in such regulations. 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, as defined under the R&D Law. The total amount to be repaid to the OCS would be adjusted to an amount which constitutes 120% to 300% of the grants, depending on the manufacturing volume that is performed outside Israel less royalties already paid to the OCS.

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.

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

These restrictions may impair our ability to enter into agreements for those products or technologies without the approval of the OCS. We cannot be certain that any approval of the OCS will be obtained on terms that are acceptable to us, or at all. 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 R&D 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.

Pursuant to Amendment Number 7, the National Authority for Technological Innovation, or NATI, a statutory corporation, has established on January 1, 2016 and is expected to replace the OCS. Pursuant to Amendment Number 7, the current restrictions under the R&D Law will be replaced by 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, which will be promulgated by NATI. The commencement date of Amendment Number 7 was January 1, 2016, however, in the meantime until new arrangements are adopted by NATI, the R&D Law as existed prior to Amendment Number 7 continues to be in force and effect. NATI should be fully constituted no later than July 28, 2018, and the new arrangements should be adopted no later than one year thereafter. As of the date of filing of this report, we are unable to assess the effect, if any, of the promulgation of such arrangements on our company. See "Business – Government regulations – Regulations in Israel."

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 R&D 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 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. See "Enforceability of Civil Liabilities" for additional information on your ability to enforce civil claim against us and our executive officers and directors.

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 recent 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 Our Shares and the ADSs

We may be a passive foreign investment company, or PFIC, for U.S. federal income tax purposes in 2015 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 ordinary shares or the ADSs.

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 but there can be no assurance that we were not a PFIC in 2015 and will not be a PFIC in subsequent years., our operating results for any such years may cause us to be a PFIC. If we are a PFIC in 2015, 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 ordinary shares or the ADSs 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 ordinary shares (or ADSs, as the case may be); (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 ordinary shares or the ADSs 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 ordinary shares and the ADSs 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 Tel Aviv Stock Exchange ("TASE") and the ADSs on the NASDAQ Capital Market, 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 ordinary shares and the ADSs will continue to be subject to wide fluctuations. The market price of our ordinary shares and the ADSs 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 ordinary shares and the ADSs 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 ordinary shares or the ADSs could reduce the market price of our ordinary shares and the ADSs.

Substantial sales of our Ordinary Shares or the ADSs, either on the TASE or on NASDAQ, may cause the market price of our ordinary shares or ADSs 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 ordinary shares or ADSs, or the perception that these sales may occur in the future, could cause a reduction in the market price of our ordinary shares or ADSs.

The issuance of any additional ordinary shares, any additional ADSs, 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 ordinary shares and the ADSs and will have a dilutive effect on our existing shareholders and holders of ADSs.

Holders of the 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, 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 our 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 for the ADSs. 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 our 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 our 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 our 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 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 our ADSs may not be able to exercise their right to vote and they may lack recourse if their 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 ordinary shares or the ADSs must come from increases in the value and trading price of our ordinary shares and the ADSs.

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

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 common stock 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 ordinary shares or ADSs less attractive if we rely on these exemptions. If some investors find our ordinary shares or ADSs less attractive as a result, there may be a less active trading market for our ordinary shares or the ADSs and the price of our ordinary shares or the ADSs 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 ordinary shares and the ADSs 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 stock or change their opinion of our ordinary shares and the ADSs, the price of our ordinary shares and the ADSs 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 ordinary shares and the ADSs will be traded on different markets and this may result in price variations.

Our ordinary shares have been traded on the TASE since February 2006 and our ADSs have been traded on the NASDAQ Capital Market since May 15, 2015. Trading in our securities on these markets takes place in different currencies (dollars on the NASDAQ Capital Market 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 our ordinary shares and the ADSs on these two markets may differ due to these and other factors. Any decrease in the price of our securities on one of these markets could cause a decrease in the trading price of our securities on the other market.

We incur additional increased costs as a result of the listing of the ADSs for trading on the NASDAQ Capital Market, 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 Capital Market. These include costs associated with corporate governance requirements of the SEC and the Marketplace Rules of the NASDAQ Stock Market, 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 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 Stock Market 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 Stock Market, 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 Stock Market, may provide less protection than is accorded to investors under the rules of the NASDAQ Stock Market applicable to domestic issuers. See "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 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, 2016.

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 ordinary share price and the ADSs 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 ordinary shares or the ADSs may suffer.

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 our ADSs on NASDAQ, and since August 2015 our ADSs have been traded on the NASDAQ under the symbol "MDGS". Each ADS represents 5 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 seven employees, including 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 our ADSs was adjusted to the current.

Based on the projected cash flows and its cash balances as of December 31, 2015, 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 the 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 1d 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, 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 NIS 375 thousand in 2015, NIS 389 thousand in 2014, and NIS 375 thousand in 2013. 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 exceed our capital expenditures in 2016 especially in production equipment due to the need to increase the volume of products and to reduce production costs.

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

B. Business 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. Though to date, substantially all of our revenues have derived from our miniaturized imaging equipment for use in medical and industrial applications. Our expertise is in the development, production and marketing of innovative surgical devices with direct visualization capabilities for the treatment of 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 FDA-cleared and CE-marked endosurgical system, known as the MUSE™ 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

Gastroesophageal Reflux Disease, or GERD, is a prevalent worldwide disorder, with over 20% of adults experiencing at least weekly GERD symptoms. Between July 2013 and June 2014, Nexium (a proton pump inhibitor prescribed for the alleviation of GERD symptoms) was the third best selling drug in the United States, with sales of over $6.3 billion and the third highest prescribed drug. This figure does not include sales of other brands of proton pump inhibitors. Studies have estimated the prevalence of GERD in the United States as between 10-20% in varying severities.

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 (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. 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. 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.

Treatment of GERD

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.

1. Drug treatment - Proton pump inhibitors (PPI)

For moderate to severe GERD, physicians usually prescribe proton pump inhibiting drugs (PPI). 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 brands on the market, best known are 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 dosage is inadequate to control GERD symptoms, except in mild cases.

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

a) In 30-40% of patients, symptom control is incomplete;

b) The drugs do not treat the disease, they only control its manifestations, therefore must be taken for life at a dosage which requires prescription. Accumulated costs are 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 had recently issued a warning on this effect as well as warnings against other untoward effects on absorption of other essential minerals, which may lead to seizures, irregular heartbeat, diarrhea and increase flatulence.

2. Interventional treatment

The most common operation for GERD is called Nissen fundoplication, a surgical procedure which prevents reflux by wrapping the upper part of the stomach around the lower esophagus and securing the wrap with sutures. Due to the presence of the wrap, increasing pressure in the stomach compresses the portion of the esophagus which is wrapped by the stomach, and prevents acidic gastric juice 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 PPI, and up to 60% still use some in long term follow up. Nevertheless, the dose is usually lower – in the over the counter range - and the response rate is excellent. 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.

In spite of the excellent clinical outcome of surgery, relatively few patients undergo surgery. We estimate that large numbers of patients who are candidates for operative treatment are either not referred by their treating physician or decline it. We believe that many patients decline to undergo operations to avoid even minute scars or 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 our industry as the “treatment gap”, there is a demand for a minimally-invasive, incision-less procedure which treats the root cause of the disease. We believe that the MUSE system is positioned to fill this need.

Our system achieves the general physiological result of Nissen 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.

The market for medical devices, for which our products are designated, and particularly the market for endoscopy treatments, is very broad, with an increasing demand for new alternatives to the currently existing surgical procedures for the treatment of various diseases. Despite the many impressive medical developments in recent decades, there are still many diseases which are not satisfactory addressed by currently existing treatments. Most currently available medical solutions may be insufficient to address such diseases since the existing treatments may involve risks and harm to the human body, may cause pain and undesirable side effects, may be very expensive or may require long recovery periods, among other reasons. The increasing need for minimally invasive and incision-less treatments, such as endoscopy-based procedures, are also augmented by the increase in the average age of the population, alongside a corresponding rise in the number of patients, and particularly patients with poor physical conditions who may face difficulties undergoing invasive medical procedures.

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 via the throat, to avoid incisions. Because of the accessibility of the digestive tract through the throat, the endoscopy field is largely focused on disorders of the esophagus, stomach and beginning of the small intestine (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.

Single-use surgical devices have become more popular during the last two decades as a means of minimizing patient cross-contamination and eliminating high sterilization costs, and also with any eye to mitigating losses relating to damaged equipment. Single-use devices can be packaged and shipped to medical centers completely sterile.

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. The significant patient benefits and cost savings associated with endoscopy have caused many governmental reimbursement programs and private health insurance plans to encourage the use of endoscopic procedures in a number of medical applications.

Our Solution and Products

The MUSE ™ system

Our primary product, the MUSE™ (Medigus Ultrasonic Surgical Endostapler) system for transoral fundoplication, is an 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 the Company's revenue is derived from the miniature video camera and related equipment, the Company's strategy is focused on the development and promotion of its MUSE System, which we therefore refer to as our 'primary product'. See also Item 5.A. Operating Results – Overview.

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. The MUSE™ system is used to perform a procedure as an alternative to a surgical procedure known as "anterior fundoplication" in which the gastric fundus (upper part of the stomach) is wrapped around the lower esophagus, and stapled in place. Fundoplication is now primarily performed by conventional open or laparoscopic surgery. The MUSE™ system offers an endoscopic, incisionless alternative. A single surgeon or gastroenterologist can perform the MUSE™ procedure, unlike in Nissen fundoplication which requires incisions hospital several days after the procedure.

The system consists of three main components – the MUSE™ controller console, the MUSE™ and several accessories (including an overtube, irrigation bottle, tubing supplies and staple cartridges). The endostapler incorporates a video camera, a surgical stapler and an ultrasonic sight, which is used to measure the distance between the anvil and the cartridge of the stapler, and to ensure their proper alignment. The device also contains an alignment pin, which is used for initial positioning of the anvil against the cartridge, and two anvil screws, which are used to reduce the thickness of the tissue that needs to be stapled to the right value and to fix the position of the anvil and the stapler during stapling. In addition, the system allows the operator to staple the fundus of the stomach to the esophagus, in two or more locations, around the circumference, thereby creating an "anterior partial fundoplication", without any incisions or violation of the peritoneal or pleural cavity. Anterior means near the front, and fundoplication means folding of the fundus (the upper part of the stomach). In a Nissen fundoplication, the top part of the stomach is wrapped 360 degrees around the esophagus. However, an anterior partial fundoplication (also known as Thal-Dor fundoplication) is a procedure in which the wrap is limited to the half of the stomach facing the front of the patient.

The exact 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 to staple the fundus of the stomach to the esophagus, in two or more locations, around the circumference, thereby creating an anterior partial fundoplication as described in the above paragraph. In addition, in the pivotal study that was presented to FDA in order to gain clearance**,** only patients who were currently taking GERD medications (i.e. 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 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.

Multi-center clinical study and 510(k) marketing clearance

The original FDA submission included short-term (6 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 prior to printing through Open Access. 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-HRQL (Health Related Quality of Life) scores in 53% of the subjects. 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 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 was granted in May 2012 for the system 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 March 2014. The modified system has also obtained a CE mark in Europe and a license from Health Canada and was approved 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 PPI 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.

Miniature Video Cameras

By definition all endoscopes must include vision apparatus to facilitate the operator's view of the internal organs of the patient. In the past, fiber optics was 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 0.99mm in diameter, and are based on either multi-use CCD (Charge Coupled Device) or less expensive single-use CMOS image sensors.

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, ENT, 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 0.99mm 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 ™ sales

We intend to continue to focus on commercializing MUSE™ system by expanding our sales and marketing infrastructure in the United States and Europe, as well as our global distribution footprint. We anticipate that increases in the use of the MUSE™ system in medical centers in a given country has the secondary effect or raising awareness of the system and accelerating subsequent sales.

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, while we provide the technology necessary to produce a device that requires miniaturized video cameras. We are working to engage in agreements which would promote less invasive or minimally invasive procedures by leveraging our camera platform.

Out-licensing 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 technology which we have developed to date, including our imaging products and the MUSE™ system, or based on technology which we may develop in the future.

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 (Thousands of NIS)		
	2015	**2014**	**2013**
Sales of Miniature Cameras and related equipment	2,160	2,336	2,451
Sales of the MUSE™ System	256	328	47
Total	2,416	2,664	2,498

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

	Revenues (Thousands of NIS)		
	2015	**2014**	**2013**
United States	1,730	1,645	1,631
Europe	324	404	237
Asia	196	481	495
Other	166	134	135
Total	2,416	2,664	2,498

Seasonality of Business

While our business is growing and changing rapidly, we believe it is subject to quarterly seasonal fluctuations because of customary capital expenditure trends by hospitals due to various hospital budget considerations which are not in our control. Hospitals tend to purchase at the beginning of their budgetary cycle, which is different among hospitals. Therefore, it is hard to predict results of a certain quarter and some quarters may be weaker than others. However, 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. Pricing for our raw materials is generally not volatile although periodic pricing fluctuations may occur.

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.

We believe we are not dependent on any of our suppliers. In general, alternative suppliers can be trained within a short period. However, we do have a small number of suppliers who provide us with, among other things, imaging optical sensors, lenses, flexible shaft and sterilization processes, the replacement of which could be longer, due to the adjustment of their products to our needs. However, we do not believe that the replacement of such suppliers would involve significant cost. See "Item 3. Risk Factors - Our reliance on third-party suppliers…".

Marketing and Distribution

Company Sales and Marketing Efforts

In the United States and Europe, our commercial goals in the short term are to initiate highly selective sites for procedural experience through a registry and other means of patient engagement. 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 Turkey, 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 preliminary distribution period of one to several years is determined, after which the agreement is automatically renewed for one year periods, unless one party notifies the other regarding the termination of the agreement;
- 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.

Marketing of Imaging Equipment

With respect to its visualization technology, we sell and market our off-the-shelf and customized products globally and also engage in co-development and other means of collaboration. Currently, a dedicated manager directly conducting these efforts. In addition, in Japan we have a representative that is compensated based on commission from the revenue from this territory. 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 3. Key Information – D. Risk Factors – Risks Related to Our Intellectual Property."

We own 19 U.S. patents and have filed 4 additional patent applications. In addition, we own 56 patents that were granted in other countries. We also have 10 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 2033.

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.

We are currently litigating a claim against EndoChoice for its patent infringement. In response, EndoChoice filed a separate trademark and unfair competition action against us and our U.S. Subsidiary. In addition, EndoChoice commenced an opposition procedure with the Israeli Patent Office against us in connection with our trademark application in Israel. We believe we will fend off EndoChoice's claims but we cannot provide any assurance we will be successful in doing so. Failure to fend off these claims may adversely affect our business in the Israeli or the U.S. market, as applicable. For more information see "Item 8. Financial Information—A. Consolidated Statements and Other Financial Information—Legal Proceedings." We will continue to vigorously protect our intellectual property.

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;
- 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 to 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 Nissen fundoplication surgery. PPIs are currently being offered by several large pharmaceutical manufacturers, many 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 Nissen 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 lower esophageal sphincter.
- Stretta (Mederi Therapeutics) — a catheter to deliver radiofrequency energy to the lower esophageal sphincter to stimulate collagen deposition (scarring) in the lower esophageal sphincter.
- GERDX™ (G-Surg) – An endoscopic plication device for the lower esophageal spincter.

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.

Competition to Miniature Video Cameras

The main devices that compete with our miniature cameras are manufactured by Awaiba, Fujikura, MicroCam (Sanovas), FISBA, Precision Optics, and Ocom. 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 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 3. Key Information – 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.

Clinical 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 3. Key Information – 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.

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, 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

Third-Party 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 PPACA, also known as the Affordable Care Act. 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.

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 will 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 **o**f 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, the 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 Industrial and Development Law, 5744-1984 (the "**R&D 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) ("**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 R&D Law generally provide for the payment of royalties of 3% to 5% (and currently limited to 3.5%) on sales of products and services based on or incorporating technology developed using grants or know-how deriving therefrom, until 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.

Regardless of any royalty payment obligations, we are further required to comply the R&D Law, as amended, and related regulations, with respect to the grants. Under the R&D Law and related regulations, when a company develops know-how, technology or products using OCS grants, the terms of these grants and the R&D Law restrict the transfer of such know-how, inside or outside of Israel, without the prior approval of the OCS. Transfer of OCS supported know-how outside of Israel will also require the payment of transfer fees to the OCS. Maximal transfer fees with respect to the transfer of know how are as follows: up to three times the original grant received plus accrued interest as of the date of transfer, when the OCS Research Committee is satisfied that the research and development activity will remain in Israel, and up to six times the value of the original grant if such condition is not met. In addition, the R&D Law restrict the transfer of manufacturing or manufacturing rights of products, technologies or know-how incorporating know-how, technology or products using OCS grants without the prior approval of the OCS and payment of increased royalties as detailed below. Therefore, if aspects of our technologies are deemed to have been developed with OCS funding, the discretionary approval of an OCS committee would be required for any transfer to third parties inside or outside of Israel of know how or manufacturing or manufacturing rights related to those aspects of such technologies. We may not receive those approvals. Furthermore, the OCS may impose certain conditions on any arrangement under which it permits us to transfer technology or development out of Israel. In addition, the OCS has the discretion to permit overseas manufacture in excess of the declared percentage (deviations of up to 10% do not require consent, but the OCS must be notified). Consent is contingent upon payment of additional royalties, at rates and subject to ceilings set out in the relevant regulations, up to three times the amount of the grants.

On July 29, 2015, the R&D Law was amended ("Amendment Number 7"). Pursuant to Amendment Number 7, the National Authority for Technological Innovation, or NATI, a statutory corporation, will be established and will replace the OCS. Pursuant to Amendment Number 7, the current restrictions under the R&D Law will be replaced by 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, which will be promulgated by NATI. The commencement date of Amendment Number 7 was January 1, 2016, however, in the meantime until new arrangements are adopted by NATI, the R&D Law as existed prior to Amendment Number 7 continues to be in force and effect. NATI should be constituted no later than July 28, 2018, and the new arrangements should be adopted no later than one year thereafter. As of the date of filing of this report, we are unable to assess the effect, if any, of the promulgation of such arrangements on our company.

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 (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 the management of the Company and 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 the Company predicts 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, the Company 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 Company's rights and obligations within the framework of its 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) The Company 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 R&D 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 R&D 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 the Company's application for support for a joint project regarding the development of an innovative, miniature diameter endoscopic product in the field of dental surgery (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 ("**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, the Company 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 the Company, 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, the company and Qioptiq are not acting to commercialize the Dental Endoscope.

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 NIS 8,636 thousand 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 NIS 794 thousand 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 3, 2015, 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. Our monthly rent payment as of March 2016 was NIS 26 thousand.

Effective July 2015, the office of our U.S. Subsidiary is located in Danville, California. The current lease agreement will be ended on June 30, 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 system has also been given marketing approval by the FDA through the 510(k) track, including a recently received Special 510(k) for our MUSE™ II, and bears a CE mark, as required in order to market the system in European Union countries. In addition, we have an AMAR for marketing in Israel and we also in the process to get regulatory approvals in China.

For the year ended December 31, 2015 we derived NIS 2,160 thousand of revenues from miniature camera and related equipment (which represents approximately 89% of our revenue), and NIS 256 thousand from MUSE and related equipment (which represents approximately 11% of our revenue). For the year ended December 31, 2014, we derived NIS 2,336 thousand of revenues from miniature camera and related equipment (88%), and NIS 328 thousand of revenues from MUSE and related equipment (12%). For the year ended December 31, 2013 we derived NIS 2,451 thousand of revenues from miniature camera and related equipment (98%), and NIS 47 thousand of revenues from MUSE and related equipment (2%).

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 its MUSE System.

We have incurred net losses in all years since our inception, and, as of December 31, 2015, we had an accumulated deficit of approximately NIS 167 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 our 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 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 $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 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".
- In October 2013, pursuant to a shelf prospectus in Israel, we raised approximately $7 million through an issuance of shares and warrants to the public. See "Item 10. Additional Information – C. Material Contracts".
- In February 2013, OrbiMed completed an investment of $8 million. See "Item 10. Additional Information – C. Material Contracts" of this annual report on Form 20-F.
- We received FDA clearance May 2012 for our original MUSE™ system and in March 2014 for our modified MUSE™ system.
- We received a CE mark in September 2012 for the modified MUSE™ system.

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 at December 31, 2015. 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:

Revenue Recognition

Our revenue in recent years is primarily based on 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.

When multiple-element arrangements exist, the amount of revenue allocated to each element is based upon the relative fair values of the various elements. The fair values of each element are determined based on the current market price of each of the elements when sold separately.

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, the 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.

Capitalization of Development Costs

We capitalize development expenditure in accordance with International Accounting Standard No. 38, or IAS 38, only if development costs can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable and we intend to and have sufficient resources to complete development and to use or sell the asset.

We capitalize development costs based on our judgment regarding technological and economic feasibility, which generally exists when a product development project reaches a defined milestone, or when entering into a transaction to sell the know-how that was derived from the development.

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 3, 2013, we issued a total of 39,945,474 warrants, to OrbiMed Israel Partners Limited Partnership ("**OrbiMed**") to purchase 3,994,547 shares. Each 10 warrants are exercisable into 1 ordinary share for payment of NIS 9.17 per share during the 18 months following the issuance of the warrant, and NIS 11.004 per share at the end of 18 months until the end of 36 months following the issuance of the warrant. The warrant 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.). On March 3, 2016, warrants (Orbimed) expired as the exercise period was ended.

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 NIS 39 million. Each 10 warrants (Series E) are 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", 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.

A binomial model was used in calculating the value of the Warrant. The interest rate between the periods is derived from a curve of Israel government bonds for a period matching the lifetime of the Warrant. The expected standard deviation is derived based on fluctuations of the Company's share prices.

In calculating the value of warrants (Series E) a Black & Scholes 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.

Results of Operations

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

Revenues

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

	For the Year Ended December 31,			
	2015		2014	
United States	1,730	72%	1,645	62%
Europe	324	13%	404	15%
Asia	196	8%	481	18%
Other	166	7%	134	5%
Total	2,416	100%	2,664	100%

	2015		2014	
MUSE and related equipment	256	11%	328	12%
Miniature camera and related equipment	2,160	89%	2,336	88%
Total	2,416	100%	2,664	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, 2015, we generated NIS 2,416 thousand of total revenues, compared to NIS 2,664 thousand in the year ended December 31, 2014, a decrease of NIS 248 thousand, or 9%. This decrease was primarily due to a NIS 176 thousand decrease in imaging equipment revenues and a NIS 72 thousand 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 NIS 1,343 thousand for the year ended December 31, 2015, or 56% of revenues, compared to NIS 1,412 thousand, or 53% of revenues for the year ended December 31, 2014. The decrease in gross profit of NIS 69 thousand, or 5% was primarily due the decrease in revenues.

Operating Expenses

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

	For the Year Ended December 31,			
	2015	2014	**Increase** (Decrease)	
		(in thousands, NIS)		%
Research and development expenses, net	17,020	14,401	2,619	18
Selling and marketing expenses	10,391	8,353	2,038	24
General and Administrative expenses	11,028	8,206	2,822	34
Other income, net	10	941	(931)	(99)
Total operating expenses, net	38,429	30,019	8,410	28

Research and Development Expenses

Research and development cost was NIS 17,020 thousand for the year ended December 31, 2015, compared to NIS 14,401 thousand for the year ended December 31, 2014. The increase of NIS 2,633 thousand, or 18% 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 NIS 10,191 thousand for the year ended December 31, 2015, compared to NIS 8,353 thousand for the year ended December 31, 2014. The increase of NIS 2,078 thousand, or 24% 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 US.

General and Administrative Expenses

General and administrative expenses were approximately NIS 11,028 thousand for the year ended December 31, 2015, compared to approximately NIS 8,206 thousand for the year ended December 31, 2014. The increase of NIS 2,852 thousand, or 34%, resulted primarily from an increase in professional expenses of approximately NIS 1,100 thousand in connection with compliance requirements of the SEC and NASDAQ regulations which we are required to comply with following our listing on NASDAQ and to the IP litigation (see Item 8. Financial Information—A. Consolidated Statements and Other Financial Information—Legal Proceedings") and increase in salary costs of approximately NIS 618 thousand attributed primarily to the recruitment of additional human resources, including a new CFO.

Other Income, Net

Other income, net, in the year ended December 31, 2015 amounted to a total of approximately NIS 10 thousand, compared to a total of approximately NIS 941 thousand for the year ended December 31, 2014. The decrease of approximately NIS 941 thousand, 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 NIS 10 thousand. For the year ended December 31, 2014, other income, net, included the Company's income from its investment portfolio in the amount of approximately NIS 66 thousand, and income in the amount of approximately NIS 875 thousand 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 NIS 394 thousand was recorded, compared to a profit of approximately NIS 3,605 thousand 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 NIS 49 thousand for the year ended December 31, 2015, compared to financial income of NIS 2,386 thousand for the year ended December 31, 2014. The decrease in finance income, net of NIS 2,435 thousand, 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 NIS 2,393 thousand (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 NIS 25 thousand in 2015.

Loss and Loss per Share

For the year ended December 31, 2015, the loss was NIS 37,005 thousand or NIS 1.3 per share, compared to loss of NIS 22,629 thousand or NIS 1.2 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, 2015, December 31, 2014 and December 31, 2013 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 US dollars 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 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 United States of America and in the European Union. Accordingly, we incur and expect to continue to incur additional expenses in non-NIS currencies, such as the US dollar and Euro**.** As a result, some of our financial liabilities are denominated in these non-NIS currencies. Due to the foregoing and the fact that our financial results are currently measured in NIS, our results could be adversely affected as a result of a strengthening or weakening of the NIS compared to these other currencies. During 2015, 2014 and 2013 we incurred net non-NIS loss of NIS 25 thousand, income of NIS 2,393 thousand and loss NIS 236 thousand, respectively.

We believe that inflation in Israel has not had a material effect on our results of operations. See further discussion under “Item 11. Quantitative and Qualitative Disclosures About Market Risk” below.

Comparison of the fiscal years ended December 31, 2014 and December 31, 2013

Revenues

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

	For the Year Ended December 31,			
	2014		2013	
United States	1,645	62%	1,631	65%
Europe	404	15%	237	10%
Asia	481	18%	495	20%
Other	134	5%	135	5%
Total	2,664	100%	2,498	100%

	2014		2013	
MUSE and related equipment	328	12%	47	2%
Miniature camera and related equipment	2,336	88%	2,451	98%
Total	2,664	100%	2,498	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, 2014, we generated NIS 2,664 thousand of total revenues, compared to NIS 2,498 thousand in the year ended December 31, 2013, an increase of NIS 166 thousand, or 6.6%. This increase was primarily due to a NIS 281 thousand increase in MUSE system revenues, offset by a decrease of NIS 115 thousand in imaging equipment revenues. The increase in the MUSE system revenues was primarily due to the increase in the quantity of products sold. The decrease in revenues in the imaging equipment revenues was primarily due to the following:

(i) during the year ended December 31, 2013 we recorded revenues for development services provided to a customer in the amount of approximately NIS 323 thousand (see 'Customer A' in note 18e to our financial statements for the year ended December 31, 2015).We did not receive any revenue from this customer during the year ended December 31, 2014; and

(ii) during the year ended December 31, 2013 we recorded revenues from equipment sales to a customer in the amount of approximately NIS 536 thousand (see 'Customer B' in note 18e to our financial statements for the year ended December 31, 2015) compared to revenues from this client of approximately NIS 169 thousand recorded for the year ended December 31,2014. The decrease in revenues of NIS 367 thousand was primarily due to decrease in the quantity of products sold ; and

(iii) during the year ended December 31, 2013 we recorded revenues from equipment sales to a customer in the amount of approximately NIS 93 thousand. We did not receive any revenue from this customer during the year ended December 31, 2014; and

(iv) during the year ended December 31, 2014, we recorded revenues of approximately NIS 370 thousand from the termination of an agreement with a customer (see note 14 to our financial statements for the year ended December 31, 2015) compared to revenues under this agreement of approximately NIS 185 thousand recorded for the year ended December 31, 2013; and

(v) during the year ended December 31, 2014 we recorded revenues for development services provided to a customer in the amount of approximately NIS 443 thousand (see 'Customer D' in note 18d to our financial statements for the year ended December 31, 2015) . We did not receive any revenue from this customer during the year ended December 31, 2013.

Gross Profit

Gross profit was NIS 1,412 thousand for the year ended December 31, 2014, or 53% of revenues, compared to NIS 1,372 thousand, or 55% of revenues for the year ended December 31, 2013. The increase in gross profit of NIS 40 thousand, or 3%, was primarily due to the increase in revenues.

Operating Expenses

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

	For the Year Ended December 31,			
	2014	2013	Increase	
		(in thousands, NIS)		%
Research and development expenses, net	14,401	8,180	6,221	76
Selling and marketing	8,353	3,234	5,119	158
General and Administrative	8,206	6,877	1,329	19
Other income, net	941	666	275	41
Total operating expenses, net	30,019	17,625	12,394	70

Research and Development Expenses, Net

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

	For the Year Ended December 31,	
	2014	2013
	(in thousands, NIS)	
Research and Development cost	14,401	8,634
Less:		
Grants and participation from the OCS	---	(454)
Research and Development Expenses, Net	14,401	8,180

Research and development cost, net was NIS 14,401 thousand for the year ended December 31, 2014, compared to NIS 8,180 thousand for the year ended December 31, 2013. The increase of NIS 6,221 thousand, or 76%, was primarily due to the increase in the acquisition of materials by the Company and services rendered to the Company by sub-contractors of approximately NIS 3,062 thousand, the increase in compensation expenses of approximately NIS 2,061 thousand, the increase in travel expenses and related expenses of approximately NIS 559 thousand as a result of the cancellation of the reduction of expenses which took place in 2013 until the completion of the investment by OrbiMed, the recruitment of additional employees and consultants by the Company in Israel and our U.S. Subsidiary and decrease of approximately NIS 454 thousand in grants received from the OCS due to the conclusion of OCS funding of approved programs.

Sales and Marketing Expenses

Sales and marketing expenses were approximately NIS 8,353 thousand for the year ended December 31, 2014, compared to approximately NIS 3,234 thousand for the year ended December 31, 2013. The increase of approximately NIS 5,119 thousand, or 158%, resulted from an increase in salaries, wages and related expenses, marketing expenses and travel expenses, attributed primarily to our increased efforts to penetrate the U.S. and European markets. Such efforts included, among other things, the recruitment of additional sales and marketing personnel in Israel, Europe and the United States and the expansion of our marketing activities including participating in exhibitions and re-branding.

General and Administrative Expenses

General and administrative expenses were approximately NIS 8,206 thousand for the year ended December 31, 2014, compared to approximately NIS 6,877 thousand for the year ended December 31, 2013. The increase of approximately NIS 1,329 thousand, or 19%, resulted primarily from an increase in salary costs of approximately NIS 838 thousand attributed primarily to the hiring of Chris Rowland as our CEO, an increase in professional expenses of approximately NIS 1,717 thousand in connection with the preparation of a shelf offering and from activities required for implementing the registration of an ADR facility offset partially by expenses in connection with the 2013 shelf prospectus offering to the public in Israel and a decrease in management fees of approximately NIS 1,352 thousand attributed to the termination of employment of Dr. Elazar Sonnenschein as the our CEO.

Other Income, Net

Other income, net, was approximately NIS 941 thousand for the year ended December 31, 2014, compared to approximately NIS 666 thousand for the year ended December 31, 2013. The increase of approximately NIS 275 thousand, or 41%, resulted primarily from the composition of other income, net, in those two periods. For the year ended December 31, 2014, other income, net, included the Company's income from its investment portfolio in the amount of approximately NIS 66 thousand, and income in the amount of approximately NIS 875 thousand in respect of the termination of the Company's agreement with a customer (see note 14 to our financial statements). In the year ended December 31, 2013, other income, net, included the Company's income from its investment portfolio in the amount of approximately NIS 327 thousand, and income in the amount of approximately NIS 339 thousand in connection with the realization of a financial asset available for sale. The decrease in income in respect of our investments portfolio as compared with the same period in 2013 resulted from a decision by our Investment Committee, as part of our risk management and a more conservative investment management approach, pursuant to which, during the second quarter of 2013 we disposed of the bonds held at that time, and invested the cash balances solely in deposits and short-term government loan notes, which have a lower return than the rates on bonds.

Profit from Change in Fair Value of Warrants Issued to Investors

Gains recorded in the financial statements on the change in the fair value of warrants issued to investors for the year ended December 31, 2014, resulted from the revaluation of the warrants which included a cashless exercise mechanism. The revaluation was performed in accordance with the fair value of the warrants as of the December 31, 2014. During the year ended December 31, 2014, a gain of approximately NIS 3,605 thousand was recorded, representing the decrease in the value of the warrants during this reporting period. The primary reasons for the decrease in value was due to 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

Financing income, net was approximately NIS 2,386 thousand for the year ended December 31, 2014, compared to financial expense, net of approximately NIS 395 thousand for the year ended December 31, 2013. The increase in financing income, net of approximately NIS 2,781 thousand, was primarily due to the increase in the average exchange rate of the U.S. dollar in relation to the NIS, which had a positive effect on our net assets (primarily cash and cash equivalents) denominated in U.S. dollars.

Loss and Loss per Share

For the year ended December 31, 2014, the loss was NIS 22,629 thousand or NIS 0.12 per share, compared to loss of NIS 5,189 thousand or NIS 0.04 per share, for the year ended December 31, 2013.

The increase in loss and loss per share in the year ended December 31, 2014, compared to the year ended December 31, 2013, is mainly due to an increase in operating expenses, net of approximately NIS 12,394 thousand, a decrease in profits due to the change in the fair value of warrants issued to investors of approximately NIS 7,939 thousand, offset by an increase in finance income of approximately NIS 2,781 thousand.

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 NIS 218 million in aggregate net proceeds from issuing our equity securities, including approximately NIS 29 million net proceeds, from our initial public offering, or IPO, of our ordinary shares and warrants on the TASE in February 2006. As of December 31, 2015, we held approximately NIS 40 million in cash and cash equivalents. 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 NIS 27 million for the year ended December 31, 2015, compared with net cash used in operating activities of approximately NIS 28 million and approximately NIS 22.5 million for the years ended December 31, 2014 and 2013, respectively. The increase from 2013 to 2014 of approximately NIS 5.5 million was primarily due to the loss for the year before taxes during the year ended December 31, 2014 of approximately NIS 22.6 million (which included a recorded profit on change in the fair value of warrants issued to investors of approximately NIS 3.6 million), compared to a loss for the year before taxes of NIS 5.1 million (which included a recorded profit on change in the fair value of warrants issued to investors of approximately NIS 11.5 million) during the year ended December 31, 2013, also due to the purchase of short term securities in the amount of approximately NIS 0.2 million during 2014 versus the purchase of short term securities in the amount of approximately NIS 6.6 million during 2013, and also due to gains from exchange differences on cash and cash equivalents in the amount of approximately NIS 2.4 million during 2014 versus the gain in the amount of approximately NIS 0.13 million during 2013..

Net cash used in investing activities for the year ended December 31, 2015 was approximately NIS 0.4 million, compared to net cash generated from investing activities of approximately NIS 7.7 million for the year ended December 31, 2014 and net cash used in investing activities of approximately NIS 8.8 million for the year ended December 31, 2013. The decrease from 2014 to 2015 of approximately NIS 8.1million was primarily due to the withdrawal of short term deposits, net in the amount of approximately NIS 8.1 million during 2014.Net cash provided by financing activities was NIS 25.5 million for the year ended December 31, 2015 (resulting the completion of a public offering of our ordinary shares and warrants under a shelf offering report issued pursuant to our shelf prospectus in July 2015), compared to net cash provided by financing activities of NIS 36 million for the year ended December 31, 2014 (resulting from the completion of a private offering of our ordinary shares and warrants in a private placement in August 2014), compared to net cash provided by financing activities of NIS 53.8 million for the year ended December 31, 2013 (resulting from the completion of a public offering of our ordinary shares and warrants under a shelf offering report issued pursuant to our shelf prospectus in Israel in October 2013, and the closing of a share purchase agreement with OrbiMed in March 2013).

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 NIS 37 million for the year ended December 31, 2015.

Based on the projected cash flows and its cash balances as of December 31, 2015, 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 the our ability to continue as a going concern.

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 our MUSE 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 activities are focused on the development of endoscopic surgical technology.

As of December 31, 2015, our research and development team, including regulatory and quality team members, consisted of 18 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.

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.

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, 2015, we had received total grants from the OCS of NIS 9.4 million.

For a description of the amount spent during each of the last three fiscal years on company-sponsored research and development activities, see "Item 5. Operating and Financial Review and Prospects – A. Operating Results."

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 products in Italy, Turkey and China (the latter pending achievement of regulatory clearance for our MUSE product 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, 2015:

	Total	Less than 1 year	1 – 3 years
		(NIS, in thousands)	
Car lease obligations	655	332	323
Premises leasing obligations	743	380	363
Total	**1,398**	**712**	**686**

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 NIS 34 thousand, as described in Note 4(2)(b) to our consolidated financial statements as at December 31, 2015.

As of December 31, 2015, 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 NIS 381 thousand. 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	51	Chairman of the Board of Directors
Christopher (Chris) Rowland	54	Chief Executive Officer, Director
Ori Hershkovitz (1)	41	External Director
Efrat Venkert (1)(2)	49	External Director
Doron Birger (1)(2)	64	Director
Anat Naschitz(2)	48	Director
Gilad Mamlok	47	Chief Financial Officer
Oded Yatzkan	50	VP Director of finance and accounting
Jeremy Starkweather	42	VP U.S Sales and Marketing
Minelu (Menashe) Sonnenschein	51	VP Israel Operations
Yaron Silberman	46	VP Sales and Marketing
Dr. Aviel Roy Shapira	65	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 December 29, 2015, 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 December 29, 2015, 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 of the Executive Leadership Program of Harvard Business School.

Ori Hershkovitz has been serving as an external director on our Board since May 2012, and on May 6, 2015, was re-elected for service as an external director for an additional 3 year term. Mr. Hershkovitz currently serves as a director of Micromedic Technologies Ltd. and Insuline Medical Ltd., publicly held companies. Mr. Hershkovitz was a Partner in Sphera Global Healthcare Fund. Mr. Hershkovitz holds a BA in Economics and Management from Tel-Aviv University, Israel.

Efrat Venkert has been serving as an external director on our Board since September 2013. 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 May 17, 2015, 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 December 29, 2015, 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. and Axiom One 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, R&D and marketing. Ms. Naschitz holds an MBA from INSEAD and an LLB from Tel-Aviv University, Israel.

Gilad Mamlok has served as our Chief Financial Officer since August 2015. From 2014 to 2015, Mr. Mamlok served as VP Finance at Covidien plc and form 2005 to 2014, as Senior VP Global Finance and Accounting at Given Imaging Ltd. From 2004 to 2005, Mr. Mamlok served as Chief Financial Officer at Metacure Israel Ltd. , a medical devices company. From 2002 to 2004, Gilad served as Chief Financial Officer at Simbionix USA Corporation, and from 1997 to 2002, Mr. Mamlok served as Director of Finance at NICE Systems Ltd. Mr. Mamlok holds a B.A. and an M.A. in economics from the Tel-Aviv University, together with Participation in a Ph.D. Program in Economics at the University of Rochester, U.S.A.

Oded Yatzkan has served as our CFO since September 2003. Since August 1, 2015, Mr. Yatzkan is serving as 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.

Jeremy Starkweather has served as our VP U.S. Sales & Marketing since June 2015. From 2014 to 2015, Mr. Starkweather served as VP Sales & Business Development at Xlumena, Inc. From 2012 to 2013, Mr. Starkweather served as Marketing Director at Boston Scientific Corporation. Mr. Starkweather holds a Bachelor of Science and Business Management from the Oral Roberts University, Tulsa, Oklahoma, U.S.

Minelu (Menashe) Sonnenschein is a founding member and officer of Medigus who has been serving as our VP Israel Operations since January 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 an 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, except for the letter of undertaking from certain shareholders to OrbiMed which was entered into in connection with OrbiMed's 2013 investment in the Company. Pursuant to the letter of undertaking, certain shareholders agreed to support the selection of four board members to be proposed by OrbiMed, two of whom would be "industry experts," as determined by OrbiMed and one of which would be chosen to serve as the Chairman of the Board of Directors. In accordance with the conditions precedent to closing in the Share Purchase Agreement entered into in connection with OrbiMed's 2013 investment in the Company, our board of directors at the closing of the investment in March 2013 consisted of Nissim Darvish (our current chairman), Anat Naschitz, Erez Chimovits and Chris Rowland (our current CEO who was subsequently appointed CEO in October 2013) Yair Rabinowitch, Gabby Sarusi and Ori Hershkovitz. Three of our directors, Nissim Darvish, Anat Naschitz and Chris Rowland, were selected pursuant to the letter of undertaking described above. The letter of undertaking has expired in March 2016.

B. Compensation

Compensation of Directors and Senior Management

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. For further details, see "Item 6. Directors, Senior Management and Employees – C. Board Practices."

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, 2015:

	Annual Compensation		Long-Term Compensation	
	NIS in thousands			
Name and Position(s)	**Salary and Related Benefits***	**Bonus****	**Shares Underlying Options*****	**Total**
Christopher (Chris) Rowland **CEO, Director**	1,431	337(1)	241	2,009
Milena Ridl**** **VP Europe**	828	115(2)	14	957
Tom Dempsey **VP U.S.**	708	124(3)		832
Minelu (Menashe) Sonnenschein **VP Israel Operations**	650	79(4)	27	756
Oded Yatzkan **VP Director of finance and accounting**	618	67(5)	18	703

* Includes car expenses.

** Bonus amounts represent the amounts paid and accrued as of the date hereof with respect to the year ended December 31, 2015. Bonus were awarded in accordance to the level of achievement of annual Company targets as well as the level of achievement of each individual's annual personal targets.

*** Represents the equity-based and phantom share based compensation expenses recorded in the Company's consolidated financial statements for the year ended December 31, 2015, based on the option's fair value, calculated in accordance with accounting guidance for equity-based compensation. For a discussion of the assumptions used in reaching this valuation, see Note 12c to our consolidated financial statements.

**** Ms. Ridl employment will be terminated on May 31, 2016.

(1) Reflecting an achievement of 75% of Company targets.
(2) Reflecting an achievement of 73% of personal targets.
(3) Reflecting an achievement of 47.25% of personal targets.
(4) Reflecting an achievement of: (i) 95% of personal targets; and (ii) 75% of Company targets.
(5) Reflecting an achievement of: (i) 91.7% of personal targets; and (ii) 75% of Company targets.

Directors' Compensation

The total amount of director's compensation paid to directors, in their capacities as such, during the year ended December 31, 2015, amounted to approximately NIS 278,000.

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 also pay Mr. Rowland such annual and per meeting fees for his service as director. We currently do not pay Nissim Darvish (our current chairman) or Anat Naschitz 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, 2015, 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 NIS 278,000. 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 15, 2016, 5,942,000 options to purchase 1,158,500 our ordinary shares were outstanding and held by certain current executive officers and directors (consisting of 12 persons) with an average exercise price of NIS 4.70 per share, of which 4,258,050 options are currently exercisable within 60 days of March 15, 2016. See "Item 6E. Share Ownership" in this annual report on Form 20-F.

Employment Agreements

The total amount of compensation accrued on behalf of our executive officers (other than directors) during the year ended on December 31, 2015, amounted to approximately NIS 7.8 million.

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 would enter into an employment agreement with Mr. Rowland, who serves as the Company's Chief Executive Officer and currently carries out his work from our U.S. Subsidiary's office in California, USA. The agreement is for a period 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 our employment agreement with Mr. Rowland, he is entitled to a gross monthly salary of US$ 26,250. 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 salary (approximately $110,000). 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. As of December 31, 2013, Mr. Rowland had not received any such annual bonus.

On March 24, 2014, May 26, 2014 and July 7, 2014, the Company's compensation committee, board of directors and special meeting of the shareholders, respectively, approved the increase of Mr. Rowland's annual target bonus for the year 2014, from US$110,000 to US$ 150,000, by meeting certain pre-determined milestones or goals, set by our board of directors, by December 31, 2014. In addition, the milestones or goals to be achieved by the Company in order for Mr. Rowland to be entitled to receiving the annual target bonus, are based on the following parameters: (i) previous years' milestones/goals yet to be achieved; (ii) revenue-based milestones, or milestones designed to promote the establishment of new treatment centers and medical staff trainings; (iii) clinical achievement-based milestones; (iv) milestones based on new goals for the Company's business progress; and (v) professional publication-based milestones.

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). Mr. Rowland may also be entitled, in addition to the amounts owing to him up to the termination of his employment, to a retirement/adaptation grant in an amount equal to six monthly salaries (total inclusive amount of approximately $158,000).

On October 9, 2013, our shareholders approved a grant of 4,500,000 options under the 2013 Share Option and Incentive Plan convertible 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.

Employment Agreement with Mr. Menashe Sonnenschein

In May 2000 the Company entered into an employment agreement with Mr. Menashe Sonnenschein, which was amended and extended several times. Mr. Sonnenschein served as our CTO until June 1, 2014, when he was appointed as our VP Israel Operations. Mr. Sonnenschein's agreement is in force until July 7, 2017, and may be terminated by either party by giving 60 days prior notice.

Between March 3, 2013 and July 7, 2014, Mr. Sonnenschein's monthly salary was NIS 28,300. As of July 7, 2014, Mr. Sonnenschein's monthly salary is NIS 38,500. In addition, between March 2011 and September 2013, Mr. Sonnenschein was entitled to annual target bonus by meeting pre-determined goals, as set by his direct supervisor and the Company's board of directors. On July 17, 2014, following shareholder approval, we granted 250,000 options under the 2013 Share Option and Incentive Plan convertible into 250,000 of our ordinary shares to Mr. Sonnenschein, for an exercise price of NIS 0.537, which vest annually in four equal parts over four years. The options granted will expire at the earliest of: (a) following 6 years from the date of the grant; (b) 30 days from the date Mr. Sonnenschein's employment shall end or he shall resign; or (c) immediately following the dismissal of Mr. Sonnenschein, for various causes. In addition, options not vested by the termination of Mr. Sonnenschein's employment agreement shall expire at such date. Between September 2013 and July 7, 2014, Mr. Sonnenschein was entitled to payment of an annual target bonus by meeting pre-determined milestones, not to exceed NIS 68,000. As of July 7, 2014, Mr. Sonnenschein is entitled to payment of an annual target bonus by meeting pre-determined milestones, which may not exceed NIS 92,500.

In addition, Mr. Sonnenschein is also entitled to various social benefits, such as allocations equal to 13.33% of his gross monthly salary to severance pay, to a manager's insurance policy or pension fund, owned by us (of which 8.33% we transfer and the rest is deducted from his monthly salary), as chosen by Mr. Sonnenschein, and 7.5% of his gross monthly salary is allocated to a study fund.

On December 29, 2015, our shareholders approved a grant of 40,000 options under the 2013 Share Option and Incentive Plan to purchase 40,000 of our ordinary shares to Mr. Sonnenschein 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 date of the grant; 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. Sonnenschein's employment agreement shall expire at such date.

C. Board Practices

Introduction

Our board of directors presently consists of six members. Pursuant to the Companies Law, the board of directors retains all of the powers in running our Company that are not specifically granted to our shareholders. Pursuant to the Companies Law and our articles of association, a resolution proposed at any meeting of the board of directors, at which a quorum is present, is adopted if approved by a vote of at least a majority of the directors present and eligible to vote at the meeting. A quorum of the board of directors (or any committee thereof, other than the audit committee or compensation committee) is at least a majority of the directors then in office who are lawfully entitled to participate in the meeting (until otherwise unanimously decided by the directors). Minutes of the meetings are recorded and kept at our offices.

Our directors (other than external directors, for whom special election requirements apply under the Companies Law) are generally each elected at a general meeting of our shareholders for terms of office ending at the annual general meeting subsequent to their election, provided that each director declare that they have the required skills and time to serve as directors, taking into account, among other things, the company's size and needs, and that they confirm that they were not convicted of any criminal offense (as set forth in the Companies Law) preventing them from service and have not been declared bankrupt. A nominee to serve as director is required to disclose whether he has been convicted of any criminal offense preventing him from service, or is prevented from service by an administrative enforcement committee, and the prevention period is still in force. In addition, our Articles of Association allow our board of directors to appoint directors to fill vacancies and/or as an addition to the board of directors (subject to the maximum number of directors set forth in our Articles of Association) to serve until the next annual general meeting.

Our board of directors is authorized to recommend to our shareholders director nominees for election. Under the Companies Law and our articles of association, nominations for directors may also be added to the agenda of future general meetings, which have yet to have been summoned, upon the request of any one or more shareholders holding at least 1% of our outstanding voting power. Furthermore, under the Companies Law, either (a): (i) two directors; or (ii) no less than one quarter of the directors in office; or (b): one or more shareholders holding, in the aggregate, either (i) 5% of our outstanding ordinary shares and 1% of our outstanding voting power; or (ii) 5% of our outstanding voting power, may request the board of directors to summon a general meeting in order to nominate one or more persons for election as directors at a special meeting. However, any such shareholders may make such a nomination only if a written notice of such shareholder's intent to make such nomination has been given to our chairman of the board (or, if we have no chairman of the board, our chief executive officer). Where the board of directors was requested to convene such a special general meeting, it shall convene such meeting within twenty-one days of the date on which the request was made, on the date designated by a notice, provided that the date of convening the meeting shall be no later than thirty-five days after the date of the notice, unless otherwise provided in respect of a meeting to which the relevant Companies Law provisions governing voting by proxy of statement positions apply.

In addition, directors (other than external directors) shall be removed prior to the end of their term by the majority of our shareholders at a general meeting of our shareholders or immediately upon the occurrence of the following events: (i) the company learns that a final judgment was issued whereby the director was convicted for any criminal offense preventing him from serving as director and the execution of the sentence was not stayed by the court; (ii) a qualified court has determined that given the nature of a criminal offense, the director is prevented from service as director; (iii) the company learned that the director was declared bankrupt, or that a corporate director has resolved to enter into voluntary liquidation or in respect of which a winding up order has been issued; or (iv) the director did not disclose all required information with respect to his nomination as director.

Under our articles of association the shareholders of the company may elect one director to serve as the chairman of the board of directors to preside at the meetings of the board of directors. Pursuant to the Companies Law, neither the chief executive officer nor any of his or her relatives is permitted to serve as the chairman of the board of directors, and a company may not vest the chairman or any of his or her relatives with the chief executive officer's authorities. In addition, a person who reports, directly or indirectly, to the chief executive officer may not serve as the chairman of the board of directors; the chairman may not be vested with authorities of a person who reports, directly or indirectly, to the chief executive officer; and the chairman may not serve in any other position in the company or a controlled company, but he or she may serve as a director or chairman of a controlled company. However, the Companies Law permits a company's shareholders to determine, for a period not exceeding three years from each such determination, that the chairman or his or her relative may serve as chief executive officer or be vested with the chief executive officer's authorities, and that the chief executive officer or his or her relative may serve as chairman or be vested with the chairman's authorities. Such determination of a company's shareholders requires either: (1) the approval of at least two-thirds of the shares of those shareholders present and voting on the matter (other than controlling shareholders and those having a personal interest in the determination); or (2) that the total number of shares opposing such determination does not exceed 2% of the total voting power in the company.

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 committee, 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. The composition and duties of our audit committee, financial statement examination committee and compensation committee are established under the Israeli Companies Law and described in this Item below.

The board of directors oversees how management monitors compliance with the Company's risk management policies and procedures, and reviews the adequacy of the risk management framework in relation to the risks faced by the Company. The board of directors is assisted in its oversight role by an internal audit. The Company's Internal Auditor undertakes both regular and ad hoc reviews of risk management controls and procedures, the results of which are reported to our audit committee.

External Directors

Under the Companies Law, an Israeli company whose shares have been offered to the public or whose shares are listed for trading on a stock exchange in or outside of Israel is required to appoint at least two external directors to serve on its board of directors. Following a recent amendment to the Companies Law enacted on February 17, 2016, or Amendment 27, any and all of such external directors are no longer required to be Israeli residents in case of a company listed on a foreign stock exchange (such as our Company). Our external directors are Mr. Hershkovitz and Ms. Venkert. At least one of the external directors is required to have "financial and accounting expertise," and the other external director or directors are required to have "professional expertise"

A person may not be appointed as an external director if the 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, other than by virtue of being an office holder. 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 maintained on a regular basis;
- 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, and a descendant, sibling and parent and the spouse of each of the foregoing.

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

A person may not serve as an external director if that person or that person's relative, partner, employer, a person to whom such person is subordinate (directly or indirectly) or any entity under the person's control has a business or professional relationship with any entity that has an affiliation with any Affiliated Party, even if such relationship is intermittent (excluding insignificant relationships). Additionally, any person who has received compensation intermittently (excluding insignificant relationships) other than compensation permitted under the Companies Law may not continue to serve as an external director.

A person cannot serve as an external director if the person's position or other affairs create, or may create, a conflict of interest with the person's responsibilities as a director or may otherwise interfere with the person's ability to serve as a director, or if such a person is an employee of the Israeli Securities Authority or of an Israeli stock exchange. If at the time an external director is appointed, all current 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. In addition, a person who is a director of a company may not be appointed as an external director of another company if at that time a director of the other company is acting as an external director of the first company.

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. A director with financial and accounting expertise is a director who by virtue of his or her education, professional experience and skill, has a high level of proficiency in and understanding of business accounting matters and financial statements so that he or she is able to fully understand our financial statements and initiate debate regarding the manner in which the financial information is presented. The assessment of the accounting and financial expertise of a director should be made by the board of directors, who has to take into consideration, inter alia, the education, experience and knowledge of the director in the following subjects: Accounting matters and audit accounting matters, which are typical to the sector in which the company works and of companies with the same size and complexity as of the company; (2) The duties and obligations of the auditing accountant; and (3) Preparing of financial statements and their approval according to applicable law, including applicable securities law.

According to the Companies Law, the board of directors of a public company must establish the minimum number of board members that are to have financial and accounting expertise while considering, *inter alia*, 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.

In March 2016, 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.

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.

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.

Election and dismissal of external directors

Under Israeli law, external directors are elected by a majority vote at a shareholders' meeting, provided that either:

- the majority of the shares that are voted at the meeting in favor of the election of the external director, excluding abstentions, include at least a majority of the votes of shareholders who are not controlling shareholders and do not have a personal interest in the appointment (excluding a personal interest that did not result from the shareholder's relationship with the controlling shareholder); or
- the total number of shares held by non-controlling shareholders or any one on their behalf that are voted against the election of the external director does not exceed two percent of the aggregate voting rights in the company.

Under Israeli law, 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 subject to one of the following:

- 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, 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 and subject to additional restrictions set forth in the Companies Law with respect to the affiliation of the external director nominee;
- the external director proposed his or her own nomination, and such nomination was approved in accordance with the requirements described in the paragraph above; or
- his or her service for each such additional term is recommended by the board of directors and is approved at a meeting of shareholders by the same majority required for the initial election of an external director (as described above).

An external director may be removed by the same special majority of the shareholders required for his or her election, if he or she ceases to meet the statutory qualifications for appointment or if he or she violates his or her fiduciary duty to the company. An external director may also be removed by order of an Israeli court if the court finds that the external director is permanently unable to exercise his or her office, has ceased to meet the statutory qualifications for his or her appointment, has violated his or her fiduciary duty to the company, or has been convicted by a court outside Israel of certain offenses detailed in the Companies Law.

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 possible to appoint such number of new external directors so that the company thereafter has two external directors.

Additional provisions

Under the Companies Law, each committee authorized to exercise any of the powers of the board of directors is required to include at least one external director and its audit and compensation committees are required to include all of the external directors.

An external director is entitled to compensation and reimbursement of expenses in accordance with regulations promulgated under the Companies Law and is prohibited from receiving any other compensation, directly or indirectly, in connection with serving as a director except for certain exculpation, indemnification and insurance provided by the company, as specifically allowed by the Companies Law.

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. The alternate director will be regarded as a director. 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 or she is required to be an external director and to have either "financial and accounting expertise" or "professional expertise," depending on the qualifications of the external director he or she is replacing. The term of appointment of an alternate director may be for one meeting of the board of directors or until notice is given of the cancellation of the appointment. A person who does not have the requisite "financial and accounting experience" or the "professional expertise," depending on the qualifications of the external director he or she is replacing, may not be appointed as an alternate director for an external director.

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. The audit committee may not include:

- the chairman of the board of directors;
- a controlling shareholder or a relative of a controlling shareholder;
- any director employed by us or by one of our controlling shareholders or by an entity controlled by our controlling shareholders (other than as a member of the board of directors); or
- any director who regularly provides services to us, to one of our controlling shareholders or to an entity controlled by our controlling shareholders.

According to the Companies Law, the majority of the members of the audit committee, as well as the majority of members present at audit committee meetings, will be required to be "independent" (as defined below) and the chairman of the audit committee will be required to be an external director. Any persons 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 term "independent director" is defined under the Companies Law as an external director or a director who meets the following conditions and who is appointed or classified as such according to the Companies Law: (1) the conditions for his or her appointment as an external director (as described above) are satisfied and the audit committee approves the director having met such conditions and (2) he or she has not served as a director of the company for over nine consecutive years with any interruption of up to two years of his or her service not being deemed a disruption to the continuity of his or her service.

Listing requirements

Under the NASDAQ Marketplace 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.

Our audit committee is currently comprised of Ms. Venkert, Mr. Hershkovitz and Mr. Birger. Ms. Venkert acts as the Chairman of our audit committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the NASDAQ Marketplace Rules. Our board of directors has determined that each of Mr. Birger and Mr. Hershkovitz 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.

Approval of transactions with related parties

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 "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

Under the Companies Law, the audit committee is responsible, among others, for (i) identifying deficiencies in the administration of the Company, including by consulting with the internal auditor, and recommending remedial actions with respect to such deficiencies; (ii) reviewing and approving related party transactions, including, among others, determining whether or not such transactions are deemed material actions or extraordinary transactions; (iii) ensuring that a competitive process is conducted for related party transactions with a controlling shareholder (regardless of whether or not such transactions are deemed extraordinary transactions), optionally based on criteria which may be determined by the audit committee annually in advance; (iv) setting forth 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; (v) evaluating the Company's internal audit program and the performance of the Company's internal auditor and the resources at his/her disposal; (vi) reviewing the scope of work of the Company's external auditor and making recommendations regarding his/her salary; and (vii) creating procedures relating to the employees' complaints regarding deficiencies in the administration of the Company. Following Amendment 27, a company whose audit committee's composition meets the requirements set for the composition of a compensation committee (as further detailed below) may have one committee acting as both audit and compensation committees.

Compensation Committee

Under the Companies Law, public companies and companies that have publicly issued debentures are required to appoint a compensation committee in accordance with the guidelines set forth thereunder.

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. The remaining members are not required to be external directors, but must be directors who qualify to serve as members of the audit committee (as described above). In accordance with the Companies Law, our compensation committee is composed of three members Mr. Hershkovitz, who serves as chairman of the committee, Ms. Venkert and Mr. Birger.

In accordance with the Companies Law, the roles of the compensation committee are, among others, as follows:

- to recommend to the board of directors the compensation policy for directors and officers, and to recommend to the board of directors once every three years whether the compensation policy that had been approved should be extended for a period of more than three years;
- to recommend to the board of directors updates to the compensation policy, from time to time, and examine its implementation;
- to decide whether to approve the terms of office and employment of directors and officers that require approval of the compensation committee; and
- to decide whether the compensation terms of the chief executive officer, which were determined pursuant to the compensation policy, will be exempted from approval by the shareholders because such approval would harm the ability to engage the chief executive officer.

In addition to the roles mentioned above our compensation committee also makes recommendations to our board of directors regarding the awarding of employee equity grants.

Furthermore, public companies must adopt a compensation policy. The compensation policy must be approved by the board of directors after receiving and considering the recommendations of the compensation committee. In addition, the compensation policy requires the approval of the general meeting of the shareholders. In public companies such as our company, shareholder approval requires one of the following: (i) the majority of shareholder votes counted at general meeting including the majority of all of the votes of those shareholders who are non-controlling shareholders and do not have a personal interest in the approval of the compensation policy, who participate at the meeting (excluding abstentions) or (ii) the total number of votes against the proposal among the shareholders mentioned in paragraph (i) does exceed two percent (2%) of the voting rights in the company. Under special circumstances, the board of directors may approve the compensation policy despite the objection of the shareholders on the condition that the compensation committee and then the board of directors decide, on the basis of detailed arguments and after discussing again the compensation policy, that approval of the compensation policy, despite the objection of the meeting of shareholders, is for the benefit of the company. We have adopted a compensation policy in accordance with the requirements of the Companies Law.

Investment Committee

Our investment committee consists of three directors, Doron Birger, Efrat Venkert and Anat 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. 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. Under the Companies Law, the internal auditor may not be an interested party or an office holder or a relative of an interested party or of an office holder, nor may the internal auditor be the company's independent auditor or the representative of the same.

An "interested party" is defined in the Companies Law as (i) a holder of 5% or more of the issued share capital or voting power in a company, (ii) any person or entity who has the right to designate one or more directors or to designate the chief executive officer of the company, or (iii) any person who serves as a director or as a chief executive officer of the company. As of the date of this prospectus, we have not yet appointed our internal auditor.

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

Fiduciary duties of office holders

The Companies Law imposes a duty of care and a fiduciary duty on all office holders of a company. The duty of care of an office holder is based on the duty of care set forth in connection with the tort of negligence under the Israeli Torts Ordinance (New Version) 5728-1968. This duty of care requires an office holder to act with the 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 fiduciary duty incumbent on an office holder requires him or her 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 which would otherwise the office holder's fiduciary duty, provided that the office holder acted in good faith, the act or its approval does not harm the company, and the office holder discloses his or her personal interest a sufficient time before the approval of such act. Any such approval is subject to the terms of the Companies Law, setting forth, among other things, the appropriate parties of the company entitled to provide such approval, and the methods of obtaining such approval.

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 the first meeting of 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, once an office holder has complied with the above disclosure requirement, 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. However, 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 provide that such a transaction, which is not an extraordinary transaction, shall be approved by the board of directors or a committee of the board of directors or any other entity (which has no personal interest in the transaction) authorized by the board of directors. If the transaction considered is an extraordinary transaction with an office holder or third party in which the office holder has a personal interest, then audit committee approval is required prior to approval by the board of directors. For the approval of compensation arrangements with directors and executive officers, see "—Compensation of directors and executive officers."

Any persons who have 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 chairman of the board of directors or the chairman 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. If a majority of the directors at a board of directors meeting have a personal interest in the transaction, such transaction also requires 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 the 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.

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. 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, and the terms of engagement of the company, directly or indirectly, with a controlling shareholder or a controlling shareholder's relative (including through a corporation controlled by a controlling shareholder), regarding the company's receipt of services from the controlling shareholder, and if such controlling shareholder is also an office holder of the company, regarding his or her terms of employment, require the approval of each of (i) the audit committee or the compensation committee with respect to the terms of the engagement of the company, (ii) the board of directors and (iii) the shareholders, in that order. 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, such transactions not involving the receipt of services or compensation can be approved for a longer term, provided that the audit committee determines that such longer term is reasonable under the circumstances.

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. Nevertheless, a recent amendment to regulations promulgated under the Companies Law will require us, after we become a public company, to disclose the annual compensation of our five most highly compensated office holders on an individual basis, rather than on an aggregate basis, as was previously permitted for Israeli public companies listed overseas. This disclosure will not be as extensive as that required of a U.S. domestic issuer.

Compensation of directors and executive officers

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 shareholders at a general meeting. 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, provided that:

- at least a majority of the shares held by all shareholders who are not controlling shareholders and do not have a personal interest in such matter, present and voting at such meeting, are voted in favor of the compensation package, excluding abstentions; or
- the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in such matter voting against the compensation package does not exceed two percent (2%) of the aggregate voting rights in the company.

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 a special majority vote as discussed above with respect to the approval of director compensation). 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 a special majority vote as discussed above with respect to the approval of director compensation). 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 report for their decision. The approval of each of the compensation committee and the board of directors should be in accordance with the company's stated compensation policy; however, in special circumstances, they may approve compensation terms of a chief executive officer that are inconsistent with such 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 a special majority vote as discussed above with respect to the approval of director compensation). In addition, the compensation committee may waive the shareholder approval requirement with regards to the approval of the engagement terms of a candidate for the chief executive officer position, if they determine that the compensation arrangement is consistent with the company's stated compensation policy, and that the chief executive officer did not have a prior business relationship with the company or a controlling shareholder of the company and that subjecting the approval of the engagement to a shareholder vote would impede the company's ability to employ the chief executive officer candidate.

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 the 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 "Description of Share Capital – Acquisitions under Israeli law") or a private placement which qualifies as a related party transaction (See "– 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 (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;
- 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;
- 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; 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 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. As of the date of this prospectus, no claims for directors' and officers' liability insurance have been filed under this policy and we are not aware of any pending or threatened litigation or proceeding involving any of our office holders, including our directors, in which indemnification is sought.

Employment and consulting agreements with executive officers

We have entered into written employment or service agreements with each of our executive officers. See "Certain Relationships and 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, 2015, we employed 55 employees: 48 in Israel, and 7 in the United States by U.S. Subsidiary, Medigus USA LLC, including the Company's Chief Executive Officer.

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,		
	2015	**2014**	**2013**
Numbers of employees by category of activity	9	5	7
Management and administrative	12	10	9
Research and development	13	8	6
Operations	9	6	4
Sales and marketing	12	11	9
Production	55	40	35
Total workforce			
Numbers of employees by geographic location			
Israel	47	36	34
Europe	1	1	
United States	7	3	1
Total workforce	55	40	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, 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 expansion orders which apply to our employees principally concern the requirement for length of the work day and workweek, mandatory contributions to a pension fund, 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%. A general practice also followed by us is the contribution of funds on behalf of most of our employees either to a fund known as managers' insurance, to a pension fund or to a combination of both.

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".

Stock 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 December 31, 2015, there were 4,700,000 ordinary shares reserved under the 2013 Plan and 1,836,050 ordinary shares issuable upon the exercise of awards issued under the 2013 Plan:

Plan	Number of options outstanding- December 31, 2015	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	2,787,500	5.37	278,750	July 17, 2020
Series F	822,300	2.05	822,300	December 29, 2021
Series G	350,000	2.05	350,000	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 6 Option Plan

In November 2009, we adopted our Series 6 Option Plan. Our directors, officers, employees and certain consultants and dealers were eligible to participate in this plan. As of December 31, 2015, there were 57,000 ordinary shares issuable upon the exercise of outstanding options under the plan. These options have an expiration date of February 8, 2016. 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. All tax beneficial options granted under this plan were submitted to the ITA, as required by applicable law. The exercise price for the Series 6 options is NIS 22.6 per share, linked to the consumer price index as of November 29 of each calendar year following the grant of the Series 6 Options, compared to the known consumer price index as of November 29 of the previous calendar year. 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 December 31, 2015, there were 126,000 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.

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 December 31, 2015, 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.

ITEM 7. MAJOR SHARHOLDERS 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 15, 2016 (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 ordinary shares is based on the 32,047,034 ordinary shares outstanding as of March 15, 2016, and 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 shares subject to warrants that are currently exercisable or exercisable within 60 days of March 15, 2016, 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. 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.

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 Partners Limited Partnership (1)	7,455,232	22.49%
Migdal Insurance & Financial Holdings Ltd (2)	5,927,097	17.52%
Senvest International LLC (3)	6,495,670	19.04%
Oren Dan (4)	1,907,139	5.95%
Armistice Capital Master Fund Ltd. (5)	3,799,549	11.63%
Directors and executive officers*		
Christopher (Chris) Rowland	331,663	1.02%
Minelu (Menashe) Sonnenschein	614,993	1.92%
Aviel Shapira	666,329	2.08%
All directors and executive officers as a group (12 persons)	1,728,301	5.32%

* each of our other directors and executive officers beneficially owned less than 1% of our ordinary shares, if any.

(1) Based on information provided to us.
(2) Based on Schedule 13G/A filed with the SEC on February 10, 2016.
(3) Based on Schedule 13G/A filed with the SEC on February 12, 2016.
(4) Based on information provided to us.
(5) Based on Schedule 13G/A filed with the SEC on February 16, 2016, and information provided to us.

Significant Changes in Percentage Ownership by Major Shareholders

Shelf Registration Public Offering in Israel dated July 8, 2015

On July 8, 2015, we completed a public offering of ordinary shares and warrants (Series 9) under a shelf offering report issued pursuant to our shelf prospectus in Israel. Subsequent to the offering, we were informed that OrbiMed 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 (Series 9), exercisable into additional 748,000 of our ordinary shares, the entities within the RIMA Senvest Management LLC group and Senvest International 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 (Series 9), exercisable into additional 750,000 of our ordinary shares, Armistice Capital Master fund purchased 1,488,100 of our ordinary shares at a price of NIS 3.8 per share and 7,440,500 of our warrants (Series 9), exercisable into additional 744,050 of our ordinary shares, and Migdal group purchased 842,000 of our ordinary shares at a price of NIS 3.8 per share and 4,210,000 of our warrants (Series 9), exercisable into additional 421,000 of our ordinary shares.

OrbiMed Securities Purchase Agreement dated June 29, 2014

In June 2014, we entered into a securities purchase agreement with OrbiMed, pursuant to which we issued to OrbiMed a total of 766,311 of our ordinary shares and a total of 3,065,244 warrants exercisable for 306,524 of our ordinary shares . For a description of the agreement, including the securities issued to OrbiMed, see "Item 10. Additional Information – C. Material Contracts."

Migdal Securities Purchase Agreement dated June 29, 2014

In June 2014, we entered into a securities purchase agreement with Migdal, pursuant to which we issued to Migdal a total 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. For a description of the agreement, including the securities issued to Migdal, see "Item 10. Additional Information – C. Material Contracts."

Private Investors Securities Purchase Agreement dated June 29, 2014

On June 29, 2014, we entered into securities purchase agreements with each of Armistice Capital Master Fund Ltd., Sabby Healthcare Volatility Master Fund Ltd., Sabby Volatility Warrant Master Fund Ltd., Senvest Israel Partners LP, Senvest International LLC, Migdal Insurance Company Ltd., and Capital Point Ltd. For a description of the agreements, including the securities issued to the above purchasers, see "Item 10. Additional Information – C. Material Contracts."

Public Offering in October 2013

On October 17, 2013, we completed a public offering of ordinary shares and warrants (Series 8) under a shelf offering report issued pursuant to our shelf prospectus in Israel. Subsequent to the offering, we were informed that OrbiMed purchased a total of 95,900 of our ordinary shares at a price of NIS 7.2 per share and 479,500 of our warrants (Series 8), exercisable into additional 47,950 of our ordinary shares, and the entities within the RIMA Senvest Management LLC group and Senvest International LLC purchased an aggregate of 1,400,000 of our ordinary shares at a price of NIS 7.2 per share and 7,000,000 of our warrants (Series 8), exercisable into additional 700,000 of our ordinary shares.

OrbiMed Share Purchase Agreement dated January 3, 2013

On January 3, 2013, we entered into a securities purchase agreement with OrbiMed, pursuant to which we issued to OrbiMed a total of 3,994,547 of our ordinary shares at a price of NIS 7.336 per share and a warrant exercisable for an additional 3,994,547 of our ordinary shares. For a description of the agreement, including the securities issued to OrbiMed, see "Item 10. Additional Information – C. Material Contracts."

Record Holders

As of December 31, 2015, 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. There were no record holders of our ordinary shares in the U.S. as of As of December 31, 2015. To the best of our knowledge, and based on information obtained from the Tel Aviv Stock Exchange Clearing House Ltd., as of December 31, 2015, residents of Israel beneficially owned approximately 42.78% of our shares and residents of the U.S. beneficially owned approximately 35.68% of our shares.

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 office holders undertaking to indemnify them to the fullest extent permitted by law. We have obtained directors & officers insurance for each of our officers and directors.

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 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 $ 52,855, and which includes a deductible of up to $35,000 per claim, other than such claims related to extraordinary events such as securities related claims (other than claims filed in the United States or Canada), for which the deductible shall not exceed $100,000, claims filed in the United States or Canada, for which the deductible shall not exceed $35,000, or securities related claims filed in the United States or Canada, for which the deductible shall not exceed $100,000.

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 USD 20 million per occurrence and for the insurance period (additional coverage for legal expenses not included), provided that the annual premium shall not exceed USD 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 USD 50,000 per occurrence.

Agreements with Orbimed

For description of our agreements with Orbimed see "Item 10 – Material Contracts."

Agreement with Luzzatto

We entered into an engagement with Luzzatto and Luzzatto Patent Attorneys (General Partnership), or Luzzatto, which is controlled by our shareholders, Kfir and Esther Luzzatto. Luzzatto provide us with patent and trademark preparation and registration services. Under the terms of the engagement we pay an hourly fee which ranges between USD 60-125 (plus V.A.T.), depending of the type of service provided. Furthermore, we reimbursed Luzzatto for its expenses against invoices or actual payment vouchers, including payment to patent attorneys abroad and fees to patent registration offices. The engagement does not specify the term or the conditions for termination thereof.

Both our audit committee and board of directors, re-approved the terms of the agreement described above, for an additional three year period in accordance with the requirements of the Companies Law.

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 (NIS, in thousands):

	For the year ended December 31,		
	2015	**2014**	**2013**
Total export sales*	2,416	2,664	2,498
as a percentage of total revenues	100%	100%	100%

* 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 June 16, 2015, we filed a claim in the District Court of Delaware, against EndoChoice, Inc., or EndoChoice, for its patent infringement seeking an injunctive order and damages. On October 6, 2015, we filed oppositions against EndoChoice's trademark applications with the Israeli Patent Office. In response, On December 29, 2015, EndoChoice filed a separate trademark and unfair competition action against us and our U.S. Subsidiary. In addition, on January 27, 2016, EndoChoice commenced an opposition procedure with the Israeli Patent Office against in connection with our trademark application in Israel. We believe we will fend off EndoChoice's claims but we cannot provide any assurance we will be successful in doing so. Failure to fend off these claims may adversely affect our business in the Israeli or the U.S. market, as applicable.

On March 16, 2016, a former secretary and internal legal advisor handed us with a notice letter prior to filing of a lawsuit alleging wrongful termination and other related claims. At this early stage, based on the opinion of our legal counsels and on the fact that as of the date of this annual report on Form 20-F there were no actual statement of claims submitted to us, our management cannot assess the outcome of these proceedings.

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. Our ADSs are listed on the NASDAQ Capital Market under the symbol "MDGS" with one ADS representing five (5) ordinary shares.

The following table sets forth, for the periods indicated, the reported high and low closing 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		US$ Price Per Ordinary Share	
	High	**Low**	**High**	**Low**
Annual:				
2015	5.6	1.6	1.41	0.41
2014	6.5	2.5	1.8	0.6
2013	11.3	5.6	3.3	1.6
2012	13.6	5.7	3.6	1.5
2011	14.7	6.6	3.8	1.7
Quarterly:				
Fourth Quarter 2015	2.9	1.6	0.8	0.4
Third Quarter 2015	4.1	2.7	1.1	0.7
Second Quarter 2015	5.6	3.7	1.4	0.9
First Quarter 2015	3.8	2.6	1	0.7
Fourth Quarter 2014	4.3	2.5	1.2	0.6
Third Quarter 2014	5.2	4.1	1.5	1.1
Second Quarter 2014	6.2	4.5	1.8	1.3
First Quarter 2014	6.5	5.2	1.9	1.4
Fourth Quarter 2013	8.3	5.6	2.4	1.6
Third Quarter 2013	9.2	7.3	2.6	2.0
Second Quarter 2013	9.6	7.6	2.6	2.0
First Quarter 2013	11.3	7.5	3.1	2.0
Most Recent Six Months:				
March 2016 (until March 15, 2016)	1.43	1.40	0.36	0.36
February 2016	1.55	1.28	0.39	0.33
January 2016	1.79	1.53	0.46	0.38
December 2015	2.36	1.60	0.61	0.41
November 2015	2.87	2.31	0.74	0.60
October 2015	2.91	2.80	0.76	0.73

On March 15, 2016, the last reported sale price of our ordinary shares on the TASE was NIS 1.397 per share, or approximately $0.359 per share (based on the exchange rate reported by the Bank of Israel for such date). On March 15, 2016, the exchange rate of the NIS to the dollar was $1.00 = NIS 3.891, as reported by the Bank of Israel.

ADSs

Our ADSs have been registered on the Nasdaq Capital Market under the symbol "MDGS" since May 15, 2015

Each ADR represents five ordinary shares.

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

	US$ Price Per ADR (adjusted to reflect change in ratio of ADR)	
	High	**Low**
Quarterly:		
Fourth Quarter 2015	4.48	2.68
Third Quarter 2015 (commencing August 5, 2015)	5.00	3.80
Most Recent Six Months:		
March 2016 (until March 15, 2016)	2.05	1.69
February 2016	2.54	1.72
January 2016	2.68	2.54
December 2015	3.39	2.68
November 2015	3.95	3.39
October 2015	4.48	3.32

On March 15, 2016, the last reported sale price of our ADS on the NASDAQ Capital Market was $ 1.81 per share.

For a description of our 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. Our ADSs, each representing five (5) ordinary share and evidenced by an American depositary receipt, or ADR, are traded on the Nasdaq Capital Market 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

Not applicable.

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.

Voting rights and conversion

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

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 some 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. Unless otherwise stipulated by the board of directors, each payment in response to a call shall be deemed to constitute a pro rata payment on account of all shares with respect to which such call was made. A shareholder shall not be entitled to his rights as shareholder, including the right to dividends, unless such shareholder has fully paid all the notices of call delivered to him, or which according to our articles of association are deemed to have been delivered to him, together with interest, linkage and expenses, if any, unless otherwise determined by the board of directors.

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 Companies Law described under "Management — External directors."

Under our articles of association, our board of directors must consist of not less than three (3) but no more than twelve (12) 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 (12) 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 "Management — Corporate governance 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 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 considered to be in a state of war with Israel at such time.

Shareholder Meetings

Under Israeli 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 Israeli 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:

Under the Israeli Companies Law, 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 director's 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 together with our articles of association require 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

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 state 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 above under "Management – 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 above under "Management – Fiduciary duties and approval of specified related party transactions and compensation under Israeli law – Compensation of directors and executive officers." Under our articles of association, any change to the rights and privileges of the holders of any class of our shares requires a simple majority of the class so affected (or such other percentage of the relevant class that may be set forth in the governing documents relevant to such class), in addition to the ordinary majority vote of all classes of shares voting together as a single class at a shareholder meeting. 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 "Management – 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.

Anti-takeover measures under Israeli law

The Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights with respect to voting, distributions or other matters and shares having preemptive rights. As of the closing of December 31, 2015, no preferred shares will be authorized under our articles of association. In the future, if we do authorize, create and issue a specific class of preferred shares, such class of shares, depending on the specific rights that may be attached to it, may have the ability to frustrate or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization and designation of a class of preferred shares will require an amendment to our articles of association, which requires the prior approval of the holders of a majority of the voting power attaching to our issued and outstanding shares at a general meeting. The convening of the meeting, the shareholders entitled to participate and the majority vote required to be obtained at such a meeting will be subject to the requirements set forth in the Companies Law as described above in "– Voting rights."

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 will be the depositary for our ADSs, Bank of New York Mellon, and its address is 101 Barclay Street, New York, NY..

Listing

Our ADSs are traded on the NASDAQ Capital Market under the symbol "MDGS."

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.

Private Issuance to OrbiMed (2013)

Share Purchase Agreement

In January 2013, we entered into a share purchase agreement with OrbiMed pursuant to which we issued an aggregate amount of 3,994,547 ordinary shares and 39,945,474 warrants, each 10 warrants exercisable into one ordinary share, for a total consideration of $8 million. The offering closed on March 3, 2013. The warrants have expired on March 3, 2016.

Shareholders' Undertaking

In connection with the above share purchase agreement, several of the Company's shareholders (Elazar Sonnenschein, Menashe Sonnenschein, Aviel Shapira, Esther and Kfir Luzzato and Yair Rabinowitch) 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. As of December 31, 2015, these shareholders collectively held 8,618,818 ordinary shares, representing approximately 26.89% of our outstanding shares. On March 3, 2016, the Shareholders' Undertaking has expired.

Securities Purchase Agreements (2014)

On June 29, 2014, we entered into securities purchase agreements with Armistice Capital Master Fund Ltd., 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 34,108,614 warrants (Series E), exercisable into an additional 3,410,861 ordinary shares for a period of 36 months from their date of issuance. Each 10 warrants are exercisable into on ordinary share at a price per share os 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 and/or US 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.

Under the terms of the securities purchase agreements, we undertook to establish a level 2 American Depository Receipt Facility, or ADR Facility, including the listing of ADSs representing ordinary shares on the NASDAQ or the New York Stock Exchange (NYSE) within seven months of the closing date, or to take all necessary actions in order to permit the resale by the investors of their shares (including the shares underlying the warrants) on the TASE by filing a prospectus or a shelf offering report with the Israeli Securities Authority and the TASE. As of the seven month anniversary of the closing date, unless the Company either (i) has an effective registration statement which permits the investors to sell their shares without restriction or limitation in the United States (an "ADR Registration Statement") or (ii) has removed all lock-up restrictions on the trading of the investors' shares (including the shares underlying the warrants) on the TASE in Israel by filing a prospectus or a shelf offering (the "TASE Lock-Up Removal"), then we will be required to pay liquidated damages in cash equal to 2.0% of the aggregate consideration of the investor's shares and warrants still held by the investors at such time and still subject to any lock up period under Israeli securities laws on every 30th day following the failure to comply with the above two requirements, until such failure if cured. In any event, liquidated damages cannot be more than 24% in total of the overall proceeds paid to the Company by the applicable investor. On January 22, 2015, we filed a prospectus on the TASE in Israel satisfying (ii) above. As a result, we are not be required to pay liquidated damages under the above agreements.

Under the terms of the securities purchase agreements with the non-Israeli investors, we also agreed, until either the ADR Registration Statement is declared effective or the date of the TASE Lock-Up Removal (or the removal of any Israeli lock-up restrictions in accordance with the Israeli Securities Law), not to issue any additional securities without the prior written consent of the Non-Israeli Investors holding securities representing a "Purchaser Majority" as defined in the agreement. We also agreed not to issue any ordinary shares, options, warrants or any other instrument convertible into, exercisable or exchangeable for ordinary shares of the Company, other than in a bona fide underwritten offering with gross proceeds of at least $20 million, until at least 180 days after the share restrictions have been released by means of one of the methods described above.

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, currently at the rate of 25% for 2016 and thereafter. However, the effective tax rate payable by a company that derives income from an Approved Enterprise and/or a Benefitted 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. On January 4, 2016 the Israeli Parliament approved an amendment for the Israeli tax Ordinance (Number 216), 2016 according to which corporate tax rate will be updated to 25% in the tax year 2016 (the "2016 Amendment").

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 prospectus, 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.

In general pursuant to the Tax Ordinance, R&D expenses are deductible over a three year period and if we meet certain conditions set forth thereto, we may apply to 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 "Benefitted 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 Benefitted 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 Benefitted 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 Benefitted 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 Benefitted Enterprise depend on, among other things, the geographic location in Israel of the Benefitted 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 Benefitted Enterprise in Israel, and a reduced corporate tax rate of between 10% to 25% 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 Benefitted 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 rate of 25%, 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 Benefitted Enterprise are generally subject to withholding tax at source at the rate of 15% or 20% if the income from which the dividend was distributed is attributable to a Benefitted Enterprise plan with a "Year of Election" prior to 2014, or such lower rate as may be provided in an applicable tax treaty.

The benefits available to a Benefitted 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 Benefitted 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.

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 onwards[1]	9%	16%

(1) In August 2013, the Israeli Parliament (the Knesset) approved an amendment to the Investments Law pursuant to which the previously scheduled gradual reduction in the tax rates applicable to Preferred Enterprises would be repealed as of 2014 and the tax rates reflected on the above table will apply.

As of 2014, 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% (iii) non-Israeli residents - 20%, 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 provisions of the 2011 Amendment shall not apply to existing Benefitted Enterprises or Approved Enterprises, which will continue to be entitled to the tax benefits under the Investments Law, as has been in effect prior to the 2011 Amendment, unless the company owning such enterprises had made an election to apply the provisions of the 2011 Amendment (such election cannot be later rescinded), which is to be filed with the Israeli Tax Authority, not later than the date prescribed for the filing of the company's annual tax return for the respective year. A company owning a Benefitted Enterprise or an Approved Enterprise which made such election by July 30, 2015 will be entitled to distribute income generated by the Approved/Beneffited Enterprise to its Israeli corporate shareholders with no withholding taxes.

We did not apply for tax benefits for Preferred Enterprise.

Taxation of our shareholders

Capital gains

Capital gain tax is imposed on the disposal of capital assets by an Israeli resident, and on the disposal 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 disposal. 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.

Individual and corporate shareholder dealing in securities in Israel are taxed at the tax rates applicable to business income– 25% for corporations in 2016 and a marginal tax rate of up to 50% in 2016 for individuals, including a 2% excess tax which is levied on individuals whose taxable income in Israel exceeds certain threshold (approximately NIS 811,000 in 2015).

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, (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% with respect to a corporation and/or an individual.

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. As of January 1, 2014, any distribution of dividends from income attributed to a Preferred Enterprise is generally subject to a tax at a rate of 20%. However, if such dividends are distributed to an Israeli company, no tax is imposed. As of January 1, 2014, dividends distributed from income attributed to an Approved Enterprise and/or a Privileged Enterprise are subject to a tax rate of 20%. Notwithstanding the above, a reduced 15% tax rate will be applicable if the dividend was distributed out of income of: (i) Approved Enterprise activated prior to 2014;or (ii) Privileged Enterprise with a "Year of Election" prior to 2014. Those rates may be further reduced under the provisions of any applicable double tax treaty.

A distribution of dividends from income, which is not attributed to an Approved Enterprise/Privileged Enterprise/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 stock 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% for individuals and 26.5% for corporations, 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% on annual income exceeding a certain threshold (NIS 810,720 for 2015, which amount is 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. 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 is a description of the material U.S. federal income tax consequences relating to the acquisition, ownership and disposition of our ordinary shares. This description addresses only the U.S. federal income tax consequences to holders that are initial purchasers of our ordinary shares pursuant to the offering and that will hold such ordinary shares as capital assets. This description does not address tax considerations applicable to holders that may be subject to special tax rules, including, without limitation:

- banks, financial institutions or insurance companies;
- real estate investment trusts, regulated investment companies or grantor trusts;
- dealers or traders in securities, commodities or currencies;
- tax exempt entities or organizations;
- certain former citizens or residents of the United States;
- persons that received our shares as compensation for the performance of services;
- persons that will hold our shares as part of a "hedging," "integrated" or "conversion" transaction or as a position in a "straddle" for U.S. federal income tax purposes;
- partnerships (including entities classified as partnerships for U.S. federal income tax purposes) or other pass-through entities, or holders that will hold our shares through such an entity;
- U.S. Holders (as defined below) whose "functional currency" is not the U.S. dollar; or
- holders that own directly, indirectly or through attribution 10% or more of the voting power or value of our shares.

Moreover, this description does not address the U.S. federal estate, gift, or alternative minimum tax consequences, or any U.S. state, local or non-U.S. tax consequences of the acquisition, ownership and disposition of our ordinary shares.

This description is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, existing, proposed and temporary U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof, in each case as in effect and available on the date hereof. All the foregoing is subject to change, which change could apply retroactively and could affect the tax consequences described below. There can be no assurances that the U.S. Internal Revenue Service, or IRS, will not take a different position concerning the tax consequences of the acquisition, ownership and disposition of our ordinary shares or that such a position would not be sustained. Holders should consult their own tax advisers concerning the U.S. federal, state, local and foreign tax consequences of acquiring, owning and disposing of our ordinary shares in their particular circumstances.

For purposes of this description, the term "U.S. Holder" means a beneficial owner of our ordinary shares that, for U.S. federal income tax purposes, is (i) a citizen or resident of the United States, (ii) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income tax regardless of its source or (iv) a trust (x) with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of its substantial decisions or (y) that has elected to be treated as a domestic trust for U.S. federal income tax purposes.

A "Non-U.S. Holder" is a beneficial owner of our ordinary shares that is neither a U.S. Holder nor a partnership (or other entity treated as a partnership for U.S. federal income tax purposes).

If a partnership (or any other entity treated as a partnership for U.S. federal income tax purposes) holds our ordinary shares, the U.S. federal income tax consequences relating to an investment in our ordinary shares will depend in part upon the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax advisor regarding the U.S. federal income tax consequences of acquiring, owning and disposing of our ordinary shares in its particular circumstances.

Unless otherwise indicated, this discussion assumes that the Company is not, and will not become, a PFIC for U.S. federal income tax purposes. See "– Passive foreign investment company consequences" below.

Persons considering an investment in our ordinary shares should consult their own tax advisors as to the particular tax consequences applicable to them relating to the acquisition, ownership and disposition of our ordinary shares, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

Taxation of dividends and other distributions on our ordinary shares

Subject to the discussion below under "Passive foreign investment company consequences," if you are a U.S. Holder, the gross amount of any distribution made to you with respect to our ordinary shares before reduction for any Israeli taxes withheld therefrom, other than certain distributions, if any, of our ordinary shares distributed pro rata to all our shareholders, generally will be includible in your income as dividend income to the extent such distribution is paid out of our current or accumulated earnings and profits as determined under U.S. federal income tax principles. Non-corporate U.S. Holders may qualify for the lower rates of taxation with respect to dividends on ordinary shares applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year), provided that certain conditions are met, including certain holding period requirements and the absence of certain risk reduction transactions. Moreover, such lower rate of taxation shall not apply if the Company is a PFIC for the taxable year in which it pays a dividend, or was a PFIC for the preceding taxable year. However, such dividends will not be eligible for the dividends received deduction generally allowed to corporate U.S. Holders. To the extent that the amount of any distribution by us exceeds our current and accumulated earnings and profits as determined under U.S. federal income tax principles, it will be treated first as a tax-free return of your adjusted tax basis in our ordinary shares and thereafter as either long-term or short-term capital gain depending upon whether the U.S. Holder has held our ordinary shares for more than one year as of the time such distribution is received.

If you are a U.S. Holder, dividends paid to you with respect to our ordinary shares will be foreign source income for foreign tax credit purposes. Subject to certain conditions and limitations, Israeli tax withheld on dividends may be deducted from your taxable income or credited against your U.S. federal income tax liability. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends generally constitute "passive category income," or, in the case of certain U.S. Holders, "general category income." A foreign tax credit for foreign taxes imposed on distributions may be denied if you do not satisfy certain minimum holding period requirements. The rules relating to the determination of the foreign tax credit are complex, and you should consult your tax advisor to determine whether and to what extent you will be entitled to this credit.

The amount of a distribution paid to a U.S. Holder in a foreign currency will be the dollar value of the foreign currency calculated by reference to the spot exchange rate on the day the U.S. Holder receives the distribution, regardless of whether the foreign currency is converted into U.S. dollars at that time. Any foreign currency gain or loss a U.S. Holder realizes on a subsequent conversion of foreign currency into U.S. dollars will be U.S. source ordinary income or loss. If dividends received in foreign currency are converted into U.S. dollars on the day they are received, a U.S. Holder generally should not be required to recognize foreign currency gain or loss in respect of the dividend.

Subject to the discussion below under "Backup withholding tax and information reporting requirements," if you are a Non-U.S. Holder, you generally will not be subject to U.S. federal income (or withholding) tax on dividends received by you on your ordinary shares, unless:

- you conduct a trade or business in the U.S. and such income is effectively connected with that trade or business (and, if required by an applicable income tax treaty, the dividends are attributable to a permanent establishment or fixed base that such holder maintains in the U.S.); or
- you are an individual and have been present in the U.S. for 183 days or more in the taxable year of such sale or exchange and certain other conditions are met.

Sale, exchange or other disposition of our ordinary shares

Subject to the discussion below under "Passive foreign investment company consequences," if you are a U.S. Holder, you generally will recognize gain or loss on the sale, exchange or other disposition of our ordinary shares equal to the difference between the amount realized on such sale, exchange or other disposition and your adjusted tax basis in our ordinary shares, and such gain or loss will be capital gain or loss. The adjusted tax basis in an ordinary share generally will be equal to the cost of such ordinary share. If you are a non-corporate U.S. Holder, capital gain from the sale, exchange or other disposition of ordinary shares is generally eligible for a preferential rate of taxation applicable to capital gains, if your holding period determined at the time of such sale, exchange or other disposition for such ordinary shares exceeds one year (i.e., such gain is long-term capital gain). The deductibility of capital losses is subject to limitations. U.S. Holders should consult their own tax advisors concerning the source of income for U.S. foreign tax credit purposes, the effect of the U.S.-Israel Tax Treaty on the source of income and the ability to claim the foreign tax credit.

Subject to the discussion below under "*Backup withholding tax and information reporting requirements*," if you are a Non-U.S. Holder, you generally will not be subject to U.S. federal income or withholding tax on any gain realized on the sale or exchange of such ordinary shares unless:

- such gain is effectively connected with your conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment or fixed base that you maintain in the United States); or
- you are an individual and have been present in the United States for 183 days or more in the taxable year of such sale or exchange and certain other conditions are met.

Passive foreign investment company consequences

If we were to be classified as a PFIC in any taxable year, a U.S. Holder would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. Holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A non-U.S. corporation will be classified as a PFIC for federal income tax purposes in any taxable year in which, after applying certain look-through rules with respect to the income and assets of subsidiaries, either:

- at least 75% of its gross income is "passive income"; or
- at least 50% of the average quarterly value of its total gross assets (which may be determined in part by the market value of our ordinary shares, which is subject to change) is attributable to assets that produce "passive income" or are held for the production of passive income.

Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income, and includes amounts derived by reason of the temporary investment of funds raised in offerings of our ordinary shares. If a non-U.S. corporation owns at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income. If we are classified as a PFIC in any year with respect to which a U.S. Holder owns our ordinary shares, we will generally continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns our ordinary shares, regardless of whether we continue to meet the tests described above.

Based on our gross income and gross assets and the nature of our business, we believe that we were not a PFIC for U.S. federal income tax purposes for the taxable year ending December 31, 2015. There can be no assurance that we will not be considered a PFIC for 2015 or any future taxable year. If we were a PFIC, and you are a U.S. Holder, then unless you make one of the elections described below, a special tax regime will apply to both (a) any "excess distribution" by us to you (generally, your ratable portion of distributions in any year which are greater than 125% of the average annual distribution received by you in the shorter of the three preceding years or your holding period for our ordinary shares) and (b) any gain realized on the sale or other disposition of the ordinary shares. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (i) the excess distribution or gain had been realized ratably over your holding period, (ii) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax, at the U.S. Holder's regular ordinary income rate for the current year and would not be subject to the interest change discussed below), and (iii) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. In addition, dividend distributions made to you will not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under "– Taxation of dividends and other distributions on our ordinary shares." Certain elections may be available that would result in an alternative treatment (such as mark-to-market treatment) of our ordinary shares.

If a U.S. Holder makes the mark-to-market election, then, in lieu of being subject to the tax and interest charge rules discussed above, the U.S. Holder generally will recognize as ordinary income any excess of the fair market value of the ordinary shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ordinary shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder's tax basis in the ordinary shares will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of ordinary shares in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election).

The mark-to-market election is available only if we are a PFIC and our ordinary shares are "regularly traded" on a "qualified exchange." Our ordinary shares will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of the ordinary shares are traded on a qualified exchange on at least 15 days during each calendar quarter. The NASDAQ Global Market is a qualified exchange for this purpose. Because a mark-to-market election cannot be made for any lower-tier PFICs that we may own, a U.S. Holder may continue to be subject to the tax and interest charge rules discussed above with respect to such holder's 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, including stock in any of the Company's subsidiaries that are treated as PFICs. If a U.S. Holder makes a mark-to market election, it will be effective for the taxable year for which the election is made and all subsequent taxable years unless our ordinary shares are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election.

U.S. Holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

If we are determined to be a PFIC, the general tax treatment for U.S. Holders described in this section would apply to indirect distributions and gains deemed to be realized by U.S. Holders in respect of any of our subsidiaries that also may be determined to be PFICs.

If a U.S. Holder owns ordinary shares during any year in which we are a PFIC, the U.S. Holder generally will be required to file an IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) with respect to the company, generally with the U.S. Holder's federal income tax return for that year.

U.S. Holders should consult their tax advisors regarding whether we are a PFIC and the potential application of the PFIC rules.

Medicare tax

Certain U.S. Holders that are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their "net investment income," which may include all or a portion of their dividend income and net gains from the disposition of ordinary shares. Each U.S. Holder that is an individual, estate or trust is urged to consult its tax advisors regarding the applicability of the Medicare tax to its income and gains in respect of its investment in our ordinary shares.

Certain reporting requirements with respect to payments of offer price

U.S. Holders paying more than $100,000 for our ordinary shares in a 12 month period generally will be required to file IRS Form 926 reporting the payment of the Offer Price for our ordinary shares to us. Substantial penalties may be imposed upon a U.S. Holder that fails to comply. Each U.S. Holder should consult its own tax advisor as to the possible obligation to file IRS Form 926.

Backup withholding tax and information reporting requirements

U.S. backup withholding tax and information reporting requirements may apply to certain payments to certain holders of our ordinary shares. Information reporting generally will apply to payments of dividends on, and to proceeds from the sale or redemption of, our ordinary shares made within the United States, or by a U.S. payer or U.S. middleman, to a holder of our ordinary shares, other than an exempt recipient (including a payee that is not a U.S. person that provides an appropriate certification and certain other persons). A payer may be required to withhold backup withholding tax from any payments of dividends on, or the proceeds from the sale or redemption of, ordinary shares within the United States, or by a U.S. payer or U.S. middleman, to a holder, other than an exempt recipient, if such holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with, or establish an exemption from, such backup withholding tax requirements. Any amounts withheld under the backup withholding rules will be allowed as a credit against the beneficial owner's U.S. federal income tax liability, if any, and any excess amounts withheld under the backup withholding rules may be refunded, provided that the required information is timely furnished to the IRS.

Foreign asset reporting

Certain U.S. Holders who are individuals are required to report information relating to an interest in our ordinary shares, subject to certain exceptions (including an exception for shares held in accounts maintained by financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. U.S. Holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of our ordinary shares.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PROSPECTIVE INVESTOR. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN ORDINARY SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

B. Dividends and Paying Agents

Not applicable.

C. Statement by Experts

Not applicable.

D. Documents on Display

We are subject to certain information reporting requirements of the Exchange Act, applicable to foreign private issuers and under those requirements will file reports with the SEC. Those other reports or other information and this annual report on Form 20- F may be inspected without charge at Omer Industrial Park, No. 7A, P.O. Box 3030, Omer 8496500, Israel, and inspected and copied at the public reference facilities of the SEC located at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains a website at *http://www.sec.gov* from which certain filings may be accessed.

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

While our revenues are primarily in the U.S. Dollar and Euro, our functional and reporting currency has been the NIS, which is the currency of the primary economic environment in which our operations are conducted. This determination is based on the fact that our expenses, which are the dominant aspect of our financial statements, including the salaries paid to most of our employees, are denominated in NIS, and are relatively larger than our revenues. We anticipate that a sizable portion of our expenses will continue to be denominated in currencies other than the U.S. dollar. If the U.S. dollar fluctuates significantly against the NIS, it may have a negative impact on our results of operations. To date, fluctuations in the exchange rates have not materially affected our results of operations or financial condition.

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, 2015, 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

Each of our American Depositary Shares, or ADSs, represents five (5) of our ordinary shares. Our 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
$0.05 (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
$0.05 (or less) per ADSs 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 have to pay on any ADS or share underlying an ADS, for example, 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 generally refuse to provide fee-attracting services until its fees for those services are paid. The depositary may collect any of its fees by deduction from any cash distributions made to ADS holders that are obligated to pay those fees.

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.

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 report are effective at such reasonable assurance level.

(b) Management report on internal control over financial reporting

This annual report on Form 20-F does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

(c) Inherent limitations on effectiveness of controls

See statement in section (b).

(d) 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, 2015, 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 each of Mr. Birger and Mr. Hershkovitz 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, 2014
	(NIS in thousands)	
Audit fees[1]	460	558
Total	460	558

_____

(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.

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 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 the Company will be unable to grant options to its 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 statements of financial position and the related consolidated statements of loss and other comprehensive loss, of changes in equity and of cash flows present fairly, in all material respects, the financial position of Medigus Ltd. and its subsidiary at December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015, 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 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.

As discussed in Note 1c to the financial statements, the Company has effected a reverse split of its ordinary shares and retrospectively applied this split to all periods presented.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1d to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1d. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Tel-Aviv, Israel
March 30, 2016

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 STATEMENTS OF FINANCIAL POSITION

	Note	December 31 2015	2014
		NIS in thousands	
Assets			
CURRENT ASSETS:			
Cash and cash equivalents	5	40,239	42,067
Financial assets at fair value through profit or loss	4		8,187
Accounts receivable:	6		
Trade		992	513
Other		3,924	1,738
Inventory	2 (i),7	1,187	1,403
		46,342	53,908
NON-CURRENT ASSETS:			
Inventory	2 (i),7		541
Property and equipment	8	880	945
Intangible assets		152	185
		1,032	1,671
TOTAL ASSETS		47,374	55,579

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

MEDIGUS LTD.
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Note	December 31	
		2015	2014
		NIS in thousands	
Liabilities and equity			
CURRENT LIABILITIES -			
Accounts payable and accruals:	10		
Trade		1,395	791
Other		5,836	3,223
		7,231	4,014
NON-CURRENT LIABILITIES:			
Warrants at fair value	4	34	428
Retirement benefit obligation, net		381	381
		415	809
COMMITMENTS	11		
TOTAL LIABILITIES		7,646	4,823
EQUITY:	12		
Ordinary share capital		3,204	2,499
Share premium		193,113	170,741
Other capital reserves		4,640	4,498
Warrants		5,586	2,828
Accumulated deficit		(166,815)	(129,810)
TOTAL EQUITY		39,728	50,756
TOTAL LIABILITIES AND EQUITY		47,374	55,579

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

MEDIGUS LTD.
CONSOLIDATED STATEMENTS OF LOSS AND OTHER COMPREHENSIVE LOSS

	Note	For the Year Ended December 31		
		2015	2014	2013
		NIS in thousands		
REVENUES	18	2,416	2,664	2,498
COST OF REVENUES	13	1,073	1,252	1,126
GROSS PROFIT		1,343	1,412	1,372
RESEARCH AND DEVELOPMENT EXPENSES, NET	13	17,020	14,401	8,180
SELLING AND MARKETING EXPENSES	13	10,391	8,353	3,234
ADMINISTRATIVE AND GENERAL EXPENSES	13	11,028	8,206	6,877
OTHER INCOME, NET	14	10	941	666
OPERATING LOSS		(37,086)	(28,607)	(16,253)
PROFIT FROM CHANGES IN FAIR VALUE OF WARRANTS ISSUED TO INVESTORS	4	394	3,605	11,544
FINANCING INCOME (EXPENSES) IN RESPECT OF DEPOSITS AND EXCHANGE DIFFERENCES		78	2,513	(182)
FINANCING EXPENSES IN RESPECT OF BANK COMMISSIONS		(127)	(127)	(213)
FINANCING INCOME (EXPENSES), NET	15	(49)	2,386	(395)
LOSS BEFORE TAXES ON INCOME		(36,741)	(22,616)	(5,104)
TAXES ON INCOME	9	(264)	(13)	(85)
LOSS FOR THE YEAR		(37,005)	(22,629)	(5,189)
OTHER COMPREHENSIVE INCOME (LOSS):				
Amounts which will not be reclassified to profit or loss - re-measurement of net liabilities for employee benefits			(105)	
Amounts which may be subsequently reclassified to profit or loss:				
Currency translation differences		2	14	
Transfer of capital reserve in respect of financial asset available for sale to statement of loss, net of tax				(254)
OTHER COMPREHENSIVE INCOME (LOSS) FOR THE YEAR, NET OF TAX		2	(91)	(254)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		(37,003)	(22,720)	(5,443)
		NIS		
BASIC AND DILUTED LOSS PER SHARE	16	(1.3)	(1.2)	(0.4)
WEIGHTED AVERAGE OF ORDINARY SHARES (IN THOUSANDS)		28,415	19,500	13,020

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

MEDIGUS LTD.
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(Continued) - 1

		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	Capital reserve from financial asset available for sale	Warrants	Accumulated deficit	Total equity
		NIS in thousands							
BALANCE AS OF JANUARY 1, 2013		902	93,925	3,922	1,912	254	3,910	(101,887)	2,938
TOTAL COMPREHENSIVE LOSS FOR THE YEAR						(254)		(5,189)	(5,443)
TRANSACTIONS WITH SHAREHOLDERS:									
Proceeds from issuance of shares and warrants	12B	744	38,191				1,671		40,606
Options granted to employees and service providers	12C			511					511
Forfeiture and expiration of options and warrants	12 C		6,262	(2,352)			(3,910)		
Amount carried to capital reserve as a result of transaction with controlling shareholder	17				138				138
TOTAL TRANSACTIONS WITH SHAREHOLDERS		744	44,453	(1,841)	138		(2,239)		41,255
BALANCE AS OF DECEMBER 31, 2013		1,646	138,378	2,081	2,050	-	1,671	(107,076)	38,750

MEDIGUS LTD.
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(Continued) - 2

	Note	Equity attributed to the owners of the company							
		Ordinary shares	Share premium	Capital reserves from options granted	Capital reserves from transactions with controlling shareholders	Currency translation differences	Warrants	Accumulated deficit	Total equity
		NIS in thousands							
BALANCE AS OF JANUARY 1, 2014		1,646	138,378	2,081	2,050		1,671	(107,076)	38,750
TOTAL COMPREHENSIVE INCOME (LOSS) FOR THE YEAR						14		(22,734)	(22,720)
TRANSACTIONS WITH SHAREHOLDERS:									
Proceeds from issuance of shares and warrants	12B	853	31,605				1,157		33,615
Options granted to employees and service providers	12C			1,111					1,111
Forfeiture and expiration of options and warrants	12C		758	(758)					
TOTAL TRANSACTIONS WITH SHAREHOLDERS		853	32,363	353			1,157		34,726
BALANCE AS OF DECEMBER 31, 2014		2,499	170,741	2,434	2,050	14	2,828	(129,810)	50,756

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
		NIS in thousands							
BALANCE AS OF JANUARY 1, 2015		2,499	170,741	2,434	2,050	14	2,828	(129,810)	50,756
TOTAL COMPREHENSIVE INCOME (LOSS) FOR THE YEAR						2		(37,005)	(37,003)
TRANSACTIONS WITH SHAREHOLDERS:									
Proceeds from issuance of shares and warrants	12B	705	22,062				2,758		25,525
Options granted to employees and service providers	12 C			450					450
Forfeiture of options	12C		310	(310)					
TOTAL TRANSACTIONS WITH SHAREHOLDERS		705	22,372	140			2,758		25,975
BALANCE AS OF DECEMBER 31, 2015		3,204	193,113	2,574	2,050	16	5,586	(166,815)	39,728

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		
	2015	**2014**	**2013**
		NIS in thousands	
CASH FLOWS FROM OPERATING ACTIVITIES:			
CASH FLOWS USED IN OPERATIONS (see Appendix)	(26,919)	(28,015)	(22,606)
Income tax paid	(175)	(13)	
Interest received	127	96	59
NET CASH USED IN OPERATING ACTIVITIES	(26,967)	(27,932)	(22,547)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(327)	(240)	(298)
Purchase of intangible assets	(48)	(149)	(77)
Withdrawal of short-term deposits		8,086	881
Investment in short-term deposits			(9,303)
Net cash generated from (used in) investing activities	(375)	7,697	(8,797)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of shares and warrants, net; note 12b	25,525	35,970	53,828
Net cash flows generated from financing activities	25,525	35,970	53,828
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,817)	15,735	22,484
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	42,067	23,926	1,312
GAINS (LOSSES) FROM EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(11)	2,406	130
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF YEAR	40,239	42,067	23,926

MEDIGUS LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS

APPENDIX TO THE STATEMENTS OF CASH FLOWS:

	For the year ended December 31		
	2015	**2014**	**2013**
		NIS in thousands	
NET CASH USED IN OPERATIONS:			
Loss for the year before taxes on income	(36,741)	(22,616)	(5,104)
Adjustment in respect of:			
Profit on change in the fair value of warrants issued to investors	(394)	(3,605)	(11,544)
Losses (gains) from exchange differences on cash and cash equivalents	13	(2,392)	(130)
Retirement benefit obligation, net		51	
Gains on change in the fair value of financial instruments at fair value through profit or loss	(10)	(66)	(278)
Revaluation of and exchange differences on short-term deposits		(13)	349
Interest received	(127)	(96)	(59)
Depreciation	392	448	315
Amortization of intangible assets	81	294	105
Amounts charged in respect of options granted to employees and service providers	450	1,111	511
Amounts carried to capital reserves as a result of transactions with controlling shareholders			138
CHANGES IN OPERATING ASSET AND LIABILITY ITEMS:			
Decrease (increase) in accounts receivable :			
Trade	(479)	(265)	71
Other	(1,645)	(134)	(873)
Increase (decrease) in accounts payable and accruals :			
Trade	604	263	298
Other	2,524	(796)	733
Decrease (increase) in inventory	216	(36)	(538)
Net sales (purchases) of financial assets at fair value through profit or loss	8,197	(163)	(6,600)
NET CASH USED IN OPERATIONS	(26,919)	(28,015)	(22,606)

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

NOTE 1 - GENERAL:

a. Medigus Ltd. (hereinafter – the "Company") together with its subsidiary (hereinafter – the "Group") is a medical device group specializing in research and development of innovative endoscopic procedures and devices. To date most of the Group's research and development activities have been focused in the development of the MUSE endoscopy system (hereinafter - "MUSE") for the treatment of gastroesophageal reflux disease (GERD), which is one of the most common chronic diseases in the western world. In addition, the Group uses the technological platform it developed for the purpose of additional special endoscopy-based systems and products and endeavors to enter into agreements and/or joint ventures with companies in the medical device industry in order to integrate the systems and products it has developed. To date, the MUSE product has not generated significant revenues and most of the Group's revenues arise from sales of miniature cameras and related equipment, which it developed and manufactures and which are used in endoscopic procedures.

In addition, the Company has FDA approval to market the MUSE endoscopy system in the USA, and it continues negotiations to market the main product and sell miniature cameras for endoscopic devices and other endoscopy instruments, which can serve as a source of future revenues.

The Company is a limited liability corporation whose shares are listed for trade 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 for trade on the NASDAQ Capital Market. As of the report date, each ADR represents five ordinary shares of the Company. The Company's depositary agent for the ADR program is The Bank of New York Mellon.

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, 84965.

b. On July 22, 2007 the Company established a wholly owned subsidiary, MEDIGUS USA LLC, in the USA (hereinafter - the "Subsidiary"). The Subsidiary did 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.

NOTE 1 – GENERAL (continued)**:**

c. On May 6, 2015 a special general meeting of the Company's shareholders approved 1:10 reverse share split such that every 10 ordinary shares par value NIS 0.01 of the Company shall be converted into one ordinary share par value NIS 0.10, without changing the rights attached to each share.

In November 2015, the Company effected the 1:10 reverse split of its ordinary shares. Concurrently with the reverse share split, the Company effected a change in the ratio of ordinary shares to each of its ADRs, such that after the reverse share split each ADR represents five ordinary shares (instead of fifty ordinary shares).

The reverse share split reduced the Company's registered share capital to 150 million ordinary shares and the number of outstanding ordinary shares to approximately 32.05 million ordinary shares.

Following the reverse share split, the Company's share option plans and outstanding options and warrants to purchase its ordinary shares were also adjusted to reflect the reverse share split.

d. During the year ended December 31, 2015, the Group had a total comprehensive loss of NIS 37 million. As of December 31, 2015 the Group had accumulated losses of NIS 167 million and a positive working capital of NIS 39 million.

Based on the projected cash flows and its cash balances as of December 31, 2015, the Group'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 these financial statements. As a result, there is substantial doubt about the Group's ability to continue as a going concern.

Management's plans include the continued commercialization of their products, taking cost reduction steps 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, 2015 and 2014 and for each of the three years in the period ended December 31, 2015, 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.

3) The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires the Group's 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 the Group's management.

4) The Group analyzes the expenses recognized in the consolidated statement of loss and other comprehensive loss using a classification method based on the expenses' function.

b. Subsidiary

The Subsidiary is an entity over which the Company has control. The Company controls an entity when the Company is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Company. They are deconsolidated from the date that control ceases. The Subsidiary is fully consolidated.

Inter-company transactions and balances as well as revenues and expenses relating to intercompany transactions have been eliminated.

Accounting policies of the Subsidiary are those of the Group and have been consistently applied.

NOTE 2 -SIGNIFICANT ACCOUNTING POLICIES (continued):

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 New Israel Shekels, which is the Company's functional and presentation currency, and rounded to the nearest thousand. The Subsidiary's functional currency is the US Dollar.

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."

3) Translation of financial statements of the Subsidiary

The results and financial position of the Subsidiary are translated into the presentation currency as follows:

(a) Assets and liabilities for each statement of financial position presented are translated at the closing rate at the date of that statement of financial position, resulting exchange differences are recognized in other comprehensive income (loss).

(b) Income and expenses for each income statement are translated at average rates on the period;

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.

Property and equipment is recognized at cost less accumulated depreciation.

Depreciation on assets is calculated using the straight line method of depreciation, in order to depreciate their cost to residual value over their estimated useful life as follows:

Machinery and equipment	6 – 10 years (primarily 10)
Furniture	7 – 14 years
Computers	3 years

NOTE 2 -SIGNIFICANT ACCOUNTING POLICIES (continued):

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 improvements.

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 (see f. below).

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:

1) 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 these licenses (three years).

Costs related to the maintenance of computer programs are recognized as expenses when incurred.

2) Research and development

Research costs are recognized as an expense when incurred. Development costs incurred in respect of design and testing of new or improved products are recognized as intangible assets only when the following criteria are met:

- It is technically feasible to complete the intangible asset so that it will be available for use;
- Management intends to complete the intangible asset and use or sell it;
- There is an ability to use or sell the intangible asset;
- It can be demonstrated how the intangible asset will generate probable future economic benefits;
- Adequate technical, financial and other resources to complete the development and to use or sell the intangible asset are available; and
- The expenditure attributable to the intangible asset during its development can be reliably measured.

Other development costs that do not meet these criteria are recognized as an expense as incurred. Development costs previously recognized as an expense are not recognized as an asset in a subsequent period. Capitalized development costs are presented as intangible assets, and are amortized from the time when the asset is available for use, meaning when it is in the place and condition intended by management, using the straight line method, over its useful life.

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 statement of financial position date.

g. Government grants

Government grants are recognized at their fair value when there is reasonable assurance that they will be received and the Group will comply with all the attached conditions.

A forgivable loan received from the government is accounted for as a government grant when there is reasonable assurance that the Group will comply with the conditions for forgiveness of the loan.

Government grants relating to costs are deferred and recognized in the income statement on a systematic basis over the period necessary to match them with the costs that they are intended to compensate.

Grants received from the Office of the Chief Scientist in the Ministry of Industry, Trade and Labor (hereinafter - the "Chief Scientist"), as participation in research and development performed by the Company (hereinafter - "Scientist Grants") are classified as "forgivable loans" as set out in International Accounting Standard 20 "Accounting for Government Grants and Disclosing the Government's Assistance" (hereinafter -"IAS 20").

The Chief Scientist grants received are recognized and measured in accordance with IAS 39. If on the date on which the right for the Chief Scientist grant is established (hereafter – "the entitlement date") the Group's management concludes that it is not reasonably assured that the Chief Scientist grant to which entitlement has been established, will not be repaid, the Group recognizes a financial liability on that date, which is accounted for under the provisions of IAS 39 regarding financial liabilities measured at amortized cost. The difference between the received grant and the fair value of the said financial liability at date of initial recognition is treated as a government grant recognized in profit or loss as a reduction of research and development expenses.

In the event that on entitlement date the Group's management concludes that there is reasonable assurance that the Chief Scientist grant which was received will not be repaid, the grant is recorded to income at that date as a reduction of research and development expenses. If in subsequent periods Group's management concludes for the first time that there is no reasonable assurance that the Chief Scientist grant received will not be repaid, the Group recognizes on that date a financial liability against profit or loss. The aforementioned financial liability is accounted for in accordance with the provisions set out in IAS 39 regarding financial liabilities measured at amortized cost.

NOTE 2 -SIGNIFICANT ACCOUNTING POLICIES (continued):

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 carried to income as reduction of research and development expenses.

h. Financial instruments:

1) Classification

The Group classifies its financial assets to the following categories: financial assets at fair value through profit or loss, loans and receivables and financial assets available for sale. The classification depends, among other things, on the purpose for which the financial assets were purchased. The Group's 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) Loans and receivables

Loans and 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 statement of financial position which are classified as non-current assets. The Group's loans and receivables are included in "accounts receivable", "short-term deposits" and "cash and cash equivalents" in the statement of financial position (see also sections j and k below).

c) Available for sale financial assets

Available for sale financial assets are non-derivatives which are not classified in any of the other categories. They are classified as non-current assets, unless management intends to dispose of them within a period of up to 12 months from the date of the statement of financial position, in which case they are classified as current assets.

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 statement of financial position, 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. Loans and 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.

Gains or losses from the changes in fair value of available for sale financial assets are recognized in other comprehensive income, except for impairment losses, and exchange rate gains and losses on available for sale financial assets which constitute monetary assets, until the asset is written off.

When a financial asset available for sale is sold or impaired, the accumulated gain or loss, which was previously recognized in other comprehensive loss, is reclassified from equity to income or loss under "other income, net".

As to methods for measurement of the Company's financial instruments, see note 4.

NOTE 2 -SIGNIFICANT ACCOUNTING POLICIES (continued):

3) Impairment of financial assets

The Group assesses at each date of the statement of financial position whether there is objective evidence that a financial asset or group of financial assets measured at depreciated cost or available for sale 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.

i. 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.

j. 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.

k. 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 maturities of three months or less.

l. 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, except for taxes relating to items carried to other comprehensive income, which are recognized in other comprehensive income.

The amount that was recorded as current taxes, is calculated based on the tax laws that have been enacted or substantively enacted at the date of the report, in countries in which the Company and its subsidiaries 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.

NOTE 2 -SIGNIFICANT ACCOUNTING POLICIES (continued):

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) that have been enacted or substantially enacted by the date of the statement of financial position and are expected to apply when the related deferred tax assets is realized or the deferred tax liabilities will be settled.

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.

m. Employee benefits

1) Retirement benefit obligation

A defined contribution plan is a post-employment employee benefit plan, to which Group companies pay 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 Group's companies, the Group's companies are obligated to pay severance pay to employees who are fired or leave their employment in certain circumstances.

The obligation of Group companies 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.

NOTE 2 -SIGNIFICANT ACCOUNTING POLICIES (continued):

2) Vacation and recreation pay

Under the 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.

n. 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 statement of financial position, 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.

o. Revenue recognition

Group 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.

NOTE 2 -SIGNIFICANT ACCOUNTING POLICIES (continued):

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.

   When multiple-element arrangements exist, the amount of revenue allocated to each element is based upon the relative fair values of the various elements. The fair value of each element is determined based on the current market price of each of the elements when sold separately.

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.

NOTE 2 -SIGNIFICANT ACCOUNTING POLICIES (continued):

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.

p. 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.

q. Loss per share

As a general rule, calculation of the basic 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):

r. 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.

Regarding classification and measurement of financial liabilities, there were no changes compared to existing model in IAS 39, 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 Company is still assessing the impact of IFRS 15.

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. Development costs

Development costs are capitalized according to the accounting policies specified in Note 2e(2). Capitalization of those costs is based on management's judgment that technological and economic feasibility exist, a situation which exists for the most part when a product development project reaches a milestone, or when the Company enters into agreement for the sale of know-how arising from the development. In determining amounts to be capitalized, management makes assumptions in relation to the future cash flows expected from the assets, discount rate to be used and expected benefit period.

To date, the Group did not capitalize significant of development costs.

b. Government grants

As of December 31, 2015 Chief Scientist grants received by the Group and for which there is an obligation to pay royalties totaled approximately – NIS 794 thousand (see also Note 11. 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 (see also Note 2g).

c. 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, 2015. 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 NIS 42 million.

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:

(1) Foreign exchange risk

The Company operates internationally and is exposed to foreign exchange risks due to exposure to foreign currencies, primarily the U.S. Dollar. 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, 2015, if the functional currency of the Company had weakened/strengthened by 10% against the Dollar, with all other variables held constant, the loss for the year would have been lower/higher by NIS 1,201 thousand (2014- NIS 2,184 thousand, 2013- NIS 749 thousand), primarily as a result of foreign exchange gains/losses on cash and cash equivalents.

(2) Price risk

The Group had investments in financial instruments which were traded on the stock exchange, and were classified as financial assets at fair value through profit or loss; the Company was exposed to fluctuations in the price of the security based on stock exchange market prices.

At December 31, 2015 the Group does not hold any of the said investments in financial instruments.

The following table summarizes the changes in fair value of financial instruments which were sensitive to changes in the price of traded securities as of December 31, 2014:

	Profit from changes			Loss from changes	
	10% increase in value	5% increase in value	Fair value December 31, 2014	5% decrease in value	10% decrease in value
	NIS in thousands				
Government bonds	819	409	8,187	(409)	(819)

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (continued):

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 and short-term deposits as of December 31, 2015 and 2014 are held with large established banks with, at least, AA rating. The Group's marketable securities were managed by a portfolio management company. As of December 31, 2014 the Group's securities were comprised solely of short-term government debentures.

Most of the Company's sales are made to a limited number of customers. To reduce the credit risk, the Company generally receives as advance payment a substantial portion of the consideration receivable from the relevant parties.

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.

As of December 31, 2015 the Group had unutilized credit facilities of NIS 50 thousand.

Liquidity risk arises from financial liabilities due to payable balances (except for institutions and advanced payments) and amounted to NIS 4,980 thousand on December 31, 2015 (2014 - NIS 3,377 thousand).

These liabilities are classified as current liabilities, and are expected to mature within 12 months from the date of the statement of financial position.

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (continued):

2) Estimates of fair value

The following is an analysis of the financial instruments measured at fair value, according to valuation methods. The levels are defined as follows:

- Quoted prices (unadjusted) in active markets for identical assets or liabilities (Level 1).
- 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, 2015 and December 31, 2014:

	December 31,				
	2015		2014		
	Level 3	Total	Level 1	Level 3	Total
	NIS in thousands				
Financial assets at fair value through profit or loss -					
financial assets held for trading			8,187		8,187
Financial liabilities at fair value through profit or loss -					
Warrants at fair value	34	34		428	428

a) Financial instruments in level 1

The fair value of financial instruments traded in active markets is based on quoted market prices at the date of the statement of financial position. A market is considered to be active if the quoted prices are readily and regularly available from an exchange, dealer, broker, industry group, pricing service or regulatory agency and those prices represent actual and regularly occurring market transactions on an arm's length basis.

The quoted market price used for financial assets at fair value through profit or loss held by the Group is the current bid price at the time of closing of trade.

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (continued):

b) Financial instruments in level 3

The Company's financial liability at fair value through profit or loss is the obligation for warrants (Orbimed) (see Note 12(b)(1)) and warrants (series E) (see Note 12(b)(3)).

	December 31,					
	2015			2014		
	standard deviation	risk-free interest	fair value (NIS thousands)	standard deviation	risk-free interest	fair value (NIS thousands)
Warrants (Orbimed) (*)	45%	0.001%	-	39%	0.35%	1
Warrants (Series E) (**)	48%	0.4%	34	47%	0.79%	427

(*) 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.

(**) In calculating the value of warrants (Series E) 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 NIS 10 thousand. The higher the standard deviation, the higher the fair value. 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.

The following table presents the changes in Level 3 instruments for the year ended December 31, 2015:

	Warrants
	NIS thousands
Opening balance at January 1	428
Gains recognized in profit or loss	(394)
Closing balance at December 31	34
Total unrealized profits for the period included in profit or loss for liabilities held at the end of the reporting period	394

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, 2014:

	Warrants
Opening balance at January **1**	--
Issue of warrants (see note 12(b)(1))	2,355
Transfer to Level 3	2,317
Gains and losses recognized in profit or loss	(4,244)
Closing balance at December 31	428
Total unrealized profits for the period included in profit or loss for liabilities held at the end of the reporting period	4,244

In 2014, the Group transferred warrants from level 2 to level 3 due to the fact that during the second quarter of 2014 the Company commenced using a standard deviation parameter that was calculated based on historical share prices instead of current standard deviation embedded in the market price of traded warrants.

NOTE 5 - CASH AND CASH EQUIVALENTS:

	As of December 31	
	2015	2014
	NIS in thousands	
Cash in banks	7,073	7,442
Short-term bank deposits	33,166	34,625
	40,239	42,067

The currencies in which the cash and cash equivalents are denominated or to which they are linked are as follows:

	As of December 31	
	2015	2014
	NIS in thousands	
NIS	26,625	18,809
US Dollar	13,372	22,965
Other currencies	242	293
	40,239	42,067

The carrying amount of the cash and cash equivalents approximates their fair value.

NOTE 6 - ACCOUNTS RECEIVABLE:

a. Trade receivables:

	As of December 31, 2015			
	NIS unlinked	Denominated in US Dollars	Denominated in Euro	Total
	NIS in thousands			
Open accounts		754	206	960
Credit cards	32			32
	32	754	206	992

	As of December 31, 2014			
	NIS unlinked	Denominated in US Dollars	Denominated in Euro	Total
	NIS in thousands			
Open accounts		301	180	481
Credit cards	32			32
	32	301	180	513

b. Other receivables:

	As of December 31	
	2015	2014
	NIS in thousands	
Institutions	284	329
Prepaid expenses	3,163*	1,276*
Advances to suppliers	372	127
Receivables	105	
Other		6
	3,924	1,738

* Including NIS 2,546 thousand (December 31, 2014: NIS 716 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. Balances included in respect of monetary items among "trade and other receivables" do not include doubtful accounts.

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 date of the statement of financial position in respect of accounts receivable is the carrying amount of all the aforementioned Group of receivables net of the non-monetary balances (institutions, prepaid expenses and advances to suppliers), amounting to NIS 1,097 thousand (December 31, 2014 - NIS 519 thousand). The Group does not hold any collateral in respect of these balances.

NOTE 7 – INVENTORY:

Composed as follows:

	As of December 31	
	2015	2014
	NIS in thousands	
Raw materials and supplies	775	1,453
Work in progress	77	68
Finished products	335	423
	1,187	1,944

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 2015:

	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	2015	2014
Property and equipment:	NIS in thousands			NIS in thousands			NIS in thousands	
Machinery and equipment	2,635	144	2,779	1,876	299	2,175	604	759
Leasehold improvements	129	53	182	129	11	140	42	
Office furniture and equipment (including computers)	1,365	130	1,495	1,179	82	1,261	234	186
	4,129	327	4,456	3,184	392	3,576	880	945

b. Composition of property and equipment and accumulated depreciation thereon, grouped by major classifications and changes therein, and their movements during 2014:

	Cost			Accumulated Depreciation			Depreciated balance
	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:	NIS in thousands			NIS in thousands			NIS in thousands
Machinery and equipment	2,492	143	2,635	1,530	346	1,876	759
Leasehold improvements	92	37	129	92	37	129	
Office furniture and equipment (including computers)	1,305	60	1,365	1,114	65	1,179	186
	3,889	240	4,129	2,736	448	3,184	945

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.

On December 6, 2011, the Law for the Amendment of the Tax Burden (Legislative Amendments), 2011 was published in the official gazette. Under this law, a previously approved gradual decrease in corporate tax was discontinued and the corporate tax rate was increased to 25% beginning with 2012.

On August 5, 2013, the Law for the Amendment of National Priorities (Legislative Amendments for Achieving the Budgetary Goals for 2013-2014), 2013 (hereinafter - the Law) was published in the official gazette. The Law stipulated, among other things, that the corporate tax rate should be increased to 26.5% (instead of 25%) for 2014 and thereafter. (As to the increase of 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).

On January 4, 2016 the Israeli Parliament approved an amendment for the Israeli tax Ordinance (Number 216), 2016 according to which corporate tax rate will be updated to 25% commencing the tax year 2016.

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):

The Law for Encouragement of Capital Investments was amended as part of the Economic Policy Law for the years 2011 and 2012 (Legislative Amendments), 2011, which was passed in the Knesset on December 29, 2010 (hereinafter – the amendment). The amendment became effective as from January 1, 2011.

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.

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. Tax losses carried forward to future years

Carry forward losses aggregate NIS 168 million and NIS 133 million as of December 31, 2015 and 2014, respectively. The Company did not record deferred taxes for 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 163 thousand as of December 31, 2015 (December 31, 2014- NIS 137 thousand).

f. 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:

	2015	2014	2013
		NIS in thousands	
Loss before taxes on income as reported in the Statements of Loss and Other Comprehensive Loss	(36,741)	(22,616)	(5,104)
Theoretical tax savings	(9,736)	(5,993)	(1,276)
Increase in taxes arising from tax losses created in the reported year for which deferred taxes were not recorded	10,000	6,006	1,361
Taxes on income reported in the Statement of Loss and Other Comprehensive Loss	264	13	85

NOTE 9 -TAXES ON INCOME (continued):

g. Tax assessments

The Company has not received final tax assessments from the date it commenced its operations (January 1, 2000).

On November 19, 2015, the Knesset approved the draft Law for Economic Efficiency (Legislative Amendments to Achieve Budget change Budget 2015 and 2016), nine years - 2015, which is an amendment to the Income Tax Ordinance, extending the period of limitation of tax assessments submitted by taxpayers, regarding tax assessments in respect of the tax year 2013 onwards, for a period of four years from the end of the tax year in which the assessment was submitted, instead of three years.

Accordingly, by law, tax assessments filed by the Company in 2011 are considered final (subject to the submission date of reports and period of limitation under the law).

h. Value Added Tax

The Company is registered as an Authorized Dealer for Value Added Tax purposes.

NOTE 10 - ACCOUNTS PAYABLE AND ACCRUALS:

a. Trade payables are denominated in the following currencies:

	As of December 31	
	2015	2014
	NIS in thousands	
NIS unlinked	716	387
US Dollar	679	184
Euro		220
	1,395	791

b. Other:

	As of December 31	
	2015	2014
	NIS in thousands	
Payroll and related expenses	1,431	619
Wages and fees of related parties and related expenses	639	722
Institutions	716	362
Provision for vacations and recreation pay	710	551
Advanced payments from customers	1,535	275
Accrued expenses	805	694
	5,836	3,223

NOTE 10 - ACCOUNTS PAYABLE AND ACCRUALS (continued)**:**

Other payable balances (except for institutions and advances from customers) are denominated in the following currencies:

	As of December 31	
	2015	2014
	NIS in thousands	
NIS unlinked	2,017	1,335
US Dollar	1,439	1,241
Euro	129	10
	3,585	2,586

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:

a. Development program supported by the Chief Scientist:

1) In 2007 the management of the Generic Technological Research and Development Department in the Israeli Ministry of Industry and Commerce (hereinafter "MAGNET") approved the activities of the consortium of bio-medical photonics (hereinafter- the "Consortium"). The Company was one of the participants of the Consortium.

The Consortium was active from June 2007 until the end of 2012. The consortium was dissolved at the end of 2013.

There is no requirement to repay the grants or pay royalties thereof.

MAGNET grants recognized by the Company during 2013 that were offset against research and development expenses amounted to NIS 181 thousand (see Note 13).

2) On July 12, 2011 the Office of the Chief Scientist of the Ministry of Industry, Trade and Labor informed the Company that it resolved to approve the Company's application for support in a joint project for the development of an innovative small-diameter endoscope used in dental surgery (hereinafter- the "Project").

The Project was carried out during two years from August 2011 until the end of July 2013.

NOTE 11 - COMMITMENTS (continued):

Chief Scientist grants that the Company recognized during 2013 that were offset against research and development expenses amounted to NIS 273 thousand (see Note 13).

In accordance with provisions of the Encouragement of Industrial Research and Development Law - 1984, the Company is required to pay royalties at the rate of 3% to 5% on all of its revenues from the product, up to 100% of the amount of the grant received (approximately NIS 794 thousand) by the Company with the addition of annual interest and linkage (see also note 3 regarding of Government Grants).

Since the commencement of the Project and as of the date of approval of these financial statements, no royalties' payments were required.

In the event of failure to comply with the terms attached to the receipt of the grants, the Company may be required to refund the amount of the grants, in whole or in part, with interest and linkage differences from the date of receipt. In the opinion of Company's management, as of the date of approval of these financial statements, the Company meets all of the said terms.

b. Lease agreements

The Group has lease agreements for buildings it uses. These agreements expire during 2017.

The annual lease fees are linked to the CPI and total approximately NIS 346 thousand as of December 31, 2015.

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	
	2015	2014	2015	2014	2015	2014	2015	2014
	In thousands				NIS in thousands			
Ordinary shares of NIS 0.1 par value*	150,000	50,000	32,047	24,995	15,000	5,000	3,204	2,499

* Traded on the Tel Aviv Stock exchange at NIS 1.753 per ordinary share of NIS 0.1 par value on December 31, 2015.

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 March 3, 2013 the Company allotted to Orbimed Israel Partners Limited Partnership (hereinafter-"Orbimed") 3,994,547 ordinary shares (39,945,474 ordinary shares before reverse split) of the Company and 39,945,474 warrants to purchase 3,994,547 additional ordinary shares (hereinafter- the "Warrants"). Each 10 warrants is exercisable into 1 share. The Warrants are exercisable in return for payment of the exercise price of NIS 9.17 per share during the 18 months following the allotment of the Warrants, and NIS 11.004 per share as from the end of the said 18 months until the end of 36 months following the allotment of the Warrants. The Warrants can also be exercised using a cashless exercise mechanism, in which the number of shares arising from the exercise of the warrant would be reduced by a number of shares, the value of which equals the cash exercise price. The Warrants would be adjusted in respect of certain events as set out in the agreement (e.g. dividend, distribution of bonus shares, etc.).

In accordance with International Accounting Standard 32: "Financial Instruments: Presentation", these Warrants are a "financial liability", which is classified in the statement of financial position as a non-current liability among "warrants at fair value".

The immediate proceeds (gross) from the allotment of all the securities offered amounted to NIS 29,664 thousand (net 29,502 thousand NIS). A total of NIS 13,222 thousand was attributed to the Warrants (Orbimed) representing the fair value thereof on that date and a total of NIS 16,280 thousand (net of issuance expenses), was allocated to the allotted shares.

As to the fair value of the said warrants as of December 31, 2015 and 2014 see note 4(2)(b).

On March 3, 2016 warrants (Orbimed) expired as the exercise period was ended.

NOTE 12 – EQUITY (continued)**:**

2) On October 17, 2013 the Company issued a shelf offering report 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 allotted 344,936 units at the price of NIS 72 per unit. Each unit was comprised of 10 ordinary shares (100 ordinary shares before reverse split) and 50 warrants (Series 8).

Each 10 warrants (Series 8) is exercisable into 1 share in consideration for an exercise price of NIS 10.8 until October 17, 2016.

The immediate proceeds (gross) from the allotment of all securities offered amounted to NIS 24,835 thousand. Net proceeds from the issuance, net of cash issuance expenses, amounted to NIS 24,326 thousand and were attributed to shares (a total of NIS 22,655 thousand) and warrants (a total of NIS 1,671 thousand) in accordance with their relative fair values.

3) On August 21, 2014 and August 26, 2014, the Company allotted in a private issue, a total of 8,527,154 ordinary shares (85,271,536 ordinary shares after reverse split) 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 NIS 39 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 statement of financial position 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.

Of the securities issued 766,311 shares (7,663,109 shares before reverse split) and 3,065,244 warrants (Series E) were issued to OrbiMed Israel Partners Limited Partnership, which is one of the controlling shareholders of the Company.

Net proceeds from the issuance, net of cash issuance expenses, amounted to approximately NIS 36 million.

The fair value of 12,260,974 warrants which were allotted on August 21, 2014 was approximately NIS 1,289 thousand. 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.

NOTE 12 – EQUITY (continued)**:**

The fair value of 21,847,640 warrants which were allotted on August 26, 2014 was approximately NIS 2,429 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 of December 31, 2015 a liability in the amount of NIS 34 thousand (December 31, 2014 - NIS 427 thousand) was presented in respect of the aforementioned warrants, representing their fair value on that date. The decrease in the fair value of the warrants over the period from the allotment date until the date of the statement of financial position 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
	NIS in thousands			
Proceeds gross	35,288	1,258	2,355	38,901
Issuance expenses	(2,830)	(101)	*(189)	(3,120)
Proceeds net	32,458	1,157	2,166	35,781

* The issuance expenses in the amount of NIS 189 thousand which were attributed to the warrants classified as a financial liability were charged directly to profit or loss.

4) 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 (1,000 ordinary shares before reverse split) 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.

NOTE 12 – EQUITY (continued)**:**

Net proceeds from the issuance, net of issuance expenses, amounted to approximately NIS 25.5 million of which a total of NIS 22.7 million were allocated to shares, and a total of NIS 2.8 million to warrants (Series 9) in accordance to the fair value ratios of the instruments.

c. Share based payments:

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, 2015	Number of options exercisable at 31 December 2015	Expiration date
February 2010	Series 6	(*)790,000	(**)2.26	491	90,000	90,000	February 8, 2016
February 2010	Series 6	970,000	(**)2.26	538	480,000	480,000	February 8, 2016
September 2011	Series A	(*)585,000	(**)0.91	279	125,000	125,000	November 2, 2017
November 2011	Series A	1,420,000	(**)0.91	536	935,000	935,000	November 2, 2017
April 2012	Series A	230,000	(**)0.91	117	200,000	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	2,649,999	September 30, 2018
July 2014	Series D	(*)310,000	(**)0.537	56	310,000	77,500	July 17, 2020
July 2014	Series D	3,070,000	(**)0.537	554	2,477,500	707,500	July 17, 2020
December 2015	Series F	(*) 157,500	2.05	116	157,500	0	December 29, 2021
December 2015	Series F	664,800	2.05	491	664,800	0	December 29, 2021
December 2015	Series G	350,000	2.05	259	350,000	0	December 29, 2021
Total		14,197,300			10,459,800	6,034,999	

NOTE 12 - EQUITY (continued)**:**

c. Share based payments: (Continued)

(*) 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.

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.

NOTE 12 - EQUITY (continued)**:**

c. Share based payments: (continued):

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	Expected dividend	Expected volatility	Risk free interest	Vesting conditions	Expected term
October 2013	1,357	0.748	None	46%	2.53%	See above	5 years
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)**:**

c. Share based payments: (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					
	2015		2014		2013	
	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	11,110,000	8.4	9,150,000	10.7	6,683,000	14.6
Granted	1,172,300	2.05	3,380,000	5.37	4,500,000	8.3
Forfeited	(485,833)	15.6	(644,667)	16.1	(622,083)	17.0
Expired	(1,336,667)	6.98	(775,333)	15.9	(1,410,917)	18.3
Outstanding at year end	10,459,800	7.58	11,110,000	8.4	9,150,000	10.7
Exercisable at year end	6,034,999	9.23	3,547,498	11.6	2,683,334	15.3

2) The amounts of expenses that were recorded for options to employees and other service providers in the reported years are NIS 450 thousand, NIS 1,111 thousand and NIS 511 thousand for the years ended December 31, 2015, 2014 and 2013, 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:

	For the year ended December 31		
	2015	**2014**	**2013**
		NIS in thousands	
Payroll and related expenses	17,749	14,429	8,321
Materials used and subcontracted work	8,226	5,459	3,282
Preparation of patents	442	522	427
Depreciation and amortization	473	637	417
Vehicle maintenance	686	677	764
Travel	2,755	2,173	869
Insurance	267	94	131
Advertising and participation in exhibitions	2,513	2,333	1,347
Management fees (see Note 17d.)		888	1,352
Office supplies and printing	283	126	190
Rent and office maintenance	925	1,063	741
Professional fees	4,743	3,343	1,626
Others	450	468	404
	39,512	32,212	19,871
Less- grants and participations from the Chief Scientist, see Note 11			454
TOTAL COST OF REVENUES, ADMINISTRATIVE AND GENERAL, SELLING AND MARKETING AND RESEARCH AND DEVELOPMENT EXPENSES, NET	39,512	32,212	19,417

NOTE 14 - OTHER INCOME, NET:

	For the Year Ended December 31		
	2015	**2014**	**2013**
		NIS in thousands	
In respect of financial assets at fair value through profit or loss:			
Interest income			49
Profit from changes in fair value	10	66	278
	10	66	327
In respect of financial asset available for sale			339
In respect of cancellation of an agreement with a customer (*)		875	
Total	10	941	666

NOTE 14 - OTHER INCOME, NET (continued)**:**

(*) 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 NIS 1,111 thousands) amounting to NIS 370 thousand. In addition, since almost all of the products relating to the remaining additional advance payments received in 2010 and 2011 totaling NIS 875 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 - FINANCING INCOME (EXPENSES), NET:

	For the Year Ended December 31		
	2015	**2014**	**2013**
	NIS in thousands		
Financing income (expenses) in respect of exchange differences	(25)	2,393	(236)
Financing income in respect of deposits	103	120	54
Financing expenses in respect of bank commissions	(127)	(127)	(213)
	(49)	2,386	(395)

NOTE 16 - 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.

	For the year ended December 31		
	2015	**2014**	**2013**
Loss attributed to shareholders (NIS in thousands)	(37,005)	(22,629)	(5,189)
Weighted average of the number of ordinary shares issued (in thousands, adjusted to reverse split)	28,415	19,500	13,020
Basic loss per share (NIS)	(1.3)	(1.2)	(0. 4)

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. The Company has one category of dilutive potential ordinary shares - share options and warrants. 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 17 -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)

	For the year ended December 31		
	2015	**2014**	**2013**
	NIS in thousands		
Preparation of patents	442	522	427
Benefits to related parties:			
Payroll and related expenses to related parties employed by the Company* (3 recipients)	2,778	3,338	1,120
Compensation to directors not employed by the Company (2015: 3 recipients, 2014: 4 recipients, 2013: 9 recipients,)	226	219	270
Management fees to a related party (see B, D and E following)		1,017	1,459
Compensation to a director employed by the Company	52	43	46
Directors' insurance	186	74	47

* Includes an amount of NIS 274 thousand (2014: NIS 725 thousand, 2013: NIS 210 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. The said amount does not include amounts charged in 2013 to the capital reserve as described in section d below.

NOTE 17 -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:

	For the year ended December 31		
	2015	**2014**	**2013**
	NIS in thousands		
For employment services:			
Payroll and other short-term benefits	*1,768	1,871	813
Management fees (see B, D and E following)			1,439
Post-retirement benefits			51
Share based payments	241	685	195
	2,009	2,556	2,498

*Including provision for bonus of NIS 337 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 $ 52,855, and which includes a deductible of up to $35,000 per claim, other than such claims related to extraordinary events such as securities related claims (other than claims filed in the United States or Canada), for which the deductible shall not exceed $100,000, claims filed in the United States or Canada, for which the deductible shall not exceed $35,000, or securities related claims filed in the United States or Canada, for which the deductible shall not exceed $100,000.

b. Balances with related parties:

	As of December 31	
	2015	**2014**
	NIS in thousands	
Current liabilities-presented in the statements of financial position among "trade and other payables")	639	722

c. As to options granted to related parties, see Note 12 C.

NOTE 17 -TRANSACTIONS AND BALANCES WITH RELATED PARTIES (continued):

d. Change in the employment terms of related parties

On March 3, 2013 the Company received notices from DLLD Consulting Ltd. (through Dr. Elazar Sonnenschein, the Company's CEO at that time and one of its controlling shareholders), from the Company's R&D director and one of its controlling shareholders, and from the Company's medical director and one of its controlling shareholders, requesting that the Company cancel the reduction of fees and salaries (where relevant) paid to the above controlling shareholders, with effect from the date of issuance of the notice. In light of the above, the fees and the salaries paid to the above controlling shareholders were increased.

Amounts relating to waiver of salaries by controlling shareholders during the reporting periods were credited to capital reserve from transactions with controlling shareholders against payroll expenses.

e. Kfir Luzzatto and Esther Luzzatto provide patents and trademarks preparation and registration services to the Company through Luzzatto and Luzzatto Patent Attorneys (General Partnership), whose partners are Kfir Luzzatto and Esther Luzzatto, directly and/or indirectly, and through Alandal Ltd., that to the best knowledge of the Company is under the ownership and control of Kfir Luzzatto and/or Esther Luzzatto. In accordance with an agreement between the Company and Luzzatto and Luzzatto Patent Attorneys of February 27, 2007, the fee paid by the Company to Luzzatto and Luzzatto Patent Attorneys amounts to USD 125 (plus V.A.T.) per hour invested by a patent attorney partner, patent writer, attorney, engineer, or technical professional, and USD 60 (plus VAT) per hour invested by a technical draftsman. The fee is paid in NIS and is linked to the representative exchange rate of the USD with trade credit terms of Net 60. In addition, Luzzatto and Luzzatto Patent Attorneys is to be reimbursed for its expenses against invoices or actual payment vouchers, including payment to patent attorneys abroad and fees to patent registration offices. It should be noted that the above agreement does not specify the engagement period or the conditions for termination thereof.

On March 24, 2014 and March 27, 2014 the audit committee and the board of directors, respectively, re-approved the terms of the agreement described above, for an additional period of three years in accordance with Amendment No. 16 of the Israeli Companies Law.

NOTE 18 – Entity level disclosures:

a. TheChief Operation Decision Maker ("CODM") decided to no longer evaluate separately the performance of theVisual segment and the MUSE segment, but rather evaluates the performance of all operations together. The CODM allocates resources and evaluates activities on a Group-wide basis and no longer receives information on a disaggregated basis. As such, the Group has only one operating segment.

b. Revenues by product:

	For the year ended December 31		
	2015	**2014**	**2013**
		NIS in thousands	
Miniature camera and related equipment	2,160	2,336	2,451
MUSE and related equipment	256	328	47
	2,416	2,664	2,498

c. Revenues by geographical area (based on the location of customers):

	For the year ended December 31		
	2015	**2014**	**2013**
		NIS in thousands	
USA	1,730	1,645	1,631
Japan	126	358	362
Others	560	661	505
	2,416	2,664	2,498

d. All of the Group's long-lived assets are located in Israel**.**

e. 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):

	For the year ended December 31		
	2015	**2014**	**2013**
		NIS in thousands	
Customer A	1,020		323
Customer B		169	536
Customer C (see also Note 14)		370	185
Customer D		443	

NOTE 19 - POST BALANCE SHEET EVENTS:

a. On March 3, 2016 the Shareholders' Undertaking with Orbimed and warrants (Orbimed) were expired, see note 12(b)(1) and note 17.

b. On February 9, 2016 570,000 options (Series 6) expired as the exercise period was ended.

c. During January-March 2016, 62,500 options (Series D) forfeited and 37,500 options (Series D) and 24,800 options (Series F) expired, due to the termination of employment of several employees.

d. On March 16, 2016, a former Company secretary and internal legal advisor (the "Employee") issued a notice letter to the Company. The letter notes a number of claims, among which is that the Employee was wrongfully terminated. At this early stage and based on the advice of its legal counsels, the Company's management cannot assess the outcome of these proceedings. Accordingly, no provision has been recorded in the financial statements.

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 to OrbiMed in connection with the January 2013 Share Purchase Agreement.(1)
2.3	Form of Ordinary Shares Purchase Warrant issued in connection with the June 2014 Securities Purchase Agreements to non-Israeli investors. (1)
2.4	Form of Ordinary Shares Purchase Warrant issued in connection with the June 2014 Securities Purchase Agreements to Israeli investors (other than Migdal). (1)
2.5	Form of Ordinary Shares Purchase Warrant issued in connection with the June 2014 Securities Purchase Agreements to Migdal. (1) ∞
4.1	Share Purchase Agreement between Medigus Ltd. and OrbiMed Israel Partners Limited Partnership dated January 3, 2013. (1)
4.2	Securities Purchase Agreement by and among Medigus Ltd. and OrbiMed Israel Partners Limited Partnership dated June 29, 2014. (1)
4.3	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)
4.4	Securities Purchase Agreement by and among Medigus Ltd. and Capital Point Ltd. dated June 29, 2014. (1)
4.5	Securities Purchase Agreement by and among Medigus Ltd. and Migdal Insurance Company Ltd. dated June 29, 2014. (1) ∞
4.6	2013 Share Option and Incentive Plan. (1)
4.7	Series 4 Option Plan. (1) ∞
4.8	Series 6 Option Plan. (1) ∞
4.9	Series A Option Plan. (1) ∞
4.10	Series B Option Plan. (1) ∞
4.11	Compensation Policy of Medigus Ltd. (2)
4.12	Lease Agreement between Medigus USA LLC and Regus Plc dated December 4, 2013. (1)
4.13	Lease Agreement between Medigus Ltd. and Sky-City Office Center for HiTech Industries Ltd. dated June 15, 2014. (1) ∞
4.14	Lease Agreement Tefen Yazamut Ltd. regarding main offices in Omer Industrial Park dated December 10, 2013. (1) ∞
4.15	Form of Indemnification and Exculpation Undertaking. (1)
8.1	List of Subsidiaries. (1)
12.1	Certification of Chief Executive Officer as required by rule 13a-14(a). (2)
12.2	Certification of Chief Financial Officer as required by rule 13a-14(a). (2)
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. (2)
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. (2)
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.(2)

(1) Previously filed with the Securities and Exchange Commission on May 7, 2015, pursuant to a registration statement on Form 20-F (File No 001-37381) and incorporated by reference herein.
(2) 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/ Gilad Mamlok
Gilad Mamlok
Chief Financial Officer

Date: March, 30, 2016

Exhibit 4.11

Executives & Directors Compensation Policy of Medigus Ltd. (the "Company")

1. Objectives of the Company's Compensation Policy

The purpose of the Company's compensation policy is to establish sustainable guidelines for the Company's applicable organs in determining the Company's compensation to its Office Holders' (as such term is defined below) in light of the following objectives of such compensation:

A. To establish a correlation between the interests of the Company's Office Holders and those of the Company and its shareholders.

B. To recruit and maintain qualified Office Holders, who may contribute to the Company's financial and commercial success, given the unique challenges it faces and its business environment.

C. To provide incentives for the Company's Office Holders, in order to ensure high-level operations without encouraging the taking of unreasonable risks.

D. To establish an appropriate balance between fixed compensation, compensation which incentivizes short-term results and compensation which reflects the Company's long-term operation.

2. Compensation Policy; Background

Objectives

Through this document, the Company will determine and publish its policy with regards to the compensation of its Office Holders, including all components of compensation, while establishing principles, considerations, parameters and rules for the determination of Office Holders' terms of tenure by the Company's organs during the application period of this compensation policy. The policy is presented to the Company's General Meeting of shareholders and subject to their approval, thereby providing an opportunity for shareholders - and particularly for those shareholders who are not controlling shareholders in the Company - to influence the method used to determine the compensation of Office Holders, and to express their opinion on the matter. The publication of the compensation policy increases and improves the effectiveness of the Company's disclosure to its investors and to the capital market. In addition to the foregoing, the compensation policy is intended to comply with the obligation set forth in Chapter 4A of Part VI of the Israeli Companies Law, 5759-1999 (hereinafter: the "**Companies Law**").

Application of the Compensation Policy

In accordance with the provisions of the Companies Law, the compensation policy will apply with respect to the terms and conditions of the tenure and employment of the Office Holders in the Company. The definition of **Office Holders** in the Companies Law includes "*a general manager, chief business manager, deputy general manager, vice general manager, any person filling any of these positions in a company even if he holds a different title, as well as a director, or a manager directly subordinate to the general manager.*" For the purpose of this policy, each Office Holder other than a director shall be referred to as an "**Executive**".

The compensation policy is not intended to establish personal terms and conditions for specific Office Holders, but rather to set forth objective principles and parameters which will apply to all Company's Office Holders. This policy sets forth maximum amounts only, and nothing in this policy shall obligate the Company to grant any particular type or amount of compensation to any Office Holder, unless expressly stated otherwise, nor shall it derogate from approval procedures mandated by law.

In accordance with the provisions of the Companies Law, the compensation policy is subject to approval every three years. Therefore, the current compensation policy shall be valid for a period of three years from the date of its approval by the General Meeting or as otherwise required by the Companies Law. The Company may, pursuant to the Companies Law, amend or renew the compensation policy within that initial period of implementation, subject to an approval at the General Meeting or as otherwise required by the Companies Law.

It should be noted that, by law, contractual agreements with Office Holders regarding the terms and conditions of their tenure and employment which were approved prior to the approval of the compensation policy adopted in September 2013 shall continue to apply, and do not require additional approval in accordance with the provisions of the policy, subject to the dates and restrictions provided regarding this subject in the Companies Law.

Establishment and Approval of the Compensation Policy

In accordance with the Companies Law, the responsibility for the determination of the compensation policy applies to the Board of Directors, after the foregoing has considered the recommendation issued by the Company's Compensation Committee. The compensation policy is subject to the approval of the General Meeting (including by a majority of those participants who are not controlling shareholders or interested parties, as provided in the Companies Law). In accordance with the provisions of the Companies Law, in the event that the General Meeting does not approve the policy, the Board of Directors will be entitled to approve the policy based on grounds provided by the Board of Directors and the Compensation Committee, according to which the foregoing action is taken in the Company's best interest.

Maintenance of the Compensation Policy

The holder of the most senior position in the Company in the field of human resources (as of the adoption of this policy - the Chief Financial Officer) under the supervision of the Company's Compensation Committee, is responsible for monitoring any changes in the Company, in its business environment, in the capital market, in the labor markets, and in other relevant factors, which may impact the Company's considerations regarding the determination of compensation for Office Holders. When applicable, the Compensation Committee shall convene to discuss the foregoing, and where necessary, present its recommendations for necessary updates to the policy to the Company's Board of Directors.

3. Characteristics of the Company and of Its Office Holders

Business Environment and Its Effect on Office Holders' Compensation

As a public company engaged in the research, development and marketing of endoscopy based medical devices, the Company has two objectives: providing its clients efficient and safe systems, and maximizing its revenues for the benefit of its shareholders.

The Company is a medical device company specializing in developing minimally invasive endosurgical tools and highly innovative imaging solutions. Further information regarding the Company's business activity may be found in the Company's filings with the Securities and Exchange Commission ("SEC").

For fulfilling the Company's objectives, the Company has established, and may be required to establish further operation centers outside of Israel and has appointed, and may be required to appoint Office Holders to serve in such centers. In light of the disparities between acceptable compensation levels and competitive market in Israel and other countries, the quantitative parameters for the determination of executive compensation are separately addressed regarding Israel and other countries.

In light of this, the Company's commercial success depends, to a large extent, both on its ability to recruit skilled Office Holders and employees with unique background and experience in the field of medical devices, and on its ability to provide its Office Holders and employees with incentives designated for the investment of outstanding personal efforts on their behalf and for achievement of goals established by the Company's Board of Directors. The need to achieve defined regulation and commercialization milestones emphasizes the necessity in conditioning parts of certain Office Holders' compensation upon personal achievements.

Description of Office Holders' Positions

A description of the positions and responsibilities of the Company's office holders to whom this policy may apply may be found in the Company's annual reports filed with the SEC.

4. Compensation Components and the Balance between them

General

An adequate balance between the components of compensation exists when a linkage is maintained between compensation and the creation of value for the Company's shareholders, while maintaining the Company's ability to recruit and maintain talented Office Holders and incentivizing them to pursue the Company's objectives. In particular, an appropriate balance between the fixed component and the variable components avoids excessively emphasizing one component, since excessively emphasizing the fixed component may result lack of initiative, whereas excessively emphasizing the variable component may encourage the taking of uncontrolled, unreasonable risks by Office Holders in a manner which is not for the Company's benefit or which does not conform with the Company's objectives.

Compensation Components

Fixed Compensation

Base salary is a fixed amount paid to an Executive on a monthly basis, regardless of the Executive's performance. This component constitutes the basis for payment of some of the additional benefits (as further elaborated below). Payment of the base salary enables the implementation of flexible and effective incentive plans, while minimizing risk-taking caused by over-compensation on variable components' basis. Both the base salary and the additional benefits must also take into account the prevailing conditions in the Company's market ("benchmarking"); however, the Company does not believe this consideration to be dominant, *inter alia* in the interest of avoiding a "salary race" between companies in its market. It should be noted that additional benefits are unique and depend upon the prevailing customs in different countries, and that when the Company engages employment agreements with Executives for positions outside of Israel, such Executives may be entitled to receive additional benefits according to the prevailing customs in the countries in which they serve, in order to ensure the competitiveness of the employment terms and conditions offered by the Company relative to its competitors in the relevant country.

Variable Compensation

Cash variable compensation is one of the components used for achieving the objectives of this compensation policy herein, and particularly for creating a correlation between the interests of the Company's Executives and those of the Company and its shareholders. In order to promote the objectives of this policy herein, the conditions for the payment of bonuses shall reflect the Company's short-term and long-term objectives, insofar as possible, and shall constitute a proportionate part of the total compensation in a manner that constitutes a dominant component in the entire compensation package, and primarily with respect to the fixed salary component, while not constitute an excessively large portion of such compensation package, in order not to create incentives for taking uncontrolled or unreasonable personal and organizational risks. In order to create incentives for Executives to achieve their goals, the variable compensation shall be determined in a manner that links the payment of compensation to short-term and long-term performance objectives. Although it is common practice to pay bonuses upon achievement of financial goals, the Company's objectives for the payment of bonuses may be dependent upon other measurable achievements, such as achieving regulatory milestones, receiving various authorizations, executing agreements, etc. as well as non-measurable "qualitative" achievements. Dependency of bonuses upon achievement of non-financial achievement is relevant to a large extent given the Company's transitional stage between being a research and development company and a commercial one.

Equity-based compensation is used to link between the Company's value for its shareholders (which is reflected by the increase of the Company's price per share) and the compensation of its Office Holders. This component is implemented by one of, or a mix of, equity compensation such as options, restricted stock units (RSUs), restricted shares and other equity-based compensation. Equity-based compensation constitutes an incentive over time, as well as an incentive to be employed by the Company over long periods of time, by setting vesting dates for the granted equity awards, by their expiration pursuant to the termination of the relevant office holder's tenure, and by conditioning the grant or vesting of equity awards (or portions thereof) on the achievement of objectives. Furthermore, accelerated vesting mechanisms may create incentives for Office Holders to remain employed by the Company and to achieve its objectives even if an extraordinary event, such as the merger or sale of the Company, change of control, or termination of employment in certain circumstances, is expected. Equity-based compensation is an important component in this compensation policy herein, since it is common practice in comparative companies and is important to the Company's ability to recruit and retain Office Holders, it is an efficient substitute for cash compensation, and is especially appropriate since some of the operations which are crucial for the Company's success are long-term ones, and some of the Company's Office Holders' efforts may only bear fruit over long periods of time.

Compensation paid upon the termination of tenure is used both as an incentive to recruit talented Executives by reducing their exposure upon terminations of their service due to various circumstances, as well as an incentive for Executives to serve in the Company for long periods of time, should the compensation be dependent upon seniority.

5. Considerations and Parameters for the Determination of Compensation

General Considerations for the Determination of Executive's Compensation

When determining the compensation of an Executive, the Company's Board of Directors, compensation committee and management shall comply with the guidelines stipulated by this policy herein, including regarding the cap on the compensation components and the quantitative parameters which have been determined in this section below, and will also consider the following factors (in addition to any other relevant factor):

The Executive's personal data, including his education, skills, expertise, and professional experience and achievements, whether in the Company or in other companies, as well as his uniqueness in the market; for this purpose, it should be noted that the medical devices market requires employment of Executives who hold unique experience and expertise, including experience working with regulatory entities such as the FDA, experience in conducting clinical experiments, experience in marketing medical devices to customers such as hospitals, and managing engagements for the purpose of medical reimbursement outside of Israel;

The Executive's position, characteristics, responsibilities, efforts required for success in the position, the extent to which such Executive is essential for the Company's success, the possibility to recruit a replacer for his position, the potential damage to the Company in the event the Executive is dismissed or resigns, his seniority and previous compensation arrangements with the Company;

The Executive's residential address and address of service – if the Executive resides in a country in which the prevailing compensation in the relevant market for his position is higher than its equivalent in Israel or in which the living conditions are more difficult or easy than the ones in Israel, the compensation (including any fringe benefits) shall be adjusted to take into account all such differences.

Prevailing salary levels for similar positions in the market – in order to ensure the Company is competitive and recruits appropriate and high-quality personnel, it must offer a salary at a level which corresponds with the prevailing salary in its market. The foregoing is particularly relevant to the medical devices market, which requires unique experience and skills, available by a limited number of office holders. The Company's market includes medical device companies, and particularly such companies which received material regulatory approvals and are focusing their efforts in commercializing their respective products worldwide; public companies whose market value, the nature of their operations or their revenue, is similar to those of the Company; and companies which primarily operate in the United States and in Europe, and which employ Executives serving and operating in these areas.

The ratio between Executive's compensation cost and the Salary Cost of other Company's employees (including the Company's Contract Employees), and particularly the ratio between the compensation cost of the foregoing Executives and the average and the median Salary Costs of employees and the effect such ratios have on the working relations in the Company[1]; the Company acknowledges it has to pay different levels of compensation to its various employees and Executives, *inter alia* for the purpose of recruiting talented and experienced Executives and employees who constitute key personnel for the achievement of the Company's objectives. It should be noted that where Executives reside and serve in such countries in which higher compensation than the one available in Israel is paid in accordance with customary market terms, the Company shall consider such higher compensation levels in its evaluation of the above ratios.

Reduction or cancellation or suspension of payment of variable components is in the Board of Directors' discretion, in cases where such reduction or cancellation or suspension of payment is deemed necessary by the Board of Directors at its absolute discretion. In addition, the Board of Directors may set a maximal exercise value of variable components which are not exercised in cash.

Establishment of Base Salary and Fringe Benefits

The base salary shall be negotiated by the Company and the relevant Executive prior to his appointment for office, and upon the Company's periodic evaluation of his base salary - during his tenure. The base salary shall be based upon the parameters specified above, provided that the base salary shall not deviate from the pre-determined cap for such Executive, as further elaborated below.

In addition to the base salary, the Company may include the following fringe benefits as well as other benefits, provided that such benefits, including the following will be in accordance with applicable law and common practice in the market from time to time: (i) allocations to pension and/or insurance funds and/or education funds (Keren Hishtalmut); (ii) directors' and officers' insurance, including loss of working capacity insurance; (iii) reimbursement for employment of service related expenses; (iv) company vehicle (type of vehicle will be determined according to the Executive's position), including reimbursement of all related expenses, and tax payments incurred in connection with the vehicle as shall be in effect from time to time (or, alternatively, reimbursement of expenses in private vehicle, which shall not exceed the cost of company vehicle and all related costs; (v) internet, laptop computer, cellular telephone for personal use, home phone expenses and daily newspaper; (vi) accommodation during employment or service related travels; (vii) mandatory allocations such as recuperation pay (*Dmei Havra'a*); and (viii) office holders' indemnification and exemption of liability in accordance with the Companies Law, the Company's Articles of Association and the Company's policy from time to time. Executives' number of vacation days will be determined in accordance with any applicable law in consideration with his seniority in the market. An Executive may be entitled to vacation days (or redemption thereof), in correlation with the Executive's seniority and position in the Company (generally up to 28 days annually), subject to the minimum vacation day's requirements per country of employment as well as the local national holidays. The Company may redeem unused vacation days, provided that such redemption is not prohibited in accordance with any applicable law.

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[1] "**Contract Employees**" shall mean employees of a Manpower Contractor of whom the Company is, in practice, the employer, and employees of a Service Contractor who are hired by the Company for the provision of services; for this purpose, the meaning of "**Manpower Contractor**" and "**Service Contractor**" are as defined in the Engagement of Employees by Manpower Contractors Law, 5756-1996. For the purposes of this Section herein, "**Salary Cost**" shall mean any payment paid for employment including employer contributions, retirement payments, vehicle and related expenses, and any other benefit or payment.

Executives who serve outside of Israel (including such Executives who serve in the Company's U.S. subsidiary or in such other subsidiaries which may exist from time to time) may be entitled to fringe benefits in accordance with applicable custom and practice in their country of service and for Executives of similar rank; Accordingly, Executives serving in the United States will be entitled, in addition to the base salary, to medical and dental insurance coverage for the Executive and his immediate family, which shall be paid by the Company, as well as employer's allocations for 401(k) funds, as well as similar or parallel benefits as customary in other global locations.

It should be noted that the amounts detailed below with respect to range of salaries, reflect the gross base salary only, and do not constitute the overall employer costs which include such fringe benefits as detailed above.

Directors' and Officers' Liability Insurance

The Company may provide its directors and officers, including those serving in any of its 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 the Company's profits, properties and undertakings. The coverage limit shall be of up to USD 20 million per occurrence and for the insurance period (additional coverage for legal expenses not included), provided that the annual premium shall not exceed USD 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 USD 50,000 per occurrence.

The Company may provide its directors and officers a liability insurance which includes an insurance coverage extensions with respect to the implementation of the ADR (American Depository Receipts) plan and/or issuance of shares or ADRs or other securities to be traded at an Israeli stock exchange or outside of Israel (including in the U.S. and including public offering which was not carried out).

The policy shall cover the directors and officers liability with respect to claims filed in Israel and outside of Israel, worldwide in accordance with international law and jurisdictions.

The policy will cover also civil actions against the Company (in distinction to claims against the directors and officers which are covered in accordance with the insurance policy) with respect to the purchase or sale of the Company's securities traded at the TASE and/or at the NASDAQ (Entity Coverage).

Payment priorities for insurance payments were set under this extension according to which the office holders' entitlement to receive payments from the insurers precedes the entitlement of the Company.

In addition, the Company may provide such directors and officers with insurance policies for: (i) expenses incurred in connection with administrative enforcement proceedings under Chapters 8-C, 8-D or 9-1 of the Israeli Securities Law, 5728-1968 (hereinafter: the "**Securities Law**"), or under Chapter 4 of part 9 of the Companies Law, including reasonable legal counseling fees; (ii) payments to a party due to a violation, as stipulated by Section 52LIV(a)(1)(a) of the Securities Law.

The policy terms shall be identical to all officers and directors (including officers and directors who are controlling shareholders of the Company and/or officer holders of the Company's controlling shareholders, from time to time, or their relatives or to whom the controlling shareholders may have personal interest).

Where a "claims made" policy regarding coverage for past events cannot be renewed or extended and/or in an event of a change of control or other circumstance which terminates the existing policy, the Company may procure run-off policies for the directors and officers serving prior to said change, including directors and officers who are controlling shareholders of the Company.

Establishment of Performance-Related Cash Variable Compensation

The Company shall establish parameters and conditions for the payment of bonuses, including maximum bonus amounts and the maximum multiplier of monthly base salaries such bonuses may include, on an annual, or multi annual, basis and threshold conditions for payment.

Eligibility for cash variable compensation shall be based upon measurable criteria, which may include financial results (such as revenue, profit or fund raising targets) and milestones such as regulatory approvals, agreement executions (such as licenses or distribution or collaboration agreements), performance of medical procedures and other business millstones (such as number of procedures or MD training). Up to 75% of such measurable objectives will be based on company-wide performance and up to 25% of such measurable objectives will be based on personal performance. Additionally, a non-material portion of the performance-related variable component (for avoidance of doubt up to 3 base salaries shall be considered a non material portion) of the performance related variable compensation amount per year) may be based on the assessment of the relevant Executive's superior (and in the case of the CEO – by the chairman of the Board of Directors) or on the Executive's contribution to the Company during the year in question and to the extent permissible pursuant to the Companies Law, the Company may increase the portion of bonus which is based on non measurable criteria up to the maximum portion permissible pursuant to the Companies Law, but not more than 50%.

In the event of a new hired Executive or of an Executive who's engagement ends during the year, his entitlement to a cash bonus will be determined on a pro rata basis. The Company may also determine threshold conditions which, unless met, will not result in payment of any bonuses.

At the end of each year, the Company shall evaluate the rate of objectives met during the preceding year. In the event that an Executive met all of his pre-determined objectives, such Executive shall be entitled to receive 100% of his performance-related compensation component, and in the case of a partial achievement of such objectives, or of some of the objectives, the Company shall pay a proportional part of such maximum component, provided that the applicable threshold conditions for payment were also met.

In connection with its disclosure of executive compensation under Item 6.B of the annual report on Form 20-F, the Company shall disclose the rate of objectives (per category of objections) that was met during the preceding year.

In addition to the annual bonuses specified above, the Compensation Committee and the Board of Directors may, from time to time and to the extent they deem it is required, approve payment of special bonus for an office holder either under special circumstances, or for special contributions, achievements or assignments. Such special bonuses shall be limited up to six (6) monthly base salaries per Executive per year. The Company considers payment of such special bonuses as an important tool for providing incentives for its Executives, especially in light of the inability to foresee all the specific grounds for payment of bonuses pursuant to the principles set forth in this compensation policy herein. Special and signing bonuses will not be included in the calculation of the maximum annual bonus as set forth below.

Signing bonus or retention bonus may also be granted for the purpose of attracting high quality personnel provided that such bonus shall be limited up to three (3) monthly base salaries per Executive or equivalent value in equity grant.

Change of control payment: change of control events, such as mergers and acquisitions, may expose the Company and its Executives to a great deal of uncertainty. By providing its Executives with compensation in events of change of control, the Company reduces to some extent the personal uncertainty of its Executives, and thus promotes full and impartial consideration of change of control opportunities. In light of the above, the Company may provide, in addition to any discretionary termination payments as set forth below, for the payment of up to six (6) monthly base salaries to Executives.

The payment of variable compensation shall be subject to the provision of a written undertaking by the Executive receiving such variable compensation to repay any amount of such variable compensation paid to him based on data which has later been found to be incorrect, and which has been restated in the Company's financial statements within a period of three years following the grant of such performance related compensation. The Compensation Committee and the Board of Directors shall be authorized not seek recovery to the extent that (i) to do so would be unreasonable or impracticable or (ii) there is low likelihood of success under governing law versus the cost and effort involved; the aforementioned undertaking shall be in accordance with any general claw-back policy as may be adopted by the Company.

Establishment of Equity-based compensation

Equity-based compensation is an effective tool, designated for the creation of incentives for Office Holders, which correspond with the long-term objectives of the Company and its shareholders. Stock options are currently appropriate key equity based compensation vehicle. In the future, the Company may offer various types of equity based compensation vehicles (e.g. restricted shares, restricted share units, phantom shares, performance shares, performance share units, etc.) as well as a mix between such vehicles. When determining the types of equity- based vehicles and the mix between them, if any, the Company will consider among other things, the types of equity awards then available to the Company and the balance between aligning officer's and shareholder's interests and the Company's risk management policy at the time.

To the extent legally available and applicable, the Company will grant options to its Israeli residents Officer Holders in accordance with Section 102 of the Israeli Income Tax Ordinance [New Version], 5721-1961 and/or means of other equity-based compensation, which may promote the Company's objectives, as determined by the Board of Directors. Office holder receiving such equity-based compensation shall bear any applicable tax.

(Reference to "**options**" in this compensation policy shall also include other means of equity-based compensation which may be provided in the future.)

Grant of options shall be in accordance with and subject to the terms of the Company's current or future applicable equity-based compensation plans, and when granting options to office holders, the Company shall set the following conditions

Maximum Grant Date Value of Options Granted to Each Office Holder – such value will be subject to the cap on equity grants, as further elaborated below, and will be based on the Black and Scholes Model (or such other applicable models).

Maximum Dilution Rate of the Company's Share Capital – the maximum dilution rate may not exceed 10% of the Company's share capital.

Vesting / Minimum Holding Period – options granted will vest over periods ranging from once a month to once a year, and will become fully vested over several years (e.g., 2-4 years) but no less than two years from the date of grant. The company may set accelerated vesting terms and conditional vesting terms for the options granted.

Conditional Vesting / Objective Dependent Exercise – the Company will consider adoption of conditional vesting and/or objective dependent exercise of options, in consideration of the Office Holder's position. Notwithstanding the aforementioned, the Company is not obligated under this compensation policy to condition the grant or exercise of options granted upon the achievement of personal or Company objectives. Such objectives may be identical to, or different from, the objectives set by the Company for the payment of bonuses and may be adjusted, when applicable, following major acquisitions, divesture, organizational changes or material changes in the Company's business environment. To the extent that options' vesting is conditioned upon the achievement of objectives, the Company may determine that such options will become fully vested upon the achievement of the relevant objective, rather than by the lapse of vesting periods.

Exercise Price for stock options – will be set as an incentive to maximize the Company's value, and will be equal to, or higher than, the price per share in the stock exchange determined by the compensation committee, or will be equal to the average price per share during a pre-determined period prior to the grant approval date as determined by the Board of Directors or the date of grant.

Cap on Base Salary and Salary Components

The cap on the variable compensation components and parameters regarding maximum base salary and annual bonus rates are specified below.

It should be noted that: (1) the base salary maximum rates refer to provision of services on a 100% basis and consist of only the (gross) base salary, excluding any fringe benefits available under this compensation policy; (2) the annual bonus cap refers to the target annual bonus to be granted upon achievement of 100% of the objectives for payment of such annual bonus; and (3) in the case of equity-based compensation, the cap refers to the value of the options granted (or of other means of such compensation) as of the date of grant based on the Black and Scholes Model (or such other applicable model) per year of vesting (taking into account the cost of previous vesting grant for that year).

It should further be noted that if an Executive (or a company controlled by him) receives fees for the provision of services in his position as an Executive, which will be made in lieu of a salary and associated benefits – then the portion of such fee that comprises the equivalent of a base salary shall be deemed to be such Executive's base salary for the purposes of this compensation policy herein, including for the determination of the cap on compensation components.

Non-Executive Directors

The Company's non-executive directors (including external directors) may be compensated by means of a periodic payment, and by means of payment for participation in Board (or committees) meetings, up to the amounts set forth in the Companies Regulations (Rules Concerning Compensation and Expenses for an External Director), 5760-2000 and in the Companies Regulations (Reliefs for Companies whose Shares are Registered for Trading on an Exchange Outside of Israel (the "**Compensation Regulations**"), as amended from time to time. Such Directors may also be entitled to receive equity-based compensation in accordance with any applicable law, but will not be entitled to receive performance-based compensation, such as bonuses, as well as fringe benefits. The Company may repay Director's expenses in accordance with any applicable law. The compensation of external directors (including equity based compensation) may be determined relative to that of "other directors", as defined in the Compensation Regulations.

The caps on each of the non executive Directors' compensation components are as follows:

Variable Equity-based Compensation	Annual Bonus
up to 75% of the periodic payment (i.e., the annual fee) as described above	Not Applicable

CEO

CEO's base salary (excluding fringe benefits) shall range between the following amounts:

CEO whose position is primarily in Israel: up to NIS 100,000, per month.

CEO whose position is primarily in the United States or Europe[2]: up to NIS 150,000, per month.

The cap on the CEO's compensation components emphasizes variable components, as the CEO serves as the Company's most senior manager.

The cap on the CEO's variable compensation components is as follows:

Maximum Number of Monthly Salaries for Variable Equity-based Compensation	Maximum Number of Monthly Salaries for Annual Bonus
5	6

Other Executives

Other Executive's base salary (excluding fringe benefits) whose position is primarily in Israel shall range up to NIS 70,000, per month.

Other Executive's whose position is primarily in the United States or Europe: up to NIS 100,000, per month.

The cap on other Executive's variable compensation components is as follows:

Maximum Number of Monthly Salaries for Variable Equity-based Compensation	Maximum Number of Monthly Salaries for Annual Bonus
4	6 (to Executive whose position is primarily in Israel) 6 (to Executive whose position is primarily in the United States or Europe)

Termination of Services; Severance Bonus

Executives shall be entitled to an advance notice period in accordance with existing agreements and in the absence of provisions in the agreements, as determined by the law. In any event, the advance notice period shall not exceed 6 months; during said notice period, Executives will be required to continue to fulfill their duties, unless the Company decides to release them from this obligation.

In addition to payments required under any applicable law, local practices, vesting of outstanding options, transfer or release of pension funds, manager's insurance policies etc., and severance bonus may be included in office holder's employment agreement, or may be paid upon Executive's severance, subject to receipt of all required approvals.

[2] For the purposes of this compensation policy herein, the NIS-USD and NIS-EURO exchange rates shall be as follwos: NIS 4 = USD 1; NIS 4.8 = EURO 1.

The Company will consider payment of a severance bonus in consideration of the objectives of this compensation policy herein, as well as: (i) the service period of the Executive in question; (ii) the Executive's terms and conditions of service; (iii) the Company's operations during Executive's service; (iv) the Executive's contribution to the achievement of the Company's objectives and to its profitability; and (v) the circumstances of the severance.

The maximum severance bonus is as follows:

Directors who do not hold other positions in the Company will not be eligible for severance bonus.

CEO/General Manager may be entitled to a severance bonus of up to six (6) monthly salaries.

Other Executives may be entitled to a severance bonus of up to three (3) monthly salaries.

(Executive's severance bonus will be based on his last monthly salary as of the termination date of his service).

The Executive's termination of service must not be in circumstances which, in the Company's opinion, justify severance pay to be revoked.

It is clarified that the severance bonus as set forth above shall not include statutory severance pay.

Others

Relocation Compensation may be granted to an Executive under relocation circumstances. Such benefits may include reimbursement for out of pocket one time payments and other ongoing expenses, such as travel, housing allowance, car or transportation allowance, home leave visit, healthcare, participation in children tuition fees etc., all as reasonable and customary for the relocated country and as approved by the Compensation Committee and Board of Directors.

General

The Company's Compensation Committee and Board of Directors shall be authorized to approve a deviation of up to 10% from any limits, caps or standards detailed in this policy, and such deviation shall be deemed to be in alignment with this policy.

ADOPTED: _____

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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15 (e)) for the 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) 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

   (c) 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; and

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, 2016

By: /s/ Christopher (Chris) Rowland
Christopher (Chris) Rowland, Chief Executive Officer

Exhibit 12.2

CERTIFICATION

I, Gilad Mamlok, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15 (e)) for the 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) 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

   (c) 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; and

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, 2016

By: /s/ Gilad Mamlok
Gilad Mamlok, 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. the Annual Report on Form 20-F for the year ended December 31, 2015 (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, 2016

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. the Annual Report on Form 20-F for the year ended December 31, 2015 (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, 2016

By: /s/ Gilad Mamlok
Gilad Mamlok
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 Statement on Form S-8 (No. 333-206803) of Medigus Ltd. (the "Company"), of our report dated March 30, 2016 relating to the financial statements, which appears in this Form 20-F.

Tel Aviv, Israel
March 30, 2016

/s/ Kesselman & Kesselman,
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited