As filed with the Securities Exchange Commission on March 7, 2013

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, 2012

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: 000-33133

GIVEN IMAGING LTD.
(Exact Name of Registrant as Specified in Its Charter)

Israel
(Jurisdiction of Incorporation or Organization)

Hermon Building, New Industrial Park
Yoqneam 20692, Israel
(Address of Principal Executive Offices)

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Fax: +972 (4) 959 2466
Hermon Building, New Industrial Park
Yoqneam 20692, Israel
(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 Each Class	Name of Each Exchange on Which Registered
Ordinary Shares, par value NIS 0.05 per share	Nasdaq Global Select Market

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

The number of outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2012:

31,080,876 Ordinary Shares, par value NIS 0.05 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 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. (Check one):

Large Accelerated Filer ☐ Accelerated Filer ☒ Non Accelerated Filer ☐

Indicate by check mark which 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 ☒

GIVEN IMAGING LTD.

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TRADEMARK DISCLAIMER

GIVEN, GIVEN & Design, PILLCAM, PILLCAM & Logo, PILLCAM EXPRESS, RAPID, RAPID ACCESS, FINGERS HOLDING A CAPSULE & Logo, ICCE, ICCE Logos, International Conference on Capsule Endoscopy, BRAVO, BRAVO PH SYSTEM, ENDONETICS, VUESPAN, VERSAFLEX, GEROFLEX, REPHLUX TRACER, ION, GASTROTRAC, BILITEC, DIGITRAPPER, PHERSAFLEX, MANOSCAN, MANOSHIELD, MANOVIEW, ACCUTRAC, ACCUVIEW, POLYGRAF ID, SMARTPILL, MOTILIGI, SMARTBAR, and THE MEASURE OF GI HEALTH are trademarks and/or registered trademarks of Given Imaging Ltd. its subsidiaries and/or affiliates in the United States and/or other countries. All other company or product names are the trademarks or registered trademarks of their respective holders. All rights not expressly granted are reserved.

CERTAIN DEFINITIONS

As used in this Annual Report, unless the context otherwise requires: the terms "Given," the "Company," "we," "us," "our" and "our company" refer to Given Imaging Ltd. and its subsidiaries; the terms "U.S. dollars," "dollars" or "$" refer to United States dollars; the terms "Shekel" or "NIS" refer to the New Israeli Shekel, the legal tender currency of the State of Israel.

CAUTIONARY LANGUAGE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 20-F contains forward-looking statements within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. We have based these forward-looking statements on our current expectations and projections about future events. These statements include but are not limited to:

- the adequacy of our cash balances and cash flow from operations to support our operations or future growth, in general or for specified periods of time;
- statements as to the potential or expected acceptance of our current and future products by the medical community, particularly gastroenterologists;
- statements as to expected increases in sales, operating results and certain expenses, including research and development and sales and marketing expenses;
- statements as to anticipated reimbursement from U.S. and non-U.S. third-party payors for our products;
- statements as to a possible sale, merger or change in control of our company;
- expectations as to the development of our products and technology, and the timing of enhancements to our products and new product launches;
- expectations as to the market opportunities for our products, as well as our ability to take advantage of those opportunities;
- expectations as to the timing, results and content of future clinical studies and publications;
- statements regarding the expected benefits from acquisitions;
- statements as to the expected outcome of legal and patent proceedings in which we are involved;
- statements as to the expectation for the content of future publications regarding our products;
- expectations as to the receipt and timing of regulatory clearances and approvals, and the anticipated timing of sales of our products in new markets or for new indications;
- estimates of the impact of changes in currency exchange rates on our operating results;
- expectations as to the adequacy of our inventory of critical components and finished products;
- expectations as to the adequacy of our manufacturing facilities; and
- statements as to our expected treatment under Israeli and U.S. federal tax legislation and the impact that new tax and corporate legislation may have on our operations.

In addition, forward-looking statements may be, but are not necessarily, identified by the use of forward-looking terminology such as "will," "may," "anticipates," "estimates," "expects," "intends," "plans," "believes," and words and terms of similar substance. Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual events, results, performance, circumstances or achievements of the Company to be materially different from any future events, results, performance, circumstances or achievements expressed or implied by such forward-looking statements. Factors that could cause actual events, results, performance, circumstances or achievements to differ from such forward-looking statements include, but are not limited to, the following: (1) our ability to develop and bring to market new products, (2) our ability to successfully complete any necessary or required clinical studies with our products and to provide evidence of the clinical and economic effectiveness of our products, (3) our ability to receive regulatory clearance or approval to market our products or changes in regulatory environment, (4) our success in implementing our sales, marketing and manufacturing plans, (5) quality issues and adverse events related to our products, such as capsule retention or aspiration, failure to attach or detach, bleeding or perforation, which could require us to recall our products and impact our sales and net income, (6) continuous supply of certain product or system components by third party suppliers, (7) the level of adoption of our products by medical practitioners, (8) the emergence of other products that may make our products obsolete, (9) lack of an appropriate bowel preparation materials to be used with our PillCam COLON capsule, (10) protection and validity of patents and other intellectual property rights, (11) the impact of currency exchange rates, (12) the effect of competition by other companies, (13) the outcome of significant litigation, (14) the availability of reimbursement or other forms of funding for our products from government and commercial payors, (15) quarterly variations in operating results, (16) the possibility of armed conflict or civil or military unrest in Israel, (17) the impact of macro-economic and market conditions in our main markets, (18) our ability to successfully integrate acquired businesses, (19) changes and reforms in applicable healthcare laws and regulations, (20) the outcome of our exploration of strategic alternatives and the terms on which any such strategic alternatives are pursued or the sale of a significant stake in our Company by our largest shareholders, and (21) other risks and factors disclosed in our filings with the U.S. Securities and Exchange Commission, including, but not limited to, risks and factors identified under such headings as "Risk Factors," "Cautionary Language Regarding Forward-Looking Statements" and "Operating and Financial Review and Prospects" in this Annual Report on Form 20-F for the year ended December 31, 2012. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report. Except to the extent of the Company's obligations under the applicable securities laws, it undertakes no obligation to release publicly any revisions to any forward-looking statements, to report events or to report the occurrence of unanticipated events.

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

Selected Financial Data

The selected consolidated statements of income data for the years ended December 31, 2012, 2011 and 2010, and the selected consolidated balance sheet data as of December 31, 2012 and 2011, have been derived from our audited consolidated financial statements set forth elsewhere in this Form 20-F. These financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. The selected consolidated statements of income data for the years ended December 31, 2009 and 2008, and the selected consolidated balance sheet data as of December 31, 2010, 2009 and 2008, have been derived from our audited consolidated financial statements not included in this Form 20-F, which have been prepared in accordance with U.S. GAAP. You should read the selected consolidated financial information set forth below in conjunction with our audited consolidated financial statements and the related notes as well as Item 5 — "Operating and Financial Review and Prospects" included elsewhere in this Annual Report on Form 20-F.

	Year Ended December 31,				
	2012	2011	2010	2009	2008
	(In Thousands, Except Share and per Share Data)				
Statements of Income Data:					
Revenues	$ 180,501	$ 177,955	$ 157,809	$ 141,763	$ 125,108
Cost of revenues	(42,971)	(41,466)	(37,629)	(33,145)	(33,001)
Gross profit	137,530	136,489	120,180	108,618	92,107
Operating expenses:					
Research and development, gross	(25,627)	(26,129)	(21,695)	(17,842)	(15,126)
In-process research and development acquired in a business combination	—	—	—	—	(4,700)
Government grants	1,439	1,113	1,477	1,109	1,530
Research and development, net	(24,188)	(25,016)	(20,218)	(16,733)	(18,296)
Sales and marketing	(76,272)	(75,014)	(67,114)	(61,428)	(60,902)
General and administrative	(22,746)	(23,078)	(25,138)	(18,919)	(19,320)
Termination of marketing agreement	—	—	—	—	5,443
Other, net	(455)	(397)	(759)	(1,220)	(867)
Total operating expenses	(123,661)	(123,505)	(113,229)	(98,300)	(93,942)
Operating profit (loss)	13,869	12,984	6,951	10,318	(1,835)
Financial income, net	847	1,343	2,599	1,584	4,004
Profit before taxes on income	14,716	14,327	9,550	11,902	2,169
Income tax benefit (expense)	(459)	(2,158)	(1,362)	1,542	(250)
Net profit	14,257	12,169	8,188	13,444	1,919
Net loss (profit) attributable to non-controlling interest	93	(191)	290	891	2,087
Net profit attributable to shareholders	$ 14,350	$ 11,978	$ 8,478	$ 14,335	$ 4,006
Net change in respect of available For sale securities	1,151	(980)	(304)	999	(600)
Total comprehensive profit attributable to shareholders	$ 15,501	$ 10,998	$ 8,174	$ 15,334	$ 3,406
Total comprehensive profit (loss) attributable to non-controlling interest	$ (93)	$ 191	$ (290)	$ (891)	$ (2,087)
Total comprehensive profit	$ 15,408	$ 11,189	$ 7,884	$ 14,443	$ 1,319
Basic Earnings attributed to shareholders per Ordinary Share	$ 0.47	$ 0.40	$ 0.29	$ 0.49	$ 0.14
Diluted Earnings attributed to shareholders per ordinary share	$ 0.45	$ 0.39	$ 0.28	$ 0.47	$ 0.13
Weighted average number of ordinary shares used in computing basic earnings per ordinary share	30,853,581	30,212,787	29,670,842	29,281,297	29,254,035
Weighted average number of ordinary shares used in computing diluted earnings per ordinary share	31,563,208	31,089,499	30,525,654	30,423,162	30,798,360

	As of December 31,				
	2012	2011	2010	2009	2008
			(In Thousands)		
Balance Sheet Data:					
Cash and cash equivalents	$ 35,442	$ 24,285	$ 34,619	$ 46,458	$ 31,697
Short term investments	58,446	64,762	51,973	31,736	28,509
Working capital	122,282	116,613	105,339	100,586	85,154
Long term marketable securities	30,188	16,003	3,873	16,956	30,063
Total assets	274,314	248,265	222,200	185,720	177,915
Long-term liabilities	14,552	13,202	13,266	5,886	5,084
Total liabilities	51,366	50,340	49,412	33,114	31,751
Retained earnings (Accumulated deficit) (1)	1,621	(12,729)	(24,707)	(33,185)	(31,721)
Total shareholders' equity	$ 222,948	$ 197,634	$ 172,688	$ 151,928	$ 144,171

(1) In March 2009 we paid a dividend of approximately $15.8 million.

Exchange rate information

The following table lists the high and low exchange rate of New Israeli Shekel to one U.S. dollar for the periods indicated as reported by the Bank of Israel:

Most Recent Six Months	High	Low
February 2013	NIS 3.733	NIS 3.663
January 2013	3.791	3.714
December 2012	3.835	3.726
November 2012	3.952	3.810
October 2012	3.895	3.792
September 2012	4.029	3.887

The following table lists the average exchange rate of New Israeli Shekel to one U.S. dollar for the periods indicated, as reported by the Bank of Israel, calculated based on the average of the exchange rates on the last day of each month during the period:

Year	Average Exchange Rate
2012	NIS 3.856
2011	3.714
2010	3.732
2009	3.927
2008	3.563

On February 28, 2013, the exchange ratio of NIS to U.S. dollar was NIS 3.708 to $1.00.

RISK FACTORS

We face a number of risks that may adversely affect our business, financial condition and operating results. The risks described below are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

If we are unable to manufacture, market or sell any of our main products, our revenue growth and profitability could be materially adversely affected.

A substantial portion of our revenues to date has resulted from sales of the PillCam SB capsule and to a lesser extent from sales of the Bravo system and our high resolution manometry products. We expect that a majority of our revenues for the foreseeable future will continue to come from sales of the PillCam SB capsule. Sales of the PillCam SB capsule contributed $116.6 million, or 65%, of our revenues in 2012, $117.6 million, or 66%, of our revenues in 2011, and $110.2 million, or 70%, of our revenues in 2010. If we are unable to manufacture, market or sell any of our main products, and PillCam SB in particular, for any reason, including, for example, product recall, natural disaster, unavailability of components, hostilities in Israel or as a result of a legal action against us, our revenue growth and profitability could be materially adversely affected. For discussion on our disaster preparedness, see Item 4 —"Information on the Company — Manufacturing — Manufacturing Facilities and Disaster-Preparedness."

Our future growth depends in part on our ability to market the PillCam SB capsule for additional indications other than obscure gastrointestinal bleeding.

To date, the PillCam SB capsule, which accounts for a significant majority of our revenues, has been used primarily for detection of obscure gastrointestinal bleeding, or OGIB. Our ability to expand the use and increase utilization of the PillCam SB capsule for the detection and monitoring of additional small bowel abnormalities, such as Crohn's disease, depends substantially on our ability to provide clinical evidence and economic analysis supporting such expanded use, our ability to educate and train our customers on these expanded use opportunities and our ability to obtain favorable and effective reimbursement coverage for the PillCam SB capsule for small bowel indications beyond OGIB. If we are unable to expand the use of the PillCam SB capsule beyond OGIB, sales of the PillCam SB capsule may decline or may not increase.

If we are unable to expand reimbursement coverage from third-party payors for procedures using our products, or if reimbursement is insufficient to create an economic benefit for purchasing or using our products when compared to alternative procedures, demand for our products may decline or may not grow.

Demand for our products depends significantly on the eligibility of the procedures performed using our products for reimbursement through government-sponsored healthcare payment systems and private third-party payors. Reimbursement practices vary significantly from country to country and within some countries, by region or state, and we must obtain reimbursement approvals on a country-by-country and/or region-by-region basis. In general, the process of obtaining reimbursement coverage approvals has been longer outside of the United States. Historically, we have experienced higher sales in territories in which we have received reimbursement coverage for our products and in territories in which health authorities and regulators approved the marketing or use of our products. We may not be able to obtain further approvals in a timely manner or at all and existing reimbursement coverage policies may be revised from time to time outside of our control by third-party payors. If physicians, hospitals and other healthcare providers are unable to obtain sufficient coverage and reimbursement from third-party payors for procedures using our products, or if reimbursement is, or is perceived by our customers to be, insufficient to create an economic incentive for purchasing or using our products or does not adequately compensate physicians and health care providers compared to the other procedures they offer, demand for our products may decline or may not grow.

If we are unable to market and sell our PillCam COLON capsule, we may miss a significant market opportunity and our revenue growth could be materially adversely affected.

We do not have regulatory clearance to market and sell PillCam COLON in the United States or Japan, two of our largest markets, and to date we have had only limited sales of our PillCam COLON capsule, primarily in countries relying on the CE mark certification system. There can be no assurance that we will be able to receive clearance from the United States Food and Drug Administration, or FDA, or the approval of the Japanese Ministry of Health, Labor and Welfare, or MHLW, for PillCam COLON in the foreseeable future or at all or that the PillCam COLON will be accepted as comparable or superior to existing technologies for visualization of the colon. In addition, any regulatory clearance or approval may be limited to specific indications only and may be more limited than the clearances or approvals for which we applied. Our ability to market and sell the PillCam COLON successfully depends on one or more of the following:

- Our ability to develop and introduce new technologies that will improve the clinical effectiveness of the PillCam COLON capsule.
- Receipt of FDA marketing clearance in the United States or regulatory approvals in other large markets such as Japan.
- The existence of clinical data sufficient to support the use of the PillCam COLON for visualization of the colon as compared to other colon visualization methods. Physicians may be reluctant to use this product without supportive clinical data and literature.
- The time it takes the physician to read the video captured by the PillCam COLON capsule.
- The level of professional education and hands-on training of medical staff in performing the PillCam COLON procedure and reading and interpreting the images captured by the capsule, since the procedure and the reading are different than what many medical staff is used to with colonoscopy.
- The availability of sufficient clinical and cost-effectiveness data for physicians to use PillCam COLON in their practice, for the American Medical Association, or AMA, to provide a favorable permanent "current procedural terminology," or CPT, code and for private third-party payors to make an adequate reimbursement decision to provide coverage for the PillCam COLON procedure.
- The availability of a reliable colon cleansing and preparation procedure for the PillCam COLON capsule that is accepted by physicians and patients.
- The absence of other safe and effective colon cancer diagnostic or screening products, which, if brought to market by third parties, could make the PillCam COLON capsule obsolete.

If we are unable to achieve one or more of the above, we may not be able to market and sell the PillCam COLON capsule and our revenue growth could be materially adversely affected.

If we are unable to establish a robust, high volume manufacturing process for PillCam COLON before obtaining regulatory clearance in the United States and/or Japan, we may be unable to meet demand for this product.

To date, we have been manufacturing our PillCam COLON capsule in a semi-automated manufacturing process, which is sufficient to meet the current demand for this product that is not yet cleared for marketing in the large markets of the United States and Japan. This capsule includes several components that are based on new technologies and are difficult to manufacture and some are being supplied to us by single source suppliers. If we are unable to develop or purchase manufacturing equipment, expand the number of suppliers for components of the PillCam COLON capsule or establish a robust, high volume manufacturing process for this capsule, we may be unable to meet demand for this capsule when demand increases, as we expect, if we are able to obtain regulatory clearances in the United States and/or Japan.

If we are unable to complete additional acquisitions or grow acquired businesses, our revenue growth could be materially adversely affected.

In the last few years our revenue growth has been largely due to acquisitions, primarily the April 2010 acquisition of Sierra Scientific Instruments LLC, now known as Given Imaging (Los Angeles) LLC, and the 2008 acquisition of the Bravo business. In October 2012, we acquired substantially all of the assets of The Smart Pill Corporation, and we expect such assets to generate several million additional dollars in revenue in 2013. At the same time, our revenues from sales of capsule endoscopy equipment have not grown in the manner we had expected. If we are unable to complete additional acquisitions or grow acquired businesses, our revenue growth could be materially adversely affected.

Acquisitions, launches of new products and other factors may have a material adverse effect on our gross margins and profitability.

The principal factors affecting our gross margins are the volume of sales of our products, the sale prices, the product mix and the percentage of our sales made as direct sales. Our average gross margins over the last three fiscal years were 76.4%. Our gross margins in 2012 were 76.2%, compared to 76.7% in 2011 and 76.2% in 2010. There is no assurance we will be able to maintain or increase our gross margins. Our gross margins may be materially adversely affected if we acquire products having lower gross margins than our current products, if we launch a new product having lower gross margins than our existing products, if we reduce our prices due to promotional activities, competition or otherwise, or if our productivity declines for any reason. If our gross margins decline, our profitability may be adversely affected.

We may lose market share and our revenues and gross margins may be negatively affected due to competition.

Olympus Corporation has a competing capsule endoscopy system for the small bowel, which it is selling in the United States, Europe, Japan, Australia and other countries. In addition, other companies are selling capsule endoscopy systems for the small bowel in Europe, Asia and Australia and possibly other countries and may be selling these systems at a lower price than ours. We also have a number of competitors in and outside the United States in the field of manometry and pH measurement. If we are unable to compete effectively in the marketplace, we may lose market share, experience delays in completing sales as a result of a longer decision making process among potential customers, or experience erosion of our gross margins as a result of price pressure.

We face competition from large, well-established manufacturers of traditional technologies for detecting gastrointestinal disorders, as well as from gastrointestinal products in general which compete for the limited capital expenditure budgets of customers.

Competition for our capsule endoscopy products also comes from traditional technologies for detecting gastrointestinal disorders and diseases, such as traditional endoscopy and radiological imaging. The principal manufacturers of gastrointestinal endoscopes are Olympus, Hoya, and Fuji Film. The principal manufacturers of equipment for radiological imaging are General Electric Healthcare Systems, Siemens Medical Solutions, Philips Medical Systems Ltd. and Toshiba Corporation. These companies have substantially greater financial resources than we do, and they have established reputations as well as research and development resources and capabilities and worldwide distribution channels for medical instruments to physicians. If we are unable to convince physicians to adopt our capsule endoscopy products over technologies developed and marketed by our competitors, our results of operations may suffer.

In addition to competition from products performing similar clinical functions to our products, there is also competition for the limited capital expenditure budgets of customers. Another capital equipment item for gastroenterology may compete with our products for the same capital budget, which is typically limited, and therefore the potential purchaser may be required to choose between the two items of capital equipment. If we are unable to market our products more effectively than other products which could be purchased using the same budget, we may be unable to maintain our current growth rate.

Because of the importance of our patent portfolio to our business, we may lose market share to our competitors if we fail to protect our intellectual property.

Protection of our intellectual property is key to our future success. We rely on patent protection, as well as a combination of copyright, trade secret, design and trademark laws, nondisclosure and confidentiality agreements and other contractual restrictions to protect our proprietary technology. However, these legal means afford only limited protection in terms of duration, geographic scope or otherwise, and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, our patent portfolio in the United States is more robust than in other jurisdictions. Currently, many of our patent applications are still pending and we will be able to use them to protect our technology against potential competitors only after they are issued. The process of issuing a patent may sometimes be lengthy and may not always result in issued patents in a form that will be advantageous to us or at all. Our patents and applications cover particular aspects of our products and technology and may be challenged, invalidated or circumvented by third parties. For more information regarding third party challenges to our patents see in Item 4- Information on the Company- Business Overview- Intellectual Property. There may be other effective technologies, designs or methods relating to capsule endoscopy. If other effective methods are not covered by our patents or applications and our competitors are able to commercialize products using these methods, it could have an adverse effect on our sales. In addition, our competitors or other parties may obtain patents that will prevent us from using technologies, designs or methods we would like to integrate into our products. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by former employees. The laws and judicial systems of foreign countries may not protect or enable enforcement of our intellectual property rights to the same extent as the laws of the United States or at all. If we do not adequately protect our intellectual property, our competitors or other parties could make products similar to ours and compete more efficiently with us, which could result in a decrease in our market share.

Because the medical device industry is litigious, we are susceptible to intellectual property suits that could cause us to incur substantial costs or pay substantial damages or prohibit us from selling our products.

There is a substantial amount of litigation over patent and other intellectual property rights in the medical device industry. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. While we have attempted to ensure that our products do not infringe other parties' valid patents and proprietary rights, searches typically performed to identify potentially infringed patents of third parties are not always conclusive and, because patent applications can take many years to issue, there may be applications now pending, which may later result in issued patents which our current or future products may infringe. In addition, our competitors or other parties may assert that our product and the methods it employs may be covered by patents held by them. If our products infringe a valid patent, we could be prevented from manufacturing or selling them unless we can obtain a license or redesign the product to avoid infringement. A license may not always be available or may require us to pay substantial royalties. We also may not be successful in any attempt to redesign our product to avoid any infringement. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate and can divert management's attention from operating our business.

If we are unable to successfully manage the introduction of new or improved products into the market, our operating results may be negatively affected.

We frequently introduce new products or significant improvements to existing components of our products. Newer products or system components may not be able to support and work with older product versions. In order for as many of our customers as possible to utilize our most advanced technology, we need to manage new product introductions and installations efficiently, addressing concerns of customers regarding product upgrade costs, time constraints and training and education in light of possible short product life cycles. If we are unable to cause our customers to use the most advanced technology available or effectively address compatibility issues between older and newer products, we may harm our competitive position and our sales may be negatively affected. In addition, failure to successfully manage the transition to newer products may result in obsolete inventory of older products, which we may be required to write off.

Changes in legislation and government regulation of the healthcare industry, as well as third-party payors' efforts to control the costs of healthcare, could materially adversely affect our business.

In response to perceived increases in health care costs in recent years, there have been and continue to be proposals by the federal government, state governments, regulators, and third-party payors to control these costs and, more generally, to reform the U.S. health care system. This legislation may, among other things, reduce Medicare provider reimbursement rates, introduce and/or pilot various new patient care and payment models and base reimbursement policies and rates on clinical outcomes and the comparative effectiveness and costs of different treatment technologies and modalities. In particular, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010. The legislation imposes significant new taxes on medical device makers in the form of a 2.3% excise tax on all U.S. medical device sales beginning in 2013. This significant increase in the tax burden on our industry could have a material, adverse impact on our results of operations and our cash flows. In addition, as part of the implementation of the various parts of these laws, there is a work instruction issued by the federal government due to take effect in the second quarter of 2013 that will limit physicians' ability to receive payment for services and procedures that are performed partly in an Ambulatory Surgical Center, or ASC, and partly in the physician's office. If this work instruction does not change, it may directly affect physicians' ability to get full reimbursement for the placement of Bravo pH monitoring at ASCs and could negatively impact sales of this product in the U.S. The adoption of significant changes to the healthcare system in the United States 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.

If we are unable to introduce new capsules and products for use in the gastrointestinal tract, our growth may be negatively affected.

Our objective is to expand the use of our capsule endoscopy and other products for a variety of indications. We intend to continue developing and introducing new capsules and products. There can be no assurance that we will be able to develop new products that will enjoy widespread market acceptance as superior offerings to existing technologies for detection of abnormalities in other parts of the gastrointestinal tract or that can be used in other parts of the gastrointestinal tract. In addition, we may be required to obtain FDA clearance in the United States and other regulatory approvals outside of the United States before commercially distributing our existing products for use in parts of the gastrointestinal tract for which they are not indicated, or introducing new products for use in the gastrointestinal tract. These regulatory processes can be lengthy and expensive and we cannot be sure that FDA clearance or other regulatory approvals will be granted. In order to obtain FDA clearance and other regulatory approvals, and to obtain reimbursement coverage for use of new products, we may be required to conduct additional clinical trials to demonstrate the diagnostic and cost-effectiveness of these new products. If future clinical trials indicate that new products are not as clinically-effective or cost-effective as current methods, or that they may cause unexpected complications or other unforeseen negative effects, we may not obtain regulatory clearance to market and sell these new products or obtain reimbursement coverage, and our growth could be adversely affected.

Any disruption to our operations or market in the United States, the primary market for our products, may result in a material reduction in our revenues and negatively affect our operating results.

Since our inception, most of our revenues have been generated from sales in the United States. Sales in the United States accounted for $109.5 million, or 61%, of our revenues in 2012, $104.6 million, or 59%, of our revenues in 2011, and $97 million, or 61%, of our revenues in 2010. Any disruption to our operations or market in the United States resulting from changes in management or the sales team of our U.S. subsidiary, adverse changes in reimbursement policies, new regulatory requirements, macro-economic changes and other events, many of which are outside our control, may result in a material reduction in our revenues and negatively affect our operating results.

If we are unable to successfully market and sell our products in China or Japan, significant potential growth opportunities for us in those countries may be materially and adversely affected.

We sell our products in Japan through a combination of our own sales force and local distributors and in China through local distributors. Our ability to increase penetration into the Japanese and Chinese markets and grow our business depends significantly on our relationship with our distributors, our ability to expand indications for the use of our products and our ability to obtain regulatory clearance for additional products other than PillCam SB. Finally, our main competitor in the field of capsule endoscopy is based in Japan and competition in the Asia-Pacific region is intense. If we are unable to successfully market and sell our products in China and Japan for any of the foregoing or other reasons, significant potential growth opportunities for us in those countries may be materially and adversely affected.

We are subject to extensive regulation by the FDA, including quality regulations, which could restrict the sale and marketing of our products and could cause us to incur significant costs.

FDA regulations may require us to submit for clearance improvements and modifications of our products, including new or improved PillCam capsules and new or improved RAPID software versions, before we are allowed to market them in the United States. FDA regulations also prohibit us from promoting or advertising our cleared products for uses not within the scope of our clearances or making unsupported safety and effectiveness claims. Noncompliance with applicable regulatory requirements can result in enforcement action which may include recalling products, ceasing product marketing, paying significant fines and penalties, and similar FDA actions which could limit product sales or delay or halt product shipment. Additionally, if we are unable to receive FDA clearance for new or improved products, such as PillCam COLON, the marketing and sale of these products will be delayed or cancelled, which in turn may materially and adversely affect our growth potential. Changes in existing regulatory requirements or adoption of new requirements may make it more difficult or prevent us from obtaining marketing clearance for our products in the United States and could materially and adversely affect our financial condition and results of operations.

We are required to adhere to the FDA's Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. The FDA also requires us to adhere to the Quality System Regulation, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging and shipping of our products. The FDA enforces the Quality System Regulation through inspections. Our quality system is also subject to the Medical Devices Directive of the European Union requiring compliance with the International Standard Organization's standards ISO 13485:2003. We also must comply with quality and safety regulations in other countries, such as Japan and Canada. If we fail a Quality System Regulation inspection by the FDA or a similar inspection by any other regulator, our operations could be disrupted and our manufacturing delayed. Failure of the Quality System Regulation inspection or other similar inspection could result in a shutdown of our manufacturing operations and a recall of our products, which would have a material adverse effect on our product sales, financial condition and results of operations.

If we fail to meet safety and quality requirements we may incur significant costs to recall our products from the market, lose market share and damage our reputation.

As a manufacturer of medical devices, our products are subject to safety and quality regulations. These regulations require us to report to regulatory bodies events where our products may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. Irrespective of an injury to any person, if we fail to meet these safety and quality requirements, we may need to recall our products from the market, or make changes to our products or shutdown our manufacturing operations, which in turn will result in losing market share, lower revenues and earnings and damage to our reputation. For details regarding recalls of our Bravo product in January and February 2012, see Item 5 – "Operating and Financial Review and Prospects - Operating Results – Revenues – Esophageal Manometry and pH Monitoring Products."

We may be materially adversely affected by the imposition and enforcement of environmental laws and regulations.

We are subject to legislation and regulation by government agencies responsible for environmental and health laws and policies in the jurisdictions in which we conduct our operations. For example, our research and development and manufacturing processes involve the handling of potentially harmful hazardous materials, and we are subject to laws and regulations governing the use, handling, storage and disposal of these materials under European Directive 2011/65/EU, known as RoSH. In addition, we are required to comply with European Union Directive 2012/19/EC, entitled Waste Electrical and Electronic Equipment (WEEE), EC No 1907/2006, entitled Registration Evaluation Authorization of Chemicals (REACH) and the European Directive 2006/66/EC, entitled Batteries and Accumulators and Waste Batteries.

If we are found to have violated environmental laws or regulations, whether as a result of human error, equipment failure or other causes, we could be held liable for damages, penalties and costs of remedial actions which could materially adversely affect our business, financial condition and results of operations. Changes in these laws and regulations, or changes in their enforcement, could also adversely impact us by increasing our cost of compliance or operations. In addition, new laws or additional regulations, or more stringent interpretations of existing laws or regulations, could require us to spend additional funds on related matters in order to stay in compliance, thus increasing our costs and having an adverse effect on our results. We may also be banned from selling non-compliant products in certain jurisdictions, which could adversely affect our financial results.

If we or our distributors do not obtain and maintain the necessary regulatory approvals in a specific country or region, we will not be able to market and sell our products in that country or region.

In addition to the United States, Germany, France, Australia, Brazil, Canada, Japan, Hong Kong and Israel, where we market and sell our products directly with our own direct sales and marketing organizations, we sell our products in more than 75 other countries through local distributors or representatives. To be able to market and sell our products in a specific country or region, we or our distributors must comply with the regulations of that country or region. While the regulations of some countries do not impose barriers to marketing and selling part or all of our products or only require notification, others require that we or our distributors obtain the approval of a specified regulatory body. These regulations, including the requirements for approvals, and the time required for regulatory review vary from country to country. Obtaining regulatory approvals is expensive and time-consuming, and we cannot be certain that we or our distributors will receive regulatory approvals for all of our products in each country or region in which we plan to market our products. If we modify our products, we or our distributors may need to apply for new regulatory approvals before we are permitted to sell them. We may not continue to meet the quality and safety standards required to maintain the authorizations that we or our distributors have received. In some countries, product registrations are done in the name of our local distributor and, if we have to change distributors, must be transferred to the new distributor. In the past, this has occasionally caused delays in our ability to sell our products in a particular territory following a change of distributors and we may experience this problem again in the future. If we or our distributors are unable to maintain our authorizations in a particular country or region, we will no longer be able to sell our products in that country or region, and our ability to generate revenues will be materially and adversely affected.

Our failure to comply with radio frequency regulations in a specific country or region could impair our ability to commercially distribute and market our products using radio frequency in such country or region.

Some of our products, such as our capsule endoscopy, Bravo and SmartPill systems include a wireless radio frequency transmitter and receiver, and are therefore subject to equipment authorization requirements in a number of countries and regions. In the United States, Europe, China and Japan, authorities require advance clearance of all radio frequency devices before they can be sold or marketed. Modifications to the approved system design and specifications may require new or further regulatory approvals before we are permitted to market and sell a modified system. If we are unable to maintain our current approvals or obtain any additional required approvals from the authorities responsible for the radio frequency regulations in these and other jurisdictions where we sell products using radio frequencies, an enforcement action could be brought to prevent the sale or use of these systems in these countries. Any such action could adversely affect our results of operations.

Some of our activities may subject us to risks under U.S. federal and state laws prohibiting "kickbacks" and false or fraudulent claims.

Certain U.S. federal and state laws, including but not limited to the federal anti-kickback statute, prohibit, among other things, the offer, payment, solicitation or receipt of any form of remuneration in return for the referral of healthcare items or services reimbursable by a federal or state health care program such as Medicare or Medicaid. While the federal anti-kickback statute applies only to products or services for which payment may be made in whole or in part by a federal or state health care program, state laws often also apply to private third-party payors such as commercial insurance plans. Other federal and state laws, including the Federal False Claims Act, prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment to Medicare, Medicaid, or other third-party payors that are false or fraudulent, or are for items or services that were not provided as claimed.

These laws may apply to the sales, marketing and other promotional activities of manufacturers of medical devices, such as us, and may limit the kinds of financial arrangements we may have with hospitals, physicians, and other potential purchasers of medical devices. The anti-kickback statute, similar federal and state laws, and false claims laws prescribe substantial civil and criminal penalties for noncompliance. A government action against us under one of these legal regimes could result in financial and other penalties, delay or prohibit sales of some or all of our products or services and, even if unsuccessful, could cause adverse publicity and be costly to respond to, and thus could have a material adverse effect on our business, results of operations and financial condition.

Failure to comply with anti-corruption laws could subject us to penalties and other adverse consequences.

We are subject to the United States Foreign Corrupt Practices Act and similar anti-corruption laws in other jurisdictions, which generally prohibit companies from engaging in bribery or other prohibited payments to government officials for the purpose of obtaining or retaining business. If our employees or other agents are found to have engaged in such practices, we might be held responsible and could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

Federal and state privacy laws may increase the costs of operation and expose us to civil and criminal sanctions.

The Health Insurance Portability and Accountability Act of 1996, as amended, and the regulations that have been issued under it, which we refer to collectively as HIPAA, and similar laws outside the United States, contain substantial restrictions and requirements with respect to the use and disclosure of individuals' protected health information. The HIPAA privacy rules prohibit "covered entities," such as healthcare providers and health plans, from using or disclosing an individual's protected health information, unless the use or disclosure is authorized by the individual or is specifically required or permitted under the privacy rules. Under the HIPAA security rules, covered entities must establish administrative, physical and technical safeguards to protect the confidentiality, integrity and availability of electronic protected health information maintained or transmitted by them or by others on their behalf. While we do not believe that we are a covered entity under HIPAA, many of our customers are covered entities subject to HIPAA. Such customers may require us to enter into business associate agreements, which obligate us to safeguard certain health information we obtain in the course of our relationship with them, restrict the manner in which we use and disclose such information and impose liability on us for failure to meet our contractual obligations.

In addition, under The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, which was signed into law as part of the U.S. stimulus package in February 2009, certain of HIPAA's privacy and security requirements are now also directly applicable to "business associates" of covered entities and subject them to direct governmental enforcement for failure to comply with these requirements. We may be deemed as a "business associate" under HIPAA of some of our customers. As a result, we may be subject as "business associates" to civil and criminal penalties for failure to comply with applicable privacy and security rule requirements. Moreover, HITECH created a new requirement obligating "business associates" to report any breach of unsecured, individually identifiable health information and imposes penalties for failing to do so.

In January 2013, HHS issued a final HITECH omnibus rule implementing significant changes to the HIPAA regulations, including the obligations of business associates and their potential liability for violating the regulations. Compliance with most of the new requirements will be required by September 23, 2013.

In addition to HIPAA, most U.S. states have enacted patient confidentiality laws that protect against the disclosure of confidential medical information, and many U.S. states have adopted or are considering adopting further legislation in this area, including privacy safeguards, security standards, and data security breach notification requirements.

These and other possible changes to HIPAA or other U.S. federal or state laws or regulations, or comparable law and regulations in countries where we conduct business, could affect our business and the costs of compliance could be significant. Failure by us to comply with any of the standards regarding patient privacy, identity theft prevention and detection, and data security may subject us to penalties, including civil monetary penalties and in some circumstances, criminal penalties. In addition, such failure may damage our reputation and adversely affect our ability to retain customers and attract new customers.

We rely on local distributors to market and distribute our products in most of the territories in which we sell them.

With the exception of Australia, Brazil, Canada, France, Germany, Japan, Hong Kong, Israel and the United States, we rely on distributors for the marketing and distribution of our products. Under most of our agreements with local distributors, a distributor is granted the right to market our products for a specified period in a particular country or region, subject to the attainment of minimum sales targets. The distributor is required to prepare and submit to us for our approval a sales plan and to obtain and maintain the requisite regulatory and reimbursement approvals for our products. Our success in generating sales in countries or regions where we have engaged local distributors depends in part on the efforts of others whom we do not control. In 2012, we derived $42.4 million, or 23.4%, of our revenues from sales to distributors, compared to $43.6 million, or 25%, in 2011 and $36.7 million, or 23%, in 2010. From time to time, we replace distributors due to a failure to meet minimum sales targets and for other reasons. If we decide or it otherwise becomes necessary to change a distributor, it may take us a period of time to locate an alternative distributor and to train its personnel to market our products and our ability to sell our products in the territory could be adversely affected. In addition, terminated distributors may challenge our decision to terminate and demand compensation and damages. See, for example, the description of the dispute with our former distributor in Portugal in Item 8 – "Financial Information – Legal Proceedings". Such challenges may adversely impact the transition to a new distributor and our results of operation. Changes in distributors' management, distributors' financial position or distributors' inventory management may also adversely affect our business.

Our reliance on single source suppliers could harm our ability to meet demand for our products in a timely manner or within budget.

We depend on single source suppliers for some of the components necessary for the production of our products. For example, we have sole suppliers for the imaging sensor and transmitter of our PillCam capsules and the printed circuit boards embedded in the capsule of the Bravo system. If the supply of these components is disrupted or terminated, or if these suppliers are unable to supply the quantities of components that we require, we may not be able to find alternative sources for these key components. Although we maintain a strategic inventory of key components, the inventory may be insufficient to satisfy demand for our products if supply is interrupted, and is subject to risk of loss due to catastrophic events such as fire at a storage facility. As a result, we may be unable to meet demand for our products, which could harm our ability to generate revenues, lead to customer dissatisfaction and damage our reputation. If we are required to change the manufacturer of any of these key components, there may be a significant delay in locating a suitable alternative manufacturer. Additionally, we may be required to verify that the new manufacturer maintains facilities and procedures that comply with FDA and other applicable quality standards and with all applicable regulations and guidelines. The delays associated with the identification of a new manufacturer could delay our ability to manufacture our products in a timely manner or within budget. Furthermore, in the event that the manufacturer of a key component of our product ceases operations or otherwise ceases to do business with us, we may not have access to the information necessary to enable another supplier to manufacture the component. The occurrence of any of these events could harm our ability to meet demand for our products in a timely manner or within budget.

Conditions in Israel affect our operations and may limit our ability to produce and sell our product which could decrease our revenues.

Our corporate offices, main manufacturing facilities and research and development facilities are located in Israel. The political and national security environment in Israel may directly affect our operations. Armed conflicts between Israel and its neighboring countries and territories occur periodically and a protracted state of hostility, varying in degree and intensity over time, has in the past led to security and economic difficulties for Israel. These hostilities, any escalation thereof or any future armed conflict or violence in the region, could prevent us from using our corporate offices and primary manufacturing facility in Israel, and therefore harm our ability to manufacture and sell our products. For details regarding our disaster recovery plans, see Item 4 — "Business Overview — Manufacturing facilities and disaster-preparedness."

If we lose our key personnel or are unable to attract and retain additional personnel, our business and ability to compete will be harmed.

We are dependent on the principal members of our management, scientific staff and sales team. In order to implement our business strategy, we will need to keep our key personnel with expertise in research and development, clinical testing, government regulation, manufacturing, sales, marketing and finance. Our product development plans depend in part on our ability to retain engineers with expertise in a variety of technical fields. The loss of a number of these persons or our inability to attract and retain qualified personnel could harm our business and our ability to compete.

Our operations could be disrupted as a result of the obligation of key personnel in Israel to perform military service.

In general, most male and some female citizens and permanent residents of Israel between the ages of 21and 45 are obligated, unless exempt, to take part in annual military reserve duty. A majority of our employees reside in Israel and many of our male employees are currently obligated to perform annual reserve duty. Additionally, all Israeli residents who perform reserve duty are subject to being called to active duty at any time under emergency circumstances. Our operations could be disrupted by the absence for a significant period of one or more of our officers or employees due to military service. Any such disruption to our operations could adversely impact our business operations.

Our international operations expose us to the risk of fluctuations in currency exchange rates.

In 2012, we derived 66% of our revenues in U.S. dollars, 23% in Euro, 5% in Japanese Yen and 4% in Australian dollars, with the remainder denominated in other currencies. The currency denomination of our revenues depends on the location of the customer or the distributor used to fulfill our customers' orders. Conversely, in 2012, in addition to our U.S. dollar and Euro-denominated expenses, 13% of our expenses were denominated in New Israeli Shekels, or Shekels. Our Shekel-denominated liabilities consist principally of salaries and related personnel expenses. We anticipate that for the foreseeable future a material portion of our liabilities will continue to be denominated in Shekels. If the value of a currency in which our assets are denominated devalues against the value of a currency in which our liabilities are denominated, there will be a negative impact on our operating margins, as well as on our net income. Our revenues and expenses may not always be fully hedged against our currency exposure through financial instruments. In addition, if we wish to maintain the dollar-denominated value of our products in non-U.S. markets, devaluation in the local currencies of our customers relative to the U.S. dollar could cause our customers to cancel or decrease orders or default on payment, or alternatively, we may experience pressure to reduce prices in these markets. In addition, as of December 31, 2012, 33% of our cash and cash equivalents were denominated in currencies other than the U.S. dollar and we are therefore subject to the risk of exchange rate fluctuations between the U.S. dollar and other currencies.

Recent global economic market conditions may negatively affect our liquidity and financial results.

As of December 31, 2012, we had $35.4 million in cash and cash equivalents, which were held in bank accounts and deposits with original maturities of three months or less located with a number of high rated banks inside and outside of Israel. In addition, as of December 31, 2012, we had $30.2 million invested in long-term marketable securities and $58.4 million in short term investments, primarily time deposits. Our cash and investments are subject to general credit, counterparty, liquidity, market and interest rate risks, which were exacerbated by the turmoil that has recently affected the financial markets and the global economy and caused credit and liquidity issues for a number of reputable financial institutions and a general economic slowdown. These risks associated with our investment portfolio may have a negative effect on our liquidity and financial results.

Market acceptance of our products in the United States and other countries is dependent upon the medical equipment purchasing and procurement practices of our customers, patient demand for our products and procedures and the reimbursement of patient's medical expenses by third-party payors, including government healthcare programs. The current uncertainty surrounding world financial markets has resulted in the purchasers of medical equipment decreasing their medical equipment purchasing and procurement activities, which trend could continue for the foreseeable future. In addition, further tightening in world credit markets may result in our customers having increased difficulty securing the financing necessary to purchase our products which may result in decreased sales. The financial condition of our customers may deteriorate and our ability to collect payments due to us may be adversely affected. Continued economic uncertainty in our main markets may result in further decline in the number of medical procedures performed by our customers or in cost-conscious patients making fewer trips to their physicians and specialists, either of which could result in reduced demand for our products and procedures. Furthermore, third-party payors, including governments, around the world facing tightening budgets could move to further reduce their offered reimbursement rates or countries may adopt healthcare reforms to reduce healthcare spending. In particular, sequestration measures may be implemented in the United States. Sequestration means mandatory spending cuts in the U.S. federal budget, including healthcare spending. These spending cuts could negatively impact the ability of some of our customers to purchase our products or reduce the fee they receive from the federal government for providing medical services with our products under government programs, such as Medicare. For as long as these circumstances continue to impact the global economy, our business and potential growth may be materially and adversely affected.

The use of any of our products could result in product liability claims that could be expensive, damage our reputation and harm our business.

Our business exposes us to an inherent risk of potential product liability claims related to the manufacturing, marketing, sale and use of medical devices. The medical device industry has historically been litigious, and we face financial exposure to product liability claims if the use of any of our products were to cause or contribute to injury or death, whether by aggravating existing patient symptoms or otherwise. There is also the possibility that defects in the design or manufacture of any of our products might necessitate a product recall. Although we maintain product liability insurance, the coverage limits of these policies may not be adequate to cover future claims. In the future, we may be unable to maintain product liability insurance on acceptable terms or at reasonable costs and such insurance may not provide us with adequate coverage against potential liabilities. A product liability claim, regardless of merit or ultimate outcome, or any product recall, could result in substantial costs to us, damage to our reputation, customer dissatisfaction and frustration, and a substantial diversion of management attention. A successful claim brought against us in excess of, or outside of, our insurance coverage could have a material adverse effect on our financial condition and results of operations.

The price of our shares could fluctuate significantly as a result of a number of factors, including varying quarterly financial performance or our failure to meet our guidance or the expectations of analysts or investors, which may lead to additional volatility in our share price.

Our ordinary shares commenced trading on the Nasdaq Global Select Market in October 2001 and on the Tel-Aviv Stock Exchange in March 2004. In 2012, the closing price of our shares has ranged from $12.69 to $19.79 per share on the Nasdaq Global Select Market and NIS50.33 to NIS75.23 on the Tel-Aviv Stock Exchange. The price of our shares could fluctuate significantly for, among other things, the following reasons: macroeconomic or general market conditions, future announcements concerning us or our competitors, the existence and outcome of litigation concerning our intellectual property assets, changes in third-party reimbursement practices, regulatory developments, new clinical or economic data regarding our current or future products and political and national security environment in Israel. In addition, it is our practice to provide guidance to the market as to our expected revenues and earnings per share based on information available to us at the time of the guidance. If our operating results do not meet our guidance or the expectations of securities analysts or investors, the price of our shares would likely decline. In addition, based on our experience to date, we believe that many of our customers delay purchasing our products until the end of the fiscal quarter because they believe this will enable them to negotiate more favorable terms. Therefore, revenues from sales are concentrated at the end of each fiscal quarter making it difficult for us to determine the success of each quarter until its end. This may result in lower than expected quarterly revenues if external or other events cause potential customers to defer their purchasing decisions even for a short period of time. Furthermore, we believe that demand for our products may be materially affected by seasonal factors during the summer months when physicians and administrators are more likely to postpone purchasing decisions due to summer vacations and patients are more likely to postpone less urgent medical procedures until later in the year. Both of these factors may result in slower sales during the summer. Share price fluctuations may be exaggerated by low trading volume and the concentration of ownership of our ordinary shares and changes in trading practices in our ordinary shares, such as short selling. Securities class action litigation has often been brought against companies following periods of volatility in the price of their shares. Any securities litigation claims brought against us could result in substantial expense and divert management's attention from our business.

The largest beneficial owner of our shares, IDB Holding Corporation Ltd., or IDB, has significant influence over matters requiring shareholder approval and events and circumstances related to IDB may impact our management and control and the price of our shares.

As of December 31, 2012, IDB beneficially owned approximately 45.6% of our ordinary shares. As a result, IDB could exercise significant influence over our operations and business strategy and has sufficient voting power to influence the outcome of many matters requiring shareholder approval. These matters may include:

- the composition of our board of directors, which has the authority to direct our business, appoint and remove our officers and declare dividends;
- the approval or rejection of a merger, consolidation or other business combination;
- the raising of future capital; and
- amendments to our articles of association which govern the rights attached to our ordinary shares.

IDB recently announced its intention to sell its ownership of our ordinary shares through a sale to a third party. Alternatively, IDB could seek to use its influence to cause a sale of our company through a merger or otherwise.

In addition, in February 2012, the Committee For Increasing Competitiveness in the Economy, formed by the government of Israel to recommend possible policy measures to deal with the impact of concentration of ownership and pyramid-like control structures on the Israeli economy, submitted its final recommendations. Among other things, the Committee recommended the gradual dismantling of pyramid control structures. We are currently a fifth-tier company within IDB's pyramid control structure. If the Committee's recommendation is adopted and becomes law, IDB may be required or incentivized to cause a change of control of our company.

This concentration of ownership of our ordinary shares could also delay or prevent proxy contests, mergers, tender offers, open-market purchase programs or other purchases of our ordinary shares that might otherwise give our other shareholders the opportunity to realize a premium over the then-prevailing market price of our ordinary shares. This concentration of ownership may also adversely affect our share price. In particular, under Israeli law, for as long as IDB owns 45% or more of our ordinary shares, any buyer of its ownership stake would not be subject to mandatory tender offer rules and could purchase, in the stock market or in privately negotiated transactions without restrictions, additional shares to obtain an ownership stake of up to 90%. In addition, we and IDB are parties to a registration rights agreement under which IDB may require us to register its shares for sale in the stock market. Any sale in the market of a large number of shares could adversely affect the price of our ordinary shares. For more details on this registration rights agreement, see Item 10 – "Transactions with Related Parties – Registration Rights Agreement."

Finally, if the buyer of IDB's shares is a U.S. person, a change of control could also result in the loss of our status as a foreign private issuer under U.S. securities laws.

Future sales of our ordinary shares in the public market and low trading volume could adversely affect our share price.

Approximately 50% of our issued and outstanding shares are "control securities" available for resale on the Nasdaq Global Select Market subject, however, to volume limitations under Rule 144. In addition, all of our ordinary shares are available for resale on the Tel-Aviv Stock Exchange, subject to compliance with Regulation S under the Securities Act of 1933. Most of these restricted securities are held by IDB. Future sales of these restricted shares, or the perception that these sales could occur, could adversely affect the market price of our ordinary shares. We have periodically experienced a low trading volume of our ordinary shares, and if one or a small number of parties buys or sells a large number of our ordinary shares, we may experience volatility in our share price and the price and liquidity of our shares may be adversely affected.

Our ordinary shares are traded on more than one market and this may result in price variations.

Our ordinary shares are traded on the Nasdaq Global Select Market and the Tel-Aviv Stock Exchange. Trading in our ordinary shares on these markets is made in different currencies (U.S. dollars on the Nasdaq Global Select Market, and Shekels on the Tel-Aviv Stock Exchange) and at different times (due to different time zones, trading days and public holidays in the United States and Israel). The trading prices of our ordinary shares on these two markets may differ due to these and other factors. Any decrease in the trading price of our ordinary shares on one of these markets could cause a decrease in the trading price of our ordinary shares on the other market.

If we are characterized as a passive foreign investment company, our U.S. shareholders may suffer adverse tax consequences.

If, for any taxable year, our passive income, or our assets which produce passive income, exceeds specified levels, we may be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. This characterization could result in adverse U.S. tax consequences for our U.S. shareholders that may include having gains realized on the sale of our shares treated as, or taxed as, ordinary income (rather than as capital gains) and potential payment of interest on the taxes payable on such gains. Furthermore, the reduced rate otherwise applicable to certain qualified dividends would not apply to dividends paid by us to our shareholders and, in the case of certain "excess distributions" made by us, interest may also be payable on the taxes payable on such dividends. We believe we were not a PFIC for the fiscal year ended December 31, 2012. However, the tests for determining PFIC status are applied annually and are based in part on reference to the market value of our shares and valuing our intangible assets using the methods prescribed for publicly traded corporations, and it is difficult to make accurate predictions of future income and assets, which are relevant to this decision. Accordingly, we cannot give any assurance that we will not become a PFIC, in particular, since the value of our shares is likely to fluctuate. For a more detailed discussion of the consequences of our being classified as a PFIC, see Item 10 - "Additional Information - Taxation - Certain Material U.S. Federal Income Tax Considerations - Passive Foreign Investment Company Considerations." U.S. shareholders should consult their U.S. tax advisors with respect to the U.S. tax consequences of investing in our ordinary shares.

Israeli law regulating government grants we have received from the Office of the Chief Scientist of the Ministry of Industry and Trade in Israel, or OCS, for research and development expenditures limit our ability to transfer manufacturing of products or know-how developed in whole or in part with such grants to third parties outside of Israel. If we fail to observe these limitations, we may be required to pay additional royalties to the OCS or be subject to criminal charges.

From time to time we receive 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. We have to repay these grants through royalty payments out of sales of products developed with these grants. In addition, as a result of our participation in royalty-bearing programs of the OCS, we are subject to restrictions on the transfer of production or intellectual property outside of Israel. These restrictions may impair our ability to outsource manufacturing, engage in a change of control transaction or otherwise transfer our know-how outside Israel and may require us to obtain the approval of the OCS for certain actions and transactions and pay additional royalties to the OCS. If we fail to comply with the R&D Law, we may be subject to criminal charges. See Item 10 - "Additional Information - Taxation - Taxation of Companies in Israel – Grants Under the Law of Encouragement of Industrial Research and Development, 1984."

We receive significant tax benefits in Israel that may be reduced or eliminated in the future.

Our investment program in leasehold improvements and equipment at our manufacturing facility in Yoqneam, Israel has been granted "approved enterprise" status and we are therefore eligible for significant tax benefits under the Israeli Law for Encouragement of Capital Investments. From time to time, the government of Israel has considered reducing or eliminating the tax benefits available to approved enterprise programs such as ours. These tax benefits 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 pay would likely increase. In addition, our approved enterprise status imposes certain requirements on us, such as the location of our manufacturing facility, location of certain subcontractors and the extent to which we may outsource portions of our production process. If we do not meet these requirements, the law permits the authorities to cancel the tax benefits retroactively. See Item 10 "Additional Information — Taxation."

Government authorities may question our tax positions or transfer pricing policies or change their laws in a manner that could increase our effective tax rate or otherwise harm our business.

We conduct operations world-wide through subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between our subsidiaries. Transfer prices are prices that one company in a group of related companies charges to another member of the group for goods, services or the use of property. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arms' length and that contemporaneous documentation is maintained to support the transfer prices. While we believe we have proper transfer pricing arrangements, our transfer pricing procedures are not binding on applicable tax authorities. Tax laws are continually changing and are subject to the interpretation of government agencies, which from time to time review and audit our business in the jurisdictions in which we conduct business throughout the world. If regulators challenge our tax positions, corporate structure, transfer pricing arrangements or intercompany transfers, we may be subject to fines and payment of back taxes, our effective tax rate may increase and our financial condition, results of operations and cash flow could be materially adversely affected.

We may not be able to enforce covenants not to compete and therefore may be unable to prevent competitors from benefiting from the expertise of some of our former employees involved in research and development activities.

We currently have non-competition agreements with substantially all of our employees who are involved in research and development, most of whom are located in Israel. These agreements prohibit our employees, if they cease working for us, from directly competing with us or working for our competitors for a limited period of time following termination of employment. In many jurisdictions, courts are increasingly refusing to enforce restrictions on competition by former employees or have interpreted them narrowly. For example, in Israel, where a majority of our research and development employees reside, courts have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or its intellectual property. If we cannot demonstrate that harm would be caused to us, we may be unable to prevent our competitors from benefiting from the expertise of our former employees.

Item 4. Information on the Company

A. History and Development of the Company

Given Imaging Ltd. was incorporated under the laws of the State of Israel on January 4, 1998. We are registered with the Israeli registrar of companies in Jerusalem. Our registration number is 51-257802-2. Our address is Hermon Building, New Industrial Park, Yoqneam 20692, Israel. Our telephone number is +972-4-909-7777. Our agent in the United States is our subsidiary Given Imaging, Inc., which is located at 3950 Shackelford Road, Suite 500, Duluth GA 30096.

See Item 5 — "Operating and Financial Review and Prospects" and Item 18 — "Financial Statements" for a description of capital expenditures by us that are in progress or took place in the past three fiscal years and see "Business Overview" below for our history and important events in the development of our business. We have not made any divestitures during the same time period.

B. Business Overview

We develop, manufacture and market innovative diagnostic products for the visualization and detection of disorders of the gastrointestinal tract. We pioneered capsule endoscopy, a proprietary approach to visual examination of the gastrointestinal tract through the use of a miniaturized video camera contained in an ingestible disposable capsule. Our principal product, which incorporates our core technology, is thePillCam platform, a proprietary wireless imaging system that uses our disposable video capsules, which we refer to as the PillCam capsules. The PillCam capsules can be easily ingested by patients and move naturally through the gastrointestinal tract without discomfort while wirelessly transmitting to a portable recorder, enabling the gastroenterologist to view high quality video, images and data on a computer workstation, utilizing our proprietary RAPID software. We believe that capsule endoscopy is a patient-friendly solution that addresses a significant market opportunity and overcomes many of the shortcomings of traditional tools for detecting gastrointestinal disorders. We believe that each segment of the gastrointestinal tract presents meaningful opportunities for patient-friendly diagnostic procedures. In 2001, we commenced marketing our PillCam capsule endoscopy platform, with our PillCam SB capsule for detection of disorders of the small bowel. Since November 2004, we have also marketed and sold the PillCam ESO capsule for visualizing the esophagus. After receiving our first CE mark in 2007, we began selling the first generation of our PillCam COLON capsule in Europe. In 2010 we began limited marketing and sales of our second-generation PillCam COLON capsule in European countries, following receipt of the CE mark for this capsule in late 2009. We have also developed the Agile patency capsule and system, which is a dissolvable capsule that enables physicians to determine whether there are obstructions or strictures in the gastrointestinal tract that may prevent passage of our PillCam SB capsule.

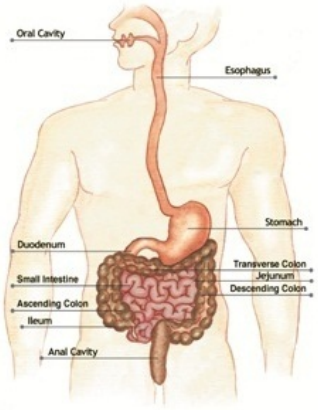
In December 2008, we acquired the Bravo pH monitoring business from Medtronic, Inc., or Medtronic. This was our first acquisition since inception. The Bravo pH monitoring system is the only wireless, catheter-free pH test for Gastro Esophageal Reflux Disease, or GERD, and uses a disposable capsule temporarily placed in the esophagus that measures pH levels and transmits the data to an external receiver. Ambulatory pH monitoring is considered the gold standard for diagnosing GERD.

On April 1, 2010, we acquired privately-held Sierra Scientific Instruments, or Sierra, for $35 million in cash. Sierra was a leading provider of specialty diagnostic devices for the gastrointestinal tract. With this acquisition, we acquired Sierra's business of developing, manufacturing and selling high-resolution pressure systems, also known as high resolution manometry, for the diagnosis of motility disorders within the GI tract. We sell our high resolution manometry systems under the name ManoScan 360. We also market and sell catheter-based pH and impedance monitoring systems we acquired from Sierra under the name Digitrapper™. In 2012, we changed the name of Sierra to Given Imaging (Los Angeles) LLC, or GILA.

In October 2012, we acquired the assets related to the SmartPill® GI Monitoring System from U.S.-based The SmartPill Corporation, for $6 million plus an earn-out. The SmartPill® is an ingestible capsule that uses sensor technology to measure pH, pressure and temperature in the gastrointestinal tract. The SmartPill System measures gastric emptying and the transit time of solid and liquid content through the entire gastrointestinal tract and is used to evaluate motility disorders like gastroparesis and constipation.

Disorders of the Gastrointestinal Tract

The gastrointestinal tract is a series of organs in the body responsible for digesting food. These organs principally include the mouth, esophagus, stomach, small intestine and colon. The following is an illustration of the gastrointestinal tract:



The upper gastrointestinal tract consists of the mouth, esophagus, stomach and duodenum, which is the first portion of the small intestine. The esophagus is an approximately 10-inch long tube that connects the throat and the stomach. The stomach is a sac-like organ that produces enzymes to break down food. The small intestine is an approximately 21-foot long hollow organ that is primarily responsible for absorption of food components. The three parts of the small intestine are the duodenum, the jejunum and the ileum. The small intestine is located in the abdominal cavity between the stomach and the large intestine, or colon. The lower gastrointestinal tract consists of the lower two-thirds of the small intestine (the jejunum and the ileum), the colon and the rectum. The colon is responsible for absorbing water before waste is excreted and the rectum, the final segment of the gastrointestinal tract, stores the waste prior to a bowel movement.

The gastrointestinal tract is susceptible to various disorders, including:

- *inflammatory bowel disease* including Crohn's disease and ulcerative colitis, both of which inflame the lining of the digestive tract;
- *obscure bleeding and iron deficiency anemia, or IDA*;
- *celiac disease*, which causes damage to the intestine due to an allergic reaction to gluten;
- *gastro-esophageal reflux disease* , or GERD, which is a chronic disease in which the acidic stomach content flows back into the esophagus due to the weakening of the valve between the esophagus and the stomach, known as the lower esophageal sphincter. Stomach acid, enzymes and bile irritate the esophagus and cause a wide range of symptoms and complications. Most commonly persistent are severe heartburn and chest pain and *esophagitis*, which is inflammation of the esophageal lining. If left untreated, GERD can cause strictures, respiratory problems, esophageal ulcers, *Barrett's esophagus*, a pre-cancerous condition and, ultimately, esophageal cancer;
- *other esophageal disorders* associated with malfunction of esophageal muscles and backward flow of food from the stomach up to the esophagus include *dysphagia*, which is a condition causing difficulty and pain in swallowing, *achalasia*, the failure of the lower esophageal sphincter to relax preventing normal passage of food to the stomach, and esophageal *spasm*, abnormal contractions of the esophagus causing pain or abnormal food transit;
- *irritable bowel syndrome*, which is a functional disorder characterized by abdominal pain or cramping and changes in bowel function without any organic manifestation;
- *peptic ulcer disease*, which occurs when the lining of the stomach or duodenum is worn away by stomach acid; and
- *growths*, such as tumor or polyps, which may be cancerous;
- *anorectal disorders*, such as *constipation*, irregular or infrequent evacuation of the bowels, *fecal incontinence*, loss of regular control of the bowels, and Hirschsprung's disease, the absence of certain nerves in the distal GI tract; and
- *motility disorders*, a family of maladies characterized by improper functioning of the gastrointestinal tract resulting in difficulty digesting and moving food through the gut; examples include *gastroparesis*, also called delayed gastric emptying, and *constipation*.

Typical symptoms of the foregoing disorders include heartburn, upper or lower abdominal pain, bleeding, diarrhea, constipation, anemia, vomiting, weight loss and nausea. Some of these symptoms are not specific to any particular disorder, but may be common to more than one underlying disorder, often requiring the gastroenterologist to make a differential diagnosis. We believe that our PillCam capsule endoscopy products and our suite of functional diagnostic products, including the Bravo pH monitoring system, our manometry and catheter-based impedance and pH monitoring systems and our SmartPill products can have a significant role in assisting gastroenterologists in making an evidence-based diagnosis of disorders of the small intestine, the esophagus and the colon. We believe that our products may also assist in ongoing management of patients with many of these disorders.

- *Small Intestine Disorders*. According to a study published in 2001 by the American Gastroenterology Association, or AGA, approximately 19 million Americans suffer from numerous disorders of the small intestine, including bleeding, Crohn's disease, celiac disease, chronic diarrhea, irritable bowel syndrome and small bowel cancer. Prior to the development of capsule endoscopy, there was no convenient and effective method for visualizing the lumen of the entire small intestine. In 2006, the American Society of Gastrointestinal Endoscopy, or ASGE, published guidelines recommending capsule endoscopy of the small bowel as a first line test for imaging small bowel mucosa.

- *Esophageal Disorders*. GERD is the most common esophageal disorder, affecting millions of lives in the United States. Estimates regarding the prevalence of GERD vary among sources. According to the AGA study mentioned above, there are approximately nine million physician office visits each year diagnosing GERD. It is estimated that approximately 10% to 15% of patients with GERD symptoms have Barrett's esophagus, a pre-cancerous condition with an associated risk for esophageal cancer. Our Bravo pH monitoring system has a leading position in the market for pH testing, which is considered the standard diagnostic procedure for GERD. Our catheter-based pH and impedance monitoring products are also used in the diagnosis of GERD. Our high resolution pressure systems are designed to assist in the diagnosis of those esophageal disorders associated with malfunction of esophageal muscles, such as dysphagia and esophageal spasms. *Esophageal varices* is another serious disorder of the esophagus. This disorder is often a life-threatening complication of serious liver disease because it can lead to severe bleeding from dilated esophageal veins. Thus, it is very important to screen patients with cirrhosis of the liver for the presence of varices and to monitor those patients with known varices. We believe that the PillCam ESO capsule may provide an effective method for visualization of the esophagus in patients with esophageal varices.

- *Colonic Disorders.* Colonic disorders, including colorectal cancer, inflammatory bowel disease such as ulcerative colitis and Crohn's colitis, diverticulosis, and lower gastrointestinal hemorrhage, account for significant mortality. According to data from the American Cancer Society, in the United States colon cancer is the third most common cancer diagnosed in both men and women and the second leading cause of death from cancer. It was recently estimated that each year approximately 150,000 Americans are diagnosed with colon cancer and approximately 50,000 Americans die from colorectal cancer. According to data published by World Gastroenterology News, the official publication of the World Gastroenterolgy Organization, it is estimated that each year approximately 400,000 Europeans are diagnosed with colon cancer and approximately 212,000 die from this disease. Importantly, most colorectal cancer cases and deaths are thought to be preventable with screening tests that allow for the detection and removal of precancerous lesions. Despite the ever-growing body of evidence supporting the benefits of colorectal cancer screening, many eligible average-risk Americans do not undergo any form of screening, including conventional screening colonoscopy. Numerous reasons have been postulated to explain this including patient fears, presumed procedural discomfort, potential procedural complications, such as bowel perforation, and embarrassment. The PillCam COLON capsule was developed for use as a safe, minimally invasive, sedation-free, patient-friendly modality to visualize the colon and rectum.

- *Anorectal disorders*. Constipation and anal incontinence, or the loss of regular control of the bowels, are the primary indications for referral for anorectal manometry. Anal incontinence is particularly important because of its profound psychological and sociological impact. Estimates of prevalence of anal incontinence in the general population range from six to 17 million people in the United States. The prevalence is higher in women than men by approximately 40-50% with a common cause being obstetrical trauma. The prevalence is particularly high among the elderly; studies in nursing home residents have found that more than 40% of subjects have fecal incontinence with this condition being a significant factor in the decision to institutionalize the individual. Prior technologies used in anorectal manometry have had limitations that can lead to unreliability of test results and patient discomfort. These arise from having relatively few points of pressure measurement (typically three to six), the use of "spot" sensors that do not measure the pressure asymmetries of this area, the use of water in some systems as the working media which can lead to untidiness, and the need to reposition the probe during the procedure. The ManoScan anorectal and ManoScan 3D anorectal systems overcome these limitations by providing a high density solid state array of pressure sensors allowing a more comprehensive assessment of pressure physiology with a single placement of the sensor probe.

- *Motility disorders*. Motility disorders of the GI tract primarily produce symptoms of increased or decreased bowel movement frequency, such as diarrhea and constipation, and can affect the quality and quantity of bowel movements. In addition, upper GI motility disorders can produce symptoms similar to other disorders (e.g. reflux), including pain, heartburn, belching, indigestion and early satiety. These disorders are very common and produce not only frequent visits to both primary care physicians and gastroenterologists, but also morbidity, loss of work time, frequent and expensive testing, and hospitalization. Given products, including high resolution and 3D esophageal manometry and SmartPill, provide best-in-class assessments of these disorders.

Current Detection Methods for Gastrointestinal Disorders

Imaging

Currently, the most commonly used imaging methods for detection of gastrointestinal disorders, including disorders of the small intestine, are endoscopy and radiological imaging.

Traditional Endoscopy

A traditional endoscope is a device consisting of a flexible tube and an optical system. There are several types of endoscopic procedures used to identify disorders in the gastrointestinal tract. The basic endoscopic procedures available include:

- *Upper Endoscopy.* In upper endoscopy, the physician inserts an endoscope, which is an approximately 3.5 foot long tube, through the patient's mouth. In esophagogastroduodenoscopy, or EGD, the gastroscope passes down the esophagus and into the stomach and duodenum for visual examination. In esophagoscopy, only the esophagus is viewed.

- *Colonoscopy.* In colonoscopy, the physician inserts a colonoscope, which is an approximately 5.5 foot long endoscope, into the patient's colon through the anus. Colonoscopy is the primary method for detecting disorders of the colon and is the standard screening tool for early detection of colon cancer in the United States.

- *Push Enteroscopy.* Push enteroscopy involves the insertion of an approximately six-foot long push enteroscope into the mouth. Due to the length and curvature of the small intestine, push enteroscopy enables the physician to view only the first one-third of the small intestine. The procedure is time consuming and difficult to perform for the physician and significantly more difficult to bear for the patient compared to traditional endoscopy.

- *Double Balloon Endoscopy*. This technique involves the use of a balloon at the end of a special enteroscope camera and an overtube, which is a tube that fits over the endoscope, and is also fitted with a balloon. This technique allows for viewing of the entire small bowel and therapeutic intervention once pathology is identified. However, it requires sedation and is skill- and time- intensive.

A traditional endoscope can perform both diagnostic and limited treatment functions. In a traditional endoscopic procedure, the physician is able to control the movement of the endoscope through the gastrointestinal tract, to stop the endoscope and examine more closely a particular area in the gastrointestinal tract and to take a tissue sample or seal a bleeding site using the endoscope. However, traditional endoscopy has some risks and limitations, including the following:

- *Requires Sedation.* Due to the need to insert a tube through the mouth or anus, a traditional endoscopic examination typically requires sedation of the patient due to patient discomfort. Administration of sedative drugs increases the cost of the procedure and introduces risks associated with potential adverse drug reactions.

- *Involves Potential Complications.* Potential complications of traditional endoscopic procedures include difficulty in breathing while the tube is inserted in the mouth, perforation or tearing of the intestinal wall, post-procedural infection and vomiting, abdominal swelling, sore throat, diarrhea and cross-contamination resulting from inadequate disinfection of endoscopes.

- *Causes Patient Anxiety, Discomfort and Pain.* Many patients are unwilling to undergo traditional endoscopic procedures due to the pain and discomfort associated with having a tube inserted through the mouth or anus.

- *Requires Substantial Time Commitment.* Patients undergoing a traditional endoscopic procedure are required to remain in the physician's office or hospital during the procedure. In addition, the effects of the sedation cause the patient to be inactive for several hours following the procedure.

Radiological Imaging

Radiological imaging is a commonly used method for initial detection of the small intestine and other parts of the gastrointestinal tract. Radiological imaging is used for detection of disorders of the esophagus only in limited situations, generally where gross structural lesions are suspected. During a radiological imaging examination, the patient swallows a contrast medium (such as barium), which is a dense liquid that coats the intestinal lining and provides contrast that allows the intestines to be visualized on x-ray film. The procedure produces a series of black and white x-ray images of the lumen, or cavity, of the small intestine. Radiological imaging is also used to visualize the colon in a test known as Barium Enema. In this test, barium or other contrast agents are poured through a tube into the anus. The barium blocks X-rays, causing the barium-filled colon to show up on the radiological image.

A more detailed examination, the double contrast small intestine procedure, or enteroclysis, requires insertion of a tube through the mouth or nose, which is then pushed through the stomach and duodenum. High density barium and then methyl cellulose, a gel-like material used to expand the intestine, are injected through the tube into the patient's small intestine prior to a series of x-ray exposures.

Gastric emptying scintigraphy, or GES, is a radiological test commonly performed to evaluate patients with symptoms that suggest an alteration of gastric emptying and/or motility. GES is the standard test for diagnosing gastroparesis or delayed stomach emptying, but it requires specialized centers and expertise to administer. This test involves ingestion of a meal that contains radioactive material which emits gamma radiation that can be detected by an imaging camera that collects these emissions and creates an image that can be analyzed. The test is time consuming and varies in accuracy among sites. It requires exposure to radiation and time spent in radiology specialty centers. The relative lack of availability of this test, its varying accuracy and its associated radiation exposure limit its use.

For constipation, the standard tool for radiological imaging involves ingesting radio-opaque markers, and is known as the Sitzmark test. Following ingestion, a patient is subjected to multiple plain abdominal X-ray examinations to track the progress of the markers through the GI tract, including the colon. The test subjects the patient to X-ray exposure and multiple visits to a radiology facility. The test has limited accuracy. These factors prevent widespread use of this tool in diagnosing potentially serious diseases producing constipation, including motility disorders. In the case of mass lesions such as cancer and other tumors that may be causing constipation, this test provides no imaging information that would aid in making a diagnosis.

Radiological imaging also has risks and limitations as a diagnostic tool, including the following:

- *No Direct Imaging of the Mucosa*. Radiological imaging does not provide a detailed view of soft tissue, including the mucosa, or internal layer of the gastrointestinal tract. In addition, radiological imaging does not provide clear visualization of ulcerations or flat malignant lesions. A lesion must have a certain mass and a distinguishable shape in order to be detected by radiology. Therefore, test results could be inconclusive or inaccurate.

- *Limited Detection of Small Pathologies*. Radiological imaging has a limited ability to detect smaller-sized disorders or pathologies (typically less than five millimeters in diameter). Larger pathologies of up to 10 millimeters in diameter may also remain undetected.

- *Limited Detection of Strictures.* Radiological imaging has a limited ability to detect strictures, which are three-dimensional phenomena, since it only produces a two-dimensional image resulting in frequent misdiagnosis.

- *Causes Patient Discomfort.* Radiological imaging is uncomfortable for patients, requiring them to ingest radioactive materials, which are uncomfortable to patients and could require the insertion of a tube into the body through the mouth or nose. These preparatory measures can induce vomiting, particularly in a double contrast procedure if the injected contrast liquids return to the stomach. In elderly patients, the passage of barium can be difficult and can result in blockage requiring the use of disimpaction techniques. There is some morbidity associated with barium induced blockage in elderly patients.

- *Exposes Patient to Radiation.* Radiological imaging poses increased risks of exposure to ionizing radiation for the patient. Tracking the progress of a disorder through repeated radiological imaging increases this risk.

Non-Imaging Diagnostic Methods

Impedance and pH Monitoring

Certain disorders of the gastrointestinal track can be detected through non-imaging tests. A common test to detect disorders in the esophagus, such as reflux disease, or GERD, is pH measurement. Traditional pH testing involves inserting a small catheter through the nostril and advancing it into the esophagus, where it remains in place for 24 hours. It can also be combined with impedance monitoring, which detects reflux events independent of the pH and thereby assists physicians in identifying acid and non-acid reflux episodes as well as providing esophageal transit data. Impedance monitoring is often combined with pH monitoring and used in GERD patients whose symptoms are not resolved with proton pump inhibitor, or PPI, therapy, which is intended to suppress acidic reflux. Impedance testing is only available with catheters.

Catheter-based pH and impedance monitoring has a few limitations:

- It is typically performed over a 24-hour test period compared to the more accurate 48-hour test period offered by the Bravo wireless capsule;
- The catheter is uncomfortable and could involve social embarrassment for the patients because there is visible indication that a medical test is taking place. As a result, patients may choose or be forced to refrain from their normal activity for the duration of the test;
- The catheter may cause throat irritation and can make eating and resting difficult;
- The procedure can be complicated by nosebleed, and on occasion can be associated with aspiration of esophageal or gastric contents into the trachea or lungs; and
- The catheter can lose its correct position as a result of patient movement, swallowing or eating, affecting the ability to properly interpret the pH or impedance reading.

Conventional Manometry

Manometry tests measure the contractile pressures inside an organ, such as the esophagus or the rectum. During this procedure, a pressure-sensitive tube, or “catheter,” is passed through the patient’s mouth or nose into the stomach for esophageal diagnosis, or through the anal canal for anorectal diagnosis. In esophageal manometry, a small amount of water is swallowed by the patient as the system records the contractile pressure wave of the esophagus and pressure activity of the upper and lower esophageal sphincters, which are valves controlling passage of food and liquids in and out of the esophagus. Anorectal manometry procedures involve insertion of the catheter in the anal canal and monitoring pressures of the anal sphincter and rectum as the patient undergoes various tightening and relaxation maneuvers. At the end of the examination, the catheter is removed and the data saved for analysis and reporting using a specially designed software. The pressure sensors on conventional manometry catheters are widely separated from one another and typically include only three to six sensors over a 10cm to 40cm long tube. As a result, conventional manometry has several limitations:

- It requires that the catheter be repeatedly repositioned by a technician or a nurse to locate various anatomical points of interest while the patient performs a series of breathing and swallowing maneuvers that are uncomfortable to the patient;
- It requires a substantial degree of technician skill and can be tedious, time consuming and lead to uncertainty as to whether the true regions of interest were properly surveyed;
- It is often uncomfortable to patients due to the length of procedure time and movement of the catheter within sensitive tissues;
- Due to the limited number of pressure sensors, relevant physiological information from locations between the sensors is not available, and certain measurement artifacts can result from movement of the catheter relative to the anatomy and vice versa; and
- Due to the limited amount of pressure sensor and movement of the catheter, the accuracy of the data collected and data analysis may be compromised.

The Given Imaging Solution

Capsule Endoscopy

Our capsule endoscopy system referred to in this annual report as the "Given System," features the PillCam capsule endoscope, a miniaturized video camera contained in a disposable capsule that is naturally ingested by the patient and delivers high quality color video images of the inside of the gastrointestinal tract in a painless manner. Capsule endoscopy with our PillCam capsules has become a standard approach to visual examination of the gastrointestinal tract and provides a solution to many of the shortcomings of other procedures by offering the following benefits:

- *Patient-Friendly Procedure with No Sedation*. Capsule endoscopy provides a patient-friendly tool for the diagnosis of patients that present symptoms of suspected disorders of the small intestine, the esophagus and the Colon. Procedures with the PillCam capsules require no sedation and the capsules are easily ingested by the patient and do not use x-rays to produce images. Procedures with PillCam SB and PillCam ESO do not require significant patient preparation. The PillCam COLON procedure requires preparation and cleansing of the colon prior to ingesting the capsule, similar to colonoscopy. The PillCam COLON procedure itself, similar to other PillCam procedures, does not require sedation or the insertion of a tube into the body. We believe that this patient-friendly solution may increase the number of patients who undergo diagnosis, screening and monitoring of gastrointestinal disorders of the small intestine, the esophagus and the colon, since traditional methods are intimidating or uncomfortable for many potential candidates.

- *Improved or Comparable Diagnostic Yield for PillCam SB*. Capsule endoscopy of the small bowel is the only wireless test that provides direct imaging of the entire small intestine. By comparison, double balloon endoscopy involves inserting a tube into the body, requires sedation and is skill- and time-intensive. Other methods provide access only to approximately the first one-third of the small intestine. As a result, clinical trials demonstrate that the PillCam SB capsule has a significantly higher diagnostic yield in detecting disorders of the small intestine when compared to other traditional modalities, including push enteroscopy and radiological imaging. Diagnostic yield means the number of patients who had a diagnosis made using a specific test expressed as a percentage. In addition, as demonstrated through clinical studies and ongoing experience with the Given System, a negative finding from the PillCam SB capsule, unlike conventional small bowel diagnostic techniques, has significant diagnostic value as it may allow physicians to rule out the existence of certain suspected abnormalities based on this finding, thereby avoiding the need to engage in additional costly or inconvenient diagnostic procedures.

- *Administered on an Outpatient Basis*. The PillCam capsule is generally administered in an outpatient setting with a brief visit to the physician's clinic or hospital. In the case of the PillCam SB and PillCam COLON capsules, the patient can go about his or her daily routine as the capsule transmits images and other data to the portable data recorder. In the case of the PillCam ESO capsule, the procedure can be completed in a short visit to the physician's office. We believe the Given System offers a significant opportunity for gastroenterologists and endoscopy departments to expand their business by increasing the number of procedures performed at their office or facility.

- *Detects Small Pathologies*. Unlike radiological imaging procedures, the PillCam video capsule provides direct visualization of the intestinal mucosa which allows detailed (up to 0.1 millimeter) visualization of small pathologies. This increases the possibility of detecting and diagnosing at an early stage, pathologies that might otherwise go undetected.

- *Natural Passage Requires no Insufflation*. Many traditional endoscopic procedures require insufflation, or the forcing of air into the gastrointestinal tract. This process can cause considerable patient discomfort. The Given System does not require insufflation because the PillCam capsule is ingested and moves with the natural contractions of the digestive tract. The absence of insufflation allows the PillCam capsule to capture images of the gastrointestinal tract in its normal physiological state. This approach, called "physiological endoscopy," allows the physician to clearly view the mucosa under more physiologic conditions.

- *Provides Convenient Digital Reporting, Storage and Remote Consulting Capabilities*. The physician can review the video produced by the Given System without seeing the patient or having him or her remain in the office or clinic during the review, thereby providing the physician with greater flexibility. In addition, the RAPID software includes various features that enhance the physician's efficiency and productivity, such as innovative display methods for faster review, localizing findings, help in identifying anatomical landmarks for easy orientation, managing images and patient information, reporting modules and convenient options for sending still images or short video files to the patient file, to the referring physician or a colleague for consultation. Some of these features are proprietary and covered by patents or patent applications, which we believe add an additional competitive advantage as physicians become more comfortable using these functions.

- *Provides a Cost-Effective Diagnostic tool*. We believe that the PillCam SB capsule endoscopy procedure is more cost-effective from a third-party payor perspective than traditional methods for imaging the gastrointestinal tract. With respect to the PillCam SB capsule for the small bowel, two economic outcomes studies reported by the Office of Health Policy and Clinical Outcomes of the Thomas Jefferson University in Philadelphia concluded that diagnosing small intestinal bleeding or Crohn's disease using the PillCam SB capsule procedure is cost-effective from a third-party payor perspective. We believe that the use of the Given System may result in additional cost savings due to the reduction in physician resources and facility costs permitted by the outpatient nature of the PillCam SB capsule procedure, its higher diagnostic yield — in the case of the PillCam SB capsule — and the potential for earlier diagnosis of disorders.

The Pillicam platform also has some limitations. The PillCam capsule moves naturally through the gastrointestinal tract; consequently, the capsule's passage is not controlled by the physician who cannot stop or steer the capsule for close-up detailed viewing of suspected disorders. In addition, the Pillicam platform, unlike a traditional endoscope, cannot take biopsies or be used for minor surgical procedures, such as cauterizing bleeding sites in the gastrointestinal tract. While endoscopes may be used in patients with obstructions or strictures in the gastrointestinal tract, the PillCam capsule may not pass naturally through the gastrointestinal tract of patients with obstructions or strictures, and accordingly is not recommended for use in these patients. Finally, review and interpretation of the capsule endoscopy video are performed after the capsule endoscopy equipment is returned to the physician and require the investment of additional time.

The PillCam capsules are not recommended for use by patients who have known or suspected gastrointestinal obstructions, narrowing, and certain other abnormalities, such as swallowing disorders. In patients with unsuspected or unknown obstructions, narrowing or certain other abnormalities of the gastrointestinal tract, the PillCam capsules can potentially become blocked from natural excretion, requiring hospitalization, and in some cases surgery, to remove it. According to the 2005 ICCE consensus report that was published in November 2005 in the peer-review journal Endoscopy, which defined practice guidelines and protocols for the use of both PillCam SB and PillCam ESO capsules by gastroenterologists, the rate of capsule retention depends on the indication. Based on a recent publication reporting results of a large prospective clinical study, the rate of capsule retention in patients with obscure gastrointestinal bleeding, or OGIB, is 1.2%; in patients with Crohn's disease it is 2.6%; and in patients with neoplastic disease it is 2.1%. Other publications state that the PillCam capsule has been reported to identify areas of narrowing of the gastrointestinal tract and there is nothing to indicate that the capsule itself is creating any obstructions or narrowing. These publications also state that, while there is no accepted method of completely avoiding capsule retention, it is clear that obtaining a good medical history is the best single method to minimize such risk. Patients with abdominal pain, distension and nausea should be suspected of having a potential for capsule retention. Other risk factors include known Crohn's disease and a history of chronic non-steroidal anti-inflamatory drug, or NSAID, use that is not necessarily current. A history of small bowel obstruction, previous small bowel resection or previous abdominal surgery is not in and of itself an indicator of probable retention. Once retention has been diagnosed, only endoscopic and surgical intervention has been shown to be effective for removal of the capsule. Surgical intervention is also recommended by the consensus report because it allows removal and treatment of the pathology that resulted in the capsule retention in the first place. There is no available data on the success of medical therapies for retention, such as initiating a course of steroids, stopping NSAIDs, or using prokinetics to aid in passing the capsule.

Non-Imaging Diagnostic Methods

Bravo pH Monitoring

The Bravo pH monitoring system is the only wireless and catheter-free pH test for GERD. It uses a disposable capsule temporarily placed in the esophagus that measures pH levels and transmits the data to an external receiver. Ambulatory pH monitoring is considered the standard diagnostic procedure for GERD. We believe that the Bravo pH monitoring system is a patient-friendly test for GERD and is a synergistic and strategic fit with our innovative capsule endoscopy products. The main advantages of the Bravo system over catheter-based technologies are as follows:

- *Patient-Friendly Procedure*. The Bravo system allows patients to maintain their regular diet and activities. The Bravo system also minimizes throat and nasal discomfort associated with conventional catheter-based pH systems and eliminates social embarrassment that accompanies traditional pH testing with no visible indication that a pH test is taking place.

- *Improved or Comparable Diagnostic Yield*. By extending pH data collection period to 48 hours, 24 hours beyond the recording capability of conventional catheter systems, the Bravo system provides the physician with additional data needed for an accurate GERD assessment. According to a 2003 study published in the American Journal of Gastroenterology, the Bravo system increases the likelihood of documenting relationships between atypical symptoms and reflux events with a 48-hour monitoring period.

- *Administered on an Outpatient Basis*. The Bravo pH testing is generally administered in an outpatient setting with a brief visit to the physician's clinic or hospital. The patient can go about his or her daily routine as the capsule transmits images and other data to the portable data recorder.

- *Provides Convenient Digital Reporting, Storage and Remote Consulting Capabilities*. The physician can review the data produced by the Bravo system without seeing the patient or having him or her remain in the office or clinic during the review, thereby providing the physician with greater flexibility.

There are risks associated with placement and use of the Bravo capsule. Occasionally, the capsule placement procedure may fail. A failure to place the capsule in the desired location within the esophagus could harm the accuracy of the data and lead to repeat procedures or, rarely, to an injury to the esophageal tissue or aspiration of the capsule. In other cases, the capsule may not detach from the esophageal wall. Failure of the Bravo capsule to attach or detach could require endoscopic or surgical intervention to remove it. Placement and 48-hour attachment of the capsule occasionally may produce pain or a sense of fullness in the esophagus or chest. This may require medication to reduce the pain during the course of the 48-hour data collection. Rarely, insertion and placement of the capsule can lead to complications which can include perforation or tears of the esophagus if the capsule introducer is not released and removed as required by the procedure. The Bravo capsule may occasionally become loose prior to completion of the 48-hour monitoring, or be displaced by food during eating, thus reducing the accuracy of the collected data.

Catheter-Based pH Monitoring

We also offer catheter-based products for pH and impedance measurement. Catheter-based pH testing involves inserting a small disposable catheter through the nostril and advancing it into the esophagus, where it measures pH levels, normally over a 24-hour period. It is typically administered on an outpatient basis and the patient is released to go about "normal" activities while a small catheter remains in place through their nose and extending to the bottom of their esophagus. The patient typically returns the next day so that the catheter may be removed and data uploaded from the recorder and into a software program for analysis.

The use of catheter-based pH monitoring is preferred over Bravo pH monitoring in cases where measurement is required over a longer section of the esophagus, such as in the case of impedance measurement, or if pH levels need to be measured at multiple locations, such as the upper and lower parts of the esophagus. The addition of impedance testing allows for the monitoring of non-acid reflux. It can be useful in association of symptoms with non-acid reflux and allow for certain tests to be done while the patient remains on acid suppressing medication.

Catheter-based pH monitoring has a number of risks and limitations. For more information, see in this Item 4 under the heading "Current Detection Methods for Gastrointestinal Disorders – Non-Imaging Diagnostic Methods – Impedance and pH Monitoring."

High-resolution manometry

We offer high-resolution manometry, or HRM, technology, which we acquired from Sierra in April 2010. Sierra was the first company to develop, market and sell solid-state high resolution manometry systems for use in the gastrointestinal tract, which are known as the ManoScan family of products. The primary applications of this technology are esophageal manometry and anorectal manometry.

Our high resolution manometry catheter includes 36 pressure sensors, compared to three to six sensors on a conventional manometry catheter, and is currently the only high resolution manometry catheter available in the market utilizing fully circumferential pressure sensors along the length of the catheter. This provides the following advantages:

- It allows for the visualization of the contractile physiology from the esophageal entry point, or the pharynx, to the stomach with a single placement of the catheter and eliminates the need for constant re-positioning of the catheter by the clinician.
- The high resolution procedure time is typically 15 to 20 minutes compared to 30 to 60 minutes with conventional manometry, which makes the high resolution manometry procedure more efficient for the medical staff and more tolerable for the patient.
- The system provides improved accuracy and reliability of the data collected during the procedure.
- ManoScan is also supplied with specialized catheters and software for anorectal manometry, providing similar advantages to those listed above.

The data are subsequently analyzed using proprietary software known as ManoView, which utilizes proprietary methods of data display and analysis designed to facilitate intuitive visualization and measurement of physiology and efficiently generate diagnostic reports.

Our ManoScan three-dimensional, high resolution sensor probes and accompanying software measure pressure at multiple locations around the circumference of the probe and distributed along its length. This allows for measurement of both the circumferential and axial distribution of pressure, which may provide significant diagnostic benefits in regions of high asymmetry such as the upper and lower esophageal sphincters and the anal sphincter.

ManoScan catheters and anorectal probes are limited use devices that typically require replacement every 200 to 400 uses. We also produce a proprietary disposable sheath that reduces the degree of equipment contamination and makes routine disinfection of the catheter between procedures more efficient. In addition to ManoScan high-resolution manometry, we also produce conventional manometry products under the Polygraph brand that remain a mainstay for esophageal and anorectal manometry in certain price sensitive markets. This system utilizes a choice of third-party single and multi-use catheters that are also distributed by us.

Manometry procedures involve a number of risks. The passage of the catheter may not be tolerated by some patients. The esophageal manometry procedure is not recommended for patients with a significant bleeding disorder or known obstruction that would prevent passage of the catheter.

SmartPill

In October 2012, we acquired the SmartPill business. The SmartPill system offers a unique way to assess motility by collecting and analyzing data from within the entire gastrointestinal tract using the SmartPill capsule. As the SmartPill capsule passes through the GI tract, it transmits data to a recorder worn by the patient. Once the single-use capsule has passed from the body, study data are downloaded from the recorder to a computer. The physician then uses our proprietary MotiliGI® software to display and analyze the data, providing test results in both graphical and report formats. The SmartPill capsule measures pressure, pH, temperature and transit times throughout the GI tract. It is used for evaluating patients with suspected delayed gastric emptying (gastroparesis) and chronic constipation.

The primary benefits of the SmartPill system are as follows:

- It is the only motility test that provides a complete transit profile of the GI tract in a single test;
- It is a single, capsule-based procedure that eliminates need for multiple tests;

- It offers increased sensitivity compared to other tests intended to evaluate transit times and motility problems, such as Gastric Emptying Scintography, or GES, and Radio Opaque Markers, or ROM;
- It enables localization of abnormalities to specific regions of the GI tract in the presence of overlapping motility symptoms;
- It enables standardization of the motility testing process;
- The test is ambulatory, allowing the patient to go about his or her normal routine throughout the test; and
- It eliminates radiation exposure associated with the GES and ROM tests

The SmartPill system also has limitations. The SmartPill capsule may not pass naturally through the gastrointestinal tract of patients with obstructions or strictures, and accordingly, is not recommended for use in such patients. In addition, the SmartPill procedure is not recommended for patients with swallowing disorders, severely obese patients and patients with pacemakers and other implanted electro medical devices.

Our Products

Capsule Endoscopy

The Given System consists of three components:

PillCam Capsules.

The PillCam capsules are miniaturized disposable color video cameras encased in a plastic shell, incorporating one or more specially developed imaging devices based on complementary metal oxide semiconductor, or CMOS, technology. Other components include optics, white-light emitting diodes for illumination, an application-specific integrated circuit device for control and image transmission, high-capacity silver oxide batteries, an antenna and other discrete electronic components.

Until their use, the PillCam capsules are stored in a sealed package. Before the patient ingests a capsule, the package is opened and the removal of the capsule from the package triggers a switch that activates the capsule. After the patient ingests the PillCam capsule with a small amount of water, the capsule passes naturally through the gastrointestinal tract. The PillCam capsules are excreted naturally from the body, usually within a day or two, without pain or discomfort.

We are currently selling the following PillCam capsules:

- *PillCam SB* — The PillCam SB video capsule is used for visualization and detection of abnormalities of the small bowel in patients ages two years and older. We started selling PillCam SB in August 2001. The PillCam SB capsule measures 11mm by 26mm (approximately 0.43 by 1.02 inches) and transmits images at a rate of two images per second, generally for eight hours or more, resulting in more than 50,000 images, at which time the operation of the capsule stops and recording ceases. After ingesting the capsule at the physician's office, the patient can continue his or her daily routine as the capsule transmits the images to a portable data recorder, which is later returned to the physician's office for review and diagnosis.
- *PillCam ESO* — The PillCam ESO capsule is used to visualize the esophageal mucosa. The PillCam ESO capsule is similar in size to the PillCam SB capsule and contains an imaging device and light source at both ends of the capsule. The procedure with PillCam ESO is fairly short and is done entirely within the physician's office. In May 2011, we received FDA clearance to market and sell PillCam ESO 3, the third generation of this capsule, which incorporates many of the latest features of Given Imaging's PillCam capsule technology, including advanced electronics and optics, a wider field of view and an image capture rate of up to 35 frames per second. With nearly double the frame rate available in the previous generation PillCam ESO, the PillCam ESO 3 capsule enables physicians to visualize the esophagus with improved confidence.

- *PillCam COLON* — PillCam COLON is the third video capsule we have developed. PillCam COLON capsule measures 11 mm by 31 mm (approximately 0.43 by 1.29 inches), slightly larger than the PillCam SB and PillCam ESO capsules. It contains an imaging device and light source at both ends of the capsule. The platform for PillCam COLON includes some of the same elements as PillCam SB and PillCam ESO, including a sensor array and data recorder. Similar to other methods of colon visualization, the PillCam COLON capsule procedure includes a colon cleansing and preparation procedure, as well as additional cleansing agents to enhance capsule propulsion. However, the procedure does not require sedation, intubation, insufflation or radiation.

  Since the lumen of the colon is wider than the small bowel and is highly compartmentalized, we have integrated several unique features into PillCam COLON 2, significantly enhancing this capsule over the first generation of the PillCam COLON capsule. The PillCam COLON 2, combined with advancements in RAPID software and the new DataRecorder 3, or DR3, offers intelligent functionality, superior imaging, and convenient workflow. PillCam COLON 2 utilizes bi-directional communication which enables real-time adjustments to maximize colon tissue coverage. New RAPID software provides unique tools to increase reading efficiency and aid in image interpretation. The combined benefits of this state-of-the-art technology offer unique capabilities for minimally invasive visualization of the colon.

- *Agile Patency System* — The Agile patency system consists of the Agile patency capsule, a dissolvable capsule the same size as the PillCam SB capsule, with a radio frequency identification, or RFID, tag packed in a lactose and barium powder. The Agile patency capsule is ingested by the patient and allows physicians to confirm free passage of a PillCam capsule in a patient's gastrointestinal tract. The reusable component of the Agile patency system is a hand-held patency Scanner, which detects the signal from the RFID tag. If the scanner indicates that the tag is no longer in the gastrointestinal tract, patency has been established and the patient can ingest a PillCam capsule without fear of it getting caught in a stricture. If the scanner indicates that the tag is located in the patient's body, an obstruction preventing the passage of the PillCam capsule may exist. If the Agile patency capsule remains in the body, it starts dissolving after 30 hours into small fragments that are naturally excreted. Since the capsule contains barium, in those instances where the Agile patency capsule is not excreted after ingestion, the physician may detect its location within the body using fluoroscopy.

  We believe that the availability of the Agile patency system contributes to the use of the PillCam SB capsule in the detection of disorders involving suspected or known gastrointestinal obstructions or narrowing, such as suspected or known Crohn's disease.

Data Recorder, Sensor Array and SensorBelt.

After ingestion by the patient, the PillCam capsule transmits information from the body to a proprietary wireless data recorder. The data recorder is worn on a belt around the waist of the patient or hangs on a shoulder strap for the duration of the examination. The latest generation of our data recorder, DR3, enables communication to the capsules in addition to receiving capsule images. This capability of bi-directional communication is expected to significantly enhance operational efficiencies of the Given System, including improved energy control, optimization of the examination record length and easier adherence to required examination regimen.

The data recorder receives the data from inside the body through an array of antennae, or a sensor array, that is secured with adhesive pads to the patient's body. SensorBelt is our latest antenna design in which the sensors are incorporated within a belt, eliminating the need for the medical staff to adhere sensors to a patient's body. This antenna is used for capsule endoscopy of the small bowel with our PillCam SB capsule. The sensor belt reduces both the time required to prepare the patient for a capsule endoscopy procedure as well as the time spent on equipment maintenance.

RAPID Software.

After the recording ceases, the data recorder is returned to the physician's office, where it is placed in a cradle that is connected to a computer with the RAPID software installed. Our proprietary RAPID software processes the capsule data stored in the data recorder using a number of proprietary algorithms relating to the visual presentation of this data. The physician can then efficiently review a video of the procedure while saving and annotating specific images for the patient's file. The physician is able to create a complete report, including thumbnail images, and even short video clips, that can be attached to the patient's electronic medical record or to an e-mail to be sent to the referring physician. The RAPID software provides users with the ability to view simultaneously two or four consecutive images, thereby accelerating review speed. The RAPID software contains a number of proprietary algorithms we developed designed to display relevant images and increase productivity and ease of use. The RAPID software is either installed on a stand-alone computer workstation or is installed on a customer's computer at the customer's location, which may be connected to the customer's network. RAPID Access is the version of software that can be installed on customers' hardware and enables PillCam capsule endoscopy study management to be performed in a network environment. RAPID Access supports a variety of customized workflow models to best suit the customers' unique needs, including import of patient demographic data and export of procedure reports, in addition to accessing network resources such as storage drives and printers. One additional version of RAPID, RAPID Reader, is a limited version of the RAPID software that can be installed on a standard personal computer, allowing the physician to review RAPID videos at any time or place as convenient. RAPID Reader also allows the physician to activate the data recorder and transfer data from the data recorder to a data storage device, like a portable USB drive. These features can also enable remote customer sites that do not have access to a permanent workstation to administer our PillCam capsules to patients and then deliver the results to a central location for processing and interpretation.

Important features of our RAPID software also include:

- "Automatic Mode," which uses advanced software algorithms to create a more efficient review of the video;
- "Quick View," which allows fast preview of the video while highlighting potentially interesting images in the video stream; and
- "RAPID Atlas," which allows the physician to compare the on-screen case image with known reference images stored in the database. The reference images can be searched by findings, diagnosis, or using Capsule Endoscopy Structured Terminology, or CEST.

We also market our RAPID RT Real-Time viewing device. This is a dedicated handheld device that enables real-time viewing during a capsule endoscopy procedure with our PillCam capsules.

Non-Imaging Products

Bravo pH Monitoring

The Bravo pH monitoring system consists of the following primary components:

- a small pH capsule about the size of a gel capsule that is attached to the wall of the esophagus and transmits data to the receiver;
- a proprietary delivery system that is used to place the Bravo capsule in the esophagus;
- a pager-sized recorder worn by the patient that receives pH data from the Bravo capsule; and
- proprietary pH analysis software used to perform the diagnosis.

The Bravo capsule, which contains a miniature pH sensor, is attached by a gastroenterologist to the esophagus using a proprietary delivery system, usually in conjunction with an endoscopy or manometry test, which are helpful in determining the exact location for the placement of Bravo capsule. The physician advances the Bravo capsule to the desired location in the esophagus. After proper placement, vacuum is applied, filling the capsule's suction chamber with a small piece of esophageal tissue. A locking pin is then advanced by depressing a plunger on top of the handle of the delivery system, securely attaching the Bravo capsule to the wall of the esophagus and the delivery system is removed. The capsule transmits pH data wirelessly to the receiver. Within days, the capsule spontaneously sloughs off the wall of the esophagus and passes through the patient's gastrointestinal tract. After the study is completed, the patient returns the receiver to the hospital or clinic, and the data is downloaded via an infrared link to a specially-configured computer, where proprietary software known as RAPID pH assists in analyzing the results and provides a comprehensive report for patient diagnosis. The Bravo pH monitoring system is cleared for use in adults and in children from age four and above.

Catheter-Based pH Monitoring

We market and sell the Digitrapper pH and impedance monitoring system. This system consists of the following primary components:

- a portable data recorder capable of recording both pH and impedance signals;

- single use pH and pH plus impedance catheters with single and dual channels of pH sensing and up to six channels of impedance sensing;
- AccuView pH and pH with impedance reflux analysis software; and
- pH buffer solutions for pre-test calibration of the pH sensors, and other minor accessories.

After calibrating, the catheter is inserted into the nose and positioned so that the pH sensor(s) are placed at a prescribed distance above the lower esophageal sphincter, or LES. An esophageal manometry test is useful in indentifying the exact location of the LES and, therefore, catheter-based pH monitoring procedures are often done following a manometry test. Following the insertion of the catheter, the patient leaves the clinic and goes about daily activities while the acidity (pH) and presence (impedance) of any reflux is recorded. The patient returns after approximately 24 hours and the clinician removes the catheter and uploads the data from the recorder to the AccuView reflux monitoring software for analysis. The program provides a comprehensive set of reflux analysis measurements and generates a report to be interpreted by the responsible physician.

Manometry

Our ManoScan high resolution manometry system is comprised of the following components:

- a workstation with a computer, monitor, electrical isolation transformer, and calibration system;
- specialized proprietary electronics that energize the pressure sensors , process their signals and send them to the workstation computer;
- a high-resolution solid-state manometry catheter that may optionally include up to 18 impedance electrodes;
- ManoScan real-time display software that guides the nurse or technician through the procedure, displays the data in real time and stores the information to file;
- ManoView Software that provides a full set data visualization, analysis, and report generation functions; and
- ManoShield, optional disposable sanitary sheath that reduces the level of contamination of equipment and facilitates routine disinfection between uses.

The ManoScan system obtains a high resolution mapping of pressure levels, and optionally, impedance levels, within organs of the human gastrointestinal tract, primarily the esophagus and anorectal organs. During a manometry procedure, a pressure-sensitive tube, or “catheter,” is passed through the patient’s mouth or nose into the stomach for esophageal diagnosis, or through the anal canal for anorectal diagnosis. In esophageal manometry, a small amount of water is swallowed by the patient as the system records the contractile pressure wave of the esophagus and pressure activity of the upper and lower esophageal sphincters, which are valves controlling passage of food and liquids in and out of the esophagus. Anorectal manometry procedures involve insertion of the catheter in the anal canal and monitoring pressures of the anal sphincter and rectum as the patient undergoes various procedures. The physician, nurse or other clinician performing the procedure uses the ManoScan real-time display software to place the catheter in the correct location and observe the data in real-time. At the end of the examination, the catheter is removed and the data saved for analysis and reporting using our ManoView software.

We also offer conventional manometry products under the Polygraf brand. Our conventional manometry system comprises analogous components to those described above for our ManoScan high resolution manometry system, but has typically only four to eight sensors, no impedance capability and no available sanitary sheaths. Its catheters may be solid state, air charged, or water perfusion based. In conventional manometry, the procedure is similar to that of high resolution manometry except that, due to the limited number of pressure sensors along the catheter, the person performing the test must move the catheter back and forth in a series of positions as the patient undergoes certain breathing and swallowing maneuvers to identify the position of the LES and other anatomical landmarks and to complete the data collection. The data analysis procedure is also generally more complex and less intuitive than in high resolution manometry.

SmartPill

The SmartPill system is comprised of the following components:

- *The SmartPill capsule* is a disposable 26 x 13 mm sensor-based capsule that moves through the GI tract by peristalsis, which is the normal rhythmic contraction of the intestinal muscles. The capsule measures pressure, pH and temperature to determine transit times of the stomach, small bowel, colon and whole gut and is capable of transmitting data continuously for five days or more.

- *The SmartPill recorder* collects and stores biomedical data sent by the capsule. It can be worn on a lanyard or belt clip and allows the patient complete mobility throughout the test. The docking station is used to transfer study data from the recorder to the computer, as well as for charging the recorder.

- *The MotiliGI software* is installed on a computer workstation and provides data analysis tools, offering physicians a variety of test reporting and exporting options to aid in the identification of motility disorders. The software calculates gastric emptying time, small bowel transit time, colonic transit time, combined small/large bowel transit time and whole gut transit time, in graphical and statistical formats and presented in a summary report.

- *The SmartBar* is an FDA-cleared edible bar that patients must eat as a standard meal immediately before ingesting the SmartPill capsule. Eating the bar is necessary to standardize the procedure and to accurately measure gastric emptying time. A SmartBar is included with every individual capsule pack purchase

In a standard SmartPill procedure, the patient eats the SmartBar and then ingests the SmartPill capsule in the physician's office. While wearing the recorder, the patient leaves the physician's office and resumes his or her normal schedule. The recorder is removed during bathing and sleeping. The SmartPill capsule is typically passed within a few days. The patient returns the recorder to the physician and the test data is downloaded in a few minutes. The physician then analyzes and interprets the test data and provides a report to the patient.

Warranty and Service

We provide standard warranties for each of our products. Warranty periods typically range between six months to two years. During the warranty period, we are obligated to repair or replace, at our election, every defective product. Our warranty-related costs are immaterial.

When a customer reports a problem with any of our products, first line service is provided by our own technical personnel in the territories in which we operate directly. In territories in which we operate through a distributor, the distributor is responsible for providing first line service. If our personnel in the field or our distributors are not able to resolve the problem, the defective part is shipped to our main facilities in Israel or Los Angeles for repair or replacement. Often, the defective part is replaced promptly out of a stock of spare parts we maintain in all of our direct territories. We are also able to resolve some service calls using remote access software that allows us to provide maintenance and support services for our products from a remote location, including our distributor's office, through a telephone line or internet connection.

When the warranty expires, our customers are offered the opportunity to sign a post-sale customer support contract with us. Under this contract, the customer pays a fixed amount per year in consideration for receiving our maintenance and support services.

Clinical Studies

Clinical studies are an important part of our product development and market development activities. We use clinical studies during product development to optimize the product parameters and the development process, typically culminating with submission of new products for registration or clearance by regulatory authorities. Many of our clinical studies are conducted for market development purposes with products that have received regulatory clearance. With these trials we strive to demonstrate the clinical and economic benefits of our products to support their use by physicians and to obtain and improve reimbursement coverage by third-party payors. Many of the investigators conducting clinical studies with our products have presented their results at major gastroenterology meetings or submitted them for publication in peer-reviewed medical journals. Accordingly, the number of presentations and publications of studies evaluating our products is constantly growing and more than 1,900 such articles, editorials and case reports have been published in peer-reviewed journals to date. These papers provide the results of clinical studies as well as accumulated experience from ongoing use of our products for a range of indications. We believe that these presentations and publications assist our marketing and educational efforts and support our efforts to obtain new reimbursement coverage policies and expand existing policies.

Since its introduction, the Bravo system has been the subject of numerous clinical studies and more than 50 peer-reviewed publications that demonstrate the successful use of the Bravo system for esophageal pH monitoring in clinical practice and highlight the benefits of the Bravo system compared to traditional catheter-based pH monitoring. These studies and publications specifically highlight the effectiveness of the 48-hour testing period with the Bravo system compared to the 24-hour testing period of the catheter-based tests and the improved patient tolerability of the procedure with the Bravo system.

The application and benefits of high-resolution manometry in the diagnosis of gastrointestinal motility disorders have been described in more than 40 peer-reviewed publications with the majority of the recent articles being based on studies that use the ManoScan family of products. These studies document the diagnostic benefits of the system in the clinical setting and its use to establish the most current methods of disease classification including the stratification of disease into sub-types with distinct management and therapies.

Numerous studies have been conducted with the SmartPill system. These studies have yielded publications highlighting the benefits of the SmartPill system. Such benefits include the system's ease of use and increased sensitivity over other available motility tests, the economic benefits of the system as a single test to measure transit time through the entire GI tract, reducing or eliminating the need to conduct multiple tests, and the standardization benefits associated with using the SmartBar.

Marketing and Distribution

Our sales and marketing operations are organized in three geographical regions: Americas (United States, Canada and Latin America); EMEA (Europe, Middle East and Africa); and Asia-Pacific/Japan (Japan, Australia, New Zealand and the rest of Asia), or AP/J. This organization enables us to focus on the particular needs of each region. For a breakdown of our revenues by products and by geography, see Item 5 — "Operating and Financial Review and Prospects — Operating Results — Revenues."

We market our products using either direct or indirect sales, depending on the potential size of the market and local market conditions. Currently, we market our products directly in Australia, Brazil, Canada, France, Germany, Hong-Kong, the United States and Israel. In Japan, in 2012 we implemented a hybrid sales model where most of our sales are done through our direct sales force and some through a local distributor. Our sales in direct markets accounted for approximately 76.6% of our revenues in 2012. In addition to our direct markets, we market and sell our products in more than 75 other countries through local distributors or representatives. Sales to our local distributors worldwide accounted for approximately 23.4% of our revenues in 2012. In each region, we support these distributors with the sales support, customer support, clinical and regulatory affairs and general management employees of our regional subsidiaries. Under standard terms of our distribution agreements, we generally grant to one distributor in each particular country or region the right to market our products for a defined period. During the contract period, the distributor is required to meet minimum sales targets set out in each distribution agreement. Generally, we may, in our sole discretion, upon prior written notice, terminate a distribution agreement with a distributor in the event that a distributor fails to meet its minimum sales targets. To date, we have changed a number of our distributors due to failure to meet minimum sales targets and for other reasons. We have the right not to renew a distribution agreement if we are unable to reach an agreement with the distributor as to minimum sales targets during any renewal period. In general, each distributor is responsible for obtaining and maintaining any regulatory approvals or registrations required to sell our products in that distributor's sales territory. Each distributor is also responsible for preparing and submitting to us for our approval a marketing plan for our products in that distributor's sales territory. After receiving our approval of the marketing plan, each distributor is responsible for implementing the marketing plan, including, participating in local and national trade shows, conducting education and training sessions and conducting marketing clinical trials in its sales territory.

Capsule Endoscopy

Most of our revenues come from recurring sales of our PillCam capsules. Our marketing strategy in our mature markets focuses on increasing the use of PillCam capsules by educating medical professionals of the benefits of capsule endoscopy and by developing new indications for use. We seek to achieve this by conducting market research to receive feedback from our customers and evaluate their needs, by having a robust professional education program, by sponsoring and supporting clinical trials to generate clinical data supporting the use of our products, and working with third-party payors to obtain appropriate reimbursement in order to expand the use of our PillCam capsules for additional medical indications covered by the regulatory clearance we have for our capsules. We seek to maintain a close relationship with our customers, educating them about the clinical and economic benefits of our products and enhancing the operating efficiencies of the Given System. We are also working to increase awareness of our products among patients through a variety of means, including through patient-focused web pages and social media channels. In new markets, our initial focus is on driving the placement of capital equipment in order to expand our market penetration in gastroenterology physician offices and gastroenterology departments within hospitals.

The clinical benefits of capsule endoscopy and its place in routine practice management are demonstrated in more than 1,900 articles published in peer-reviewed journals. We also use trade shows and scientific meetings and offer workshops, courses, videos and seminars to educate our customers. We routinely participate in industry conferences and trade shows, such as the Digestive Disease Week, or DDW, and the annual meeting of the American College of Gastroenterology, or ACG, in the United States, and the United European Gastro Week, or UEGW, and numerous other national, regional and local trade shows. In addition, we routinely hold numerous regional and local courses and seminars and trained hundreds of physicians and nurses on capsule endoscopy and our products. Also, we occasionally collaborate with reputable institutions that are experienced users of our products to develop centers of excellence for our products and are working with these centers to develop training curriculum about our products and their use in clinical practice. We believe that these education programs helped also to expand the knowledge of participating physicians and provide an independent endorsement of the clinical value and importance of the Given System.

A variety of special interest groups related to capsule endoscopy have been formed in the United States, Europe, Japan, Australia and in other regions to provide a dynamic forum to share knowledge, encourage research, and support the advancement of capsule endoscopy. One of the first groups formed was the Capsule Endoscopy Special Interest Group, which is sponsored by the American Society of Gastrointestinal Endoscopy, or ASGE. In Europe, a group of leading gastroenterologists gathered to form the European Capsule Endoscopy Group, or ECEG. A similar group, the Japanese Association for Capsule Endoscopy, or JACE, exists in Japan and plays an important role in educating the Japanese physician community on the practical application of capsule endoscopy. In Australia, there is the Australian Small Bowel and Capsule Endoscopy Interest Group, which is an interest group for the Gastroenterological Society of Australia. We believe that these special interest groups provide an important contribution to the adoption of capsule endoscopy around the world.

Bravo pH Monitoring

In most cases, we sell the Bravo pH monitoring system through the same sales force and distribution channels that sell our capsule endoscopy products. We believe that we can capture the existing market opportunity and increase the utilization of this product, primarily due to:

- our sizable field sales force and numerous professional education activities, compared to the limited resources used to market and sell this product prior to our acquiring it;
- our comprehensive suite of diagnostic solutions for gastroenterologists and the considerable overlap that exists between the customer base of our various product lines;
- the synergy that we believe exists between our capsule-based, patient-friendly technologies of capsule endoscopy, SmartPill and Bravo;
- our ability to provide the market with a single platform that provides Bravo and catheter-based monitoring capability and high-resolution manometry in an integrated workstation environment, displacing multiple workstations with incompatible interfaces supplied by multiple vendors;
- the existence of widespread reimbursement coverage in the United States with higher reimbursement rates than those applicable to catheter-based pH monitoring products;
- the increased awareness that we believe exists for management of GERD symptoms, partly due to consumer advertisement of GERD medications by pharmaceutical companies; and
- untapped potential for market development outside the United States, where the use of wireless pH monitoring is not well established.

The Bravo system has been endorsed by professional societies and organizations in the United States. In 2005, the ASGE Technology Committee issued an evaluation report addressing the use of the Bravo system for investigation of suspected reflux disease. The report concluded that wireless pH monitoring offers a safe and comfortable alternative to pH monitoring by conventional trans-nasal catheter systems. In 2007, the ACG published updated guidelines for esophageal pH monitoring, which expanded the guidelines to include the use of wireless esophageal pH monitoring, pointing out the extended testing period available with the wireless technology.

Catheter-Based Reflux Monitoring and Manometry

We market and sell our catheter-based pH, impedance and manometry products in the United States, Australia, France and Hong Kong through the same sales organization selling our capsule endoscopy and Bravo products. Elsewhere, we sell these products through independent distributors. Some of these distributors do not have written agreements with us. Some of these distributors have had a prior relationship with us, having also distributed our capsule endoscopy or Bravo products, and others have not, which has resulted in us having more than one distributor in certain territories distributing different product lines.

We believe that we can expand our market share and the market as a whole due to the following factors:

- our sizable field sales force and numerous professional education activities, compared to the limited resources available from Sierra prior to our acquisition of it and compared to other competitors in this space;
- the considerable overlap that exists between our Bravo customer base and ManoScan customer base and opportunities for each among customers that do not have both;
- the ability to provide the market with a single platform that provides Bravo and catheter-based monitoring capability and high-resolution manometry in an integrated workstation environment to displace existing multiple workstations with incompatible interfaces supplied by multiple vendors;
- advocacy for the use of high-resolution manometry to displace conventional manometry by leading experts in the field as evidenced in the Chicago Classification of esophageal disorders in development by a consensus group of internationally recognized experts using our ManoScan 360 high resolution manometry system; and
- education of the gastroenterological community as to the growing medical evidence of risk associated with the existing widespread use of proton pump inhibitor, or PPI, an acid suppression medication, and the need for reflux testing.

SmartPill

We market and sell our SmartPill motility monitoring system in the United States through our direct sales force. This product is not yet well known outside the United States and sales outside the United States have been insignificant. We plan to expand the markets for this product and sell it outside the United States either through our own sales force or through independent distributors. We believe that we can capture the existing market opportunity and increase the utilization of this product, primarily due to:

- our sizable field sales force and numerous professional education activities, compared to the limited resources used to market and sell this product prior to our acquiring it;
- our comprehensive suite of diagnostic solutions for gastroenterologists and the considerable overlap that exists among the customer bases of our various product lines
- the synergies that we believe exist between our capsule-based, patient-friendly technologies of capsule endoscopy, SmartPill and Bravo;
- our available resources and expertise in conducting clinical trials necessary to further establish clinical evidence for the benefits of this product;
- the potential for increased sales if we are able to obtain broad and favorable reimbursement coverage for this product; and
- untapped potential for market development outside the United States, where the use of SmartPill is not well established.

Manufacturing

PillCam Capsules

We manufacture the PillCam capsules at our facilities in Yoqneam, Israel. The manufacture of the PillCam capsules is a complex process involving a number of separate processes and components. Our manufacturing process consists primarily of assembling externally purchased components and sub-assemblies in an environmentally controlled area. Each PillCam capsule is inspected and tested multiple times as it moves from subassembly level to a final packaged product.

For most of our capsule endoscopy products we have a robust, efficient, fully- or semi-automated manufacturing process. To date, we have been manufacturing our PillCam COLON capsule in a fixture-assisted manufacturing process, which is sufficient to meet the current demand for this product that is not yet cleared for marketing in the large markets of the United States and Japan. This capsule includes several components that are based on new technologies and are difficult to manufacture and some are being supplied to us by single source suppliers. We are working to establish a robust, high volume manufacturing process for the PillCam COLON capsule to allow us to meet the increased demand we expect if we are able to obtain regulatory clearances in the United States and/or Japan.

We believe we have adequate capacity to manufacture capsules needed to satisfy estimated demand for the foreseeable future.

We depend on single source suppliers for some of the components necessary for the production of our PillCam capsules. For example, we have sole suppliers for the imaging sensor and transmitter of all types of our PillCam capsules and for a few important components of our PillCam COLON capsule. With some of our single source suppliers we do not have written contracts or long term contracts. We believe that in the ordinary course of business we would be able to arrange substitute sources of supply for critical components within approximately two years of lead time. We believe that if we need to find a substitute source of supply, our inventory of components and finished products, together with our right or expected ability to submit final purchase orders prior to termination of our agreements with some of these suppliers, should be sufficient to continue sales of the Given System for all or most of the lead-time period.

For a description of the risks associated with our dependence on single source suppliers, see Item 3 — "Risk Factors — Our reliance on single source suppliers could harm our ability to meet demand for our products in a timely manner or within budget."

Portable Data Recorder and Sensor Array

We designed our portable data recorder, sensor array and their related accessories. Some components of these accessories are manufactured externally and assembled and tested at our facilities. Sensor arrays are manufactured and assembled externally and are tested at our facilities.

Computer Workstation

Our computer workstation is specially configured in accordance with our specifications and is pre-loaded with our proprietary RAPID software and integrated software that together allow us to service the workstation from remote locations through standard telephone connections.

Bravo pH Monitoring System

The Bravo pH monitoring system consists primarily of the following components:

- a small pH capsule that is attached to the wall of the esophagus and transmits data to the receiver;
- a proprietary delivery system that is used to place the Bravo capsule in the esophagus;
- a pager-sized receiver worn by the patient that receives pH data from the Bravo capsule; and
- a proprietary pH analysis software.

We manufacture the Bravo product in our own manufacturing facility in Israel. The manufacturing process of the Bravo system consists primarily of assembling externally purchased components and sub-assemblies in an environmentally controlled area. We believe we have adequate capacity to satisfy estimated demand for Bravo system for the foreseeable future.

We depend on single source suppliers for some components necessary for the production of the Bravo system. We do not have written contracts or long-term contracts with some of these suppliers. We believe that if we need to find an alternative source of supply, our inventory of components, sub-assemblies and finished products and our right or expected ability, as applicable, to submit final purchase orders prior to termination of the applicable supply relationship, together are sufficient to continue sales of the Bravo product for all or most of the lead time that will be required to develop alternative sources of supply.

High Resolution Manometry Systems

High resolution catheters

The manufacture of the high-resolution and three-dimensional high-resolution ManoScan manometry catheters involves a number of complex processes. The manufacturing activities primarily consist of assembling externally purchased or processed components and subassemblies and integrating them through manual processes, which include standard assembly techniques as well as custom developed techniques, processes and equipment. The manufacturing takes place on a production floor with most activities performed at individual workstation benches. Most sub-assemblies are tested prior to integration into the final assembly. After assembly, each catheter is inspected, tested and packaged.

We manufacture the various ManoScan catheters at our facility in Los Angeles, California. We currently manufacture nine different types of catheters and three different types of sensors to support these catheter configurations. We have one production line focused on the various sensor assemblies, one production line focused on the various electrical harness assemblies and one line focused on final catheter assembly. We believe we have adequate capacity to support manufacturing of catheters needed to satisfy estimated demand for the foreseeable future.

We rely on some single source suppliers that provide unique components or that have developed unique processes to manufacture certain components for the catheter assemblies. With many of these suppliers we do not have written contracts or long term contracts for some other components necessary for the production of our high resolution manometry catheters. We maintain high inventory levels of some critical components or otherwise believe that we would be able to arrange substitute sources of supply for all of our single source components within approximately three to twelve months of lead time. We believe that if we need to find a substitute source of supply, our relationship with our suppliers, our inventory of components, sub-assemblies and finished products and our right or expected ability to submit final purchase orders prior to termination of the supply relationship with these suppliers, are sufficient to continue sales of our high-resolution catheters for all or most of the lead-time period.

Manometry Data Modules, Carts and Computer Workstations

Our high resolution ManoScan data modules are designed internally and manufactured with mostly externally procured components and subassemblies. All final assemblies are tested at our manufacturing facility. We have transitioned most of the manufacturing operations of the ManoScan data modules to our facility in Israel, with our facility in Los Angeles being used as a backup manufacturing facility. The primary components used in manufacturing on these items are off-the-shelf electronic components used on the various printed circuit board assemblies.

The ManoScan cart systems are designed internally and manufactured at an external subcontractor location within the United States. We provide certain components to the subcontractor and they are responsible for all assembly and testing. We believe that based upon our planned inventory levels and projected ability to execute final buy assemblies, our business will not be materially adversely affected if the relationship with this subcontractor is terminated and qualification of new cart manufacturer becomes necessary.

Our computer workstation is based upon a generic platform manufactured by a U.S-based supplier and configured in accordance with our specifications. We pre-load the workstation with our proprietary ManoView software.

Our conventional manometry platform, known as Polygraf, is manufactured by a subcontractor in Denmark. The relationship with this vendor was inherited as a result of a merger between Sierra and the gastroenterology diagnostic division of Alpine Biomed Corporation in September 2009 and we have since continued taking receipt of these devices from this supplier. We own the intellectual property associated with the Polygraf manometry platform. This product incorporates components that are no longer commercially available and we are working to develop a new design. We believe we have acquired sufficient inventory to prevent any supply interruption until the new design is available.

Disposable Sheaths

We design and manufacture various disposable sheaths for use with our high resolution and three dimensional high resolution catheters under the name ManoShield. Our facility in Vietnam is the primary manufacturing facility for ManoShields. These accessories are packaged in kits that include some off-the-shelf type components as well as some custom designed components manufactured specifically for this application. We rely on a few single source suppliers who provide unique components or who have developed unique processes to manufacture certain components to the disposable sheath assemblies according to our specifications. We do not have written agreements with these suppliers. We believe that based upon our planned inventory levels and projected ability to execute final buy orders, we should be able to maintain product availability continuity during the lead time required to qualify a replacement supplier, if necessary.

Disposable and Ambulatory pH Monitoring Devices

Our ambulatory reflux products are made up of three main components:

- *Disposable pH Catheters*. We design all of our disposable pH catheter devices in our Los Angeles facility and transfer to our Vietnam facility for production. The catheter manufacturing uses a number of custom developed processes that are used within the Vietnam facility. Most of the raw material components are procured as standard items from a variety of worldwide sources.

- *Ambulatory Recorders.* We manufacture two different ambulatory data recorders:

    - We procure one configuration from a supplier in Denmark. We own the design and intellectual property for this device. This device will be replaced by a new product in 2013.

    - We have designed one configuration in-house and manufacture it in our facility in Yoqneam, Israel.

- *Analysis Software*. We own two different internally-developed, proprietary analysis software applications which can be installed on a computer workstation.

The SmartPill System

We manufacture the SmartPill motility monitoring system primarily in our manufacturing facility in Israel. The manufacturing process for this system consists primarily of assembling externally purchased components and sub-assemblies in an environmentally controlled area. The SmartPill data recorder and cradle designs are owned by us; however these items are manufactured for us by external vendors. We believe we have adequate capacity to satisfy estimated demand for the SmartPill system for the foreseeable future.

We depend on single source suppliers for some components of the SmartPill system, such as the pH sensor of the capsule and the SmartBar. We do not have written contracts or long-term contracts with some of these suppliers. We believe that if we need to find a substitute source of supply, our relationship with our suppliers, our inventory of components, sub-assemblies and finished products and, as applicable, our right or expected ability to submit final purchase orders prior to termination of the applicable supply relationship, together are sufficient to continue sales of our SmartPill system for all or most of the lead time that will be regulated to develop alternative sources of supply.

Other Gastrointestinal Diagnostics Equipment and Supplies

We have a number of third-party developed or manufactured products and devices that we sell as part of our product portfolio. We depend on a number of single source relationships to maintain continuity of supply of these products. In some instances, there are alternate third-party solutions that would serve as adequate replacements; in other cases, we would need to work on transfer of manufacturing process should relationships with these suppliers be terminated.

Manufacturing Facilities and Disaster-Preparedness

In order to maintain our special tax benefits under our approved enterprise status in Israel, we conduct most of our manufacturing and a majority of our subcontracting in specific locations in Israel. We also have manufacturing facilities in Los Angeles for the manufacturing of our high resolution manometry catheters and a facility in Vietnam for the manufacturing of our pH and pH impedance catheters and other accessories. For more information, see Item 10 — “Additional Information — Taxation — Certain Material Israeli Tax Considerations and Government Programs — Taxation of Companies in Israel — Tax Benefits under the Law for the Encouragement of Capital Investments, 1959.”

We have also taken the following measures for disaster-preparedness:

- Our production lines in Israel are located in two adjacent but separate buildings and we can alternate the production activity between these two buildings if we are unable to use one of them.
- We have a basic assembly and basic test equipment for portions of our PillCam products in our Los Angeles facility.
- Our practice is to hold inventory of critical components, such as the imaging sensor and the transmitter of our PillCam capsules, for a period of time ranging from two months to 3-½ years, depending on the risk profile we allocate to each critical component.
- Our practice is to hold approximately six to ten weeks of inventory of finished products at our offices in Israel and at our subsidiaries.

The FDA requires us to adhere to the Quality System Regulation which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process. In addition, we are required to comply with the Medical Devices Directive of the European Union requiring adherence to the International Standard Organization's standard ISO 13485:2003 and quality and safety regulations in other countries, such as Japan and Canada. These quality standards contain requirements that are generally similar to the Quality System Regulation required by the FDA.

Intellectual Property

An important part of our competitive strategy is to seek, when appropriate, protection for our products and proprietary technology through the use of various United States and foreign patents, trademarks, trade secrets and contractual arrangements. We intend to prosecute and defend our proprietary technology.

As of December 31, 2012, we owned or co-owned 379 issued patents in the United States, Australia, Belgium, Canada, China, France, Germany, India, Israel, Italy, Japan, South Korea, Spain, Taiwan and the United Kingdom covering different elements of our technology. Most of our patents cover inventions of our employees and consultants and some we acquired from third parties. For example, as part of the acquisition of the Bravo pH monitoring business in late 2008, the acquisition of Sierra in April 2010 and the acquisition of SmartPill in 2012, we acquired a number of patents and patent applications relating to various aspects of these products and technologies.

These patents expire between 2014 and 2029. We also hold two utility models in Germany. As of December 31, 2012, we also had more than 300 pending patent applications worldwide based on approximately180 priority applications relating to various elements and functions of our products and related enhancements.

In 2012, two of our patents in Germany, which we previously succeeded in asserting against a competitor, were invalidated by the German patent office. We are waiting to receive the written decision to consider our next steps. Also, in February 2013, two Korean patents we asserted against a competitor were invalidated by the Korean Patent Court on appeal by the competitor of an earlier decision of the Korean Intellectual Property Tribunal to affirm the validity of these patents. We are waiting to receive the written decision of the Korean Patent Court to consider our next steps.

Competition

Capsule endoscopy

While we have the largest market share in the capsule endoscopy field in most countries, generally competition has intensified in recent years with known and new competitors performing research and development in the field of capsule endoscopy and working to establish competing sales channels and grow their presence in various markets in this field. Our competitors in the field of capsule endoscopy include Olympus Corporation, Intromedic Co. Ltd. and Chongqing Jinshan Science and Technology Co. We believe that we have a competitive advantage compared to other sellers of capsule endoscopes. First, we were the first company to sell and market capsule endoscopes and have the largest installed base of customers and a recognized and trusted brand name. Second, we are focused on a diversified capsule and software portfolio for visualization of the esophagus, small bowel and colon while our competitors offer only a small bowel capsule at this time. Third, we believe our technology is superior to the technology embedded in the products introduced by competitors and we continue to invest to maintain this competitive advantage. Fourth, we provide comprehensive customer support, extensive professional education and training to physicians and nurses, and support clinical research worldwide. Finally, our capsule endoscopy products are supported by the largest body of clinical evidence having been tested in hundreds of clinical studies with the results presented at major gastroenterology meetings and in more than 1,900 peer-reviewed-articles.

In addition, we face competition from existing technologies for detecting gastrointestinal disorders and diseases, including traditional endoscopy and radiology. Our success depends in part on convincing physicians to adopt our PillCam capsule endoscopy system over other technologies.

Three companies control the major portion of the worldwide gastrointestinal traditional endoscopy market. These companies, Olympus, Hoya and Fuji Film Corporation, or Fuji Film, have marketed and sold flexible endoscopic equipment for many years. These companies have substantially greater financial resources than we do, and they have established reputations as well as worldwide distribution channels for medical instruments to gastroenterologists. We are aware of research and development efforts by some of these companies and other individuals and companies to develop and bring to market imaging capsules or other minimally invasive imaging techniques.

In addition, there are several companies focused on radiological diagnostics that provide x-ray machines and other imaging products used for barium series radiological examinations. These companies include but are not limited to GE Healthcare, Siemens Medical Solutions, Philips Medical Systems and Toshiba Corporation.

Motility and pH Monitoring

With the acquisition of the Bravo product in late 2008 and the acquisition of Sierra in April 2010, we became a leading company in the field of manometry and pH measurement. Our main competitors in this field are Sandhill Scientific, Inc., a privately-held U.S. company, and Medical Measurements Systems, a privately-held company based in the Netherlands. In pH measurement, we are the only company offering both wireless pH monitoring technology and catheter-based pH monitoring capability. We provide the market with a single platform that provides Bravo and catheter-based monitoring capability and high-resolution manometry in an integrated workstation environment to displace existing multiple workstations with incompatible interfaces supplied by multiple vendors.

In motility measurement, also known as manometry, we market and sell an industry-leading high resolution and three dimensional high resolution manometry system. We believe our technology is superior to the technology used by our competitors. For example, we are the only company offering and selling three-dimensional high resolution catheters. Our ManoScan 360 high resolution manometry system has been used by the group of internationally recognized experts in the field of manometry who created the Chicago Classification of esophageal disorders. In addition, this technology was developed internally and we own or have exclusive license to use the know-how of our high resolution manometry technology, while the technology embedded in the high resolution manometry catheters sold by our main competitors was not developed by them and they are dependent on a single source supplier for the supply of these catheters. Finally, we have the largest sales force among our competitors in this field. We can leverage our sizable field sales force and the customer base of our capsule endoscopy and Bravo products to market and sell our manometry and pH measurement products and we expect this will increase our market share.

In late 2012, we acquired the SmartPill business, further solidifying our leadership in the diagnosis of motility disorders. With this acquisition, we have achieved a comprehensive suite of diagnostic solutions for motility problems and we can benefit from the considerable overlap that exists among the customer bases of our various product lines. The SmartPill system also fits well with our capsule-based, patient-friendly technologies of capsule endoscopy and Bravo. The SmartPill system has no direct competition in the field of GI. Primary competition comes from various radiology tests, such as GES and ROM. The ability to measure transit time in the entire gut in a single test and the ability to use the system in a gastroenterology clinic without the need to refer patients to radiology tests, are significant competitive advantages for the SmartPill system.

U.S. Government Regulation

FDA Clearance and Regulation

All of the products we market and sell in the United States have received FDA clearance. All of our products that have been cleared to date by the FDA have been cleared through the 510(k) clearance process that is further described below. Currently, we have FDA clearance to market the Given System with our PillCam SB and PillCam ESO capsules, as well as our functional diagnostic products, such as Bravo, Digitrapper, ManoScan and SmartPill in the United States. Our capsule endoscopy, manometry and SmartPill products are categorized as Class II devices. Our pH monitoring products are categorized as a Class I exempt device, the lowest risk category for medical devices.

FDA Clearance and Regulation of the Future Products

Any new medical device that we wish to commercially distribute in the United States will likely require either 510(k) clearance or premarket application approval from the FDA prior to commercial distribution. 510(k) clearance or amendment to premarket application is also required when a change is made to a legally marketed device or to expand the product label.

510(k) Clearance Process. To obtain 510(k) clearance, an applicant must submit a premarket notification demonstrating that the proposed device is substantially equivalent in intended use and in safety and effectiveness to a "predicate device" — either a previously 510(k) cleared device or a pre-amendment device for which the FDA has not called for premarket applications. The FDA's 510(k) clearance process usually takes from three to 12 months, but it can last longer. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could even require a premarket application approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with the determination, the agency may retroactively require the manufacturer to seek 510(k) clearance or premarket application approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or pre-market application approval is obtained. Our PillCam SB and PillCam ESO capsules, the RAPID software and data recorder, the Bravo system and Sierra's products have each received FDA marketing clearance under the 510(k) clearance process. Our future products may not be eligible for the same abbreviated regulatory treatment. Recently, the FDA has announced plans to review the 510(k) clearance process. Changes in existing regulatory requirements or adoption of new requirements may make it more difficult or prevent us from obtaining marketing clearance for our products in the United States.

De Novo Classification. If the FDA denies 510(k) clearance of a device because it is novel and an adequate predicate device does not exist, the "de novo classification" procedure can be invoked based upon reasonable assurance that the device is safe and effective for its intended use. This procedure approximates the level of scrutiny in the 510(k) process but may add several months to the clearance process. If the FDA grants the request, the device is permitted to enter commercial distribution in the same manner as if 510(k) clearance had been granted. We received our original FDA clearance for the Given System with our PillCam SB capsule pursuant to the de novo classification procedure which is intended for novel but low risk devices. In 2011, in an effort to make the regulatory clearance process more efficient, the FDA published draft guidelines of an improved de novo process referred to as "direct de novo." Under this process, applicants can submit their 510(k) concurrently with the additional information normally required by the FDA in the de novo process, thereby avoiding the two-step process of the traditional de novo and potentially shortening the time for clearance. In November 2012, we submitted our PillCam COLON capsule for clearance with FDA under the direct de novo route.

Premarket Application Approval Process. If the FDA denies 510(k) clearance for a product and denies de novo classification, the product must follow the premarket application approval process, which requires proof of the safety and effectiveness of the device to the FDA's satisfaction. A premarket application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. After approval of a premarket application, a new premarket application or premarket application supplement is required in the event of a modification to the device, its labeling or its manufacturing process. The premarket application approval pathway is much more costly, lengthy and uncertain. It typically takes from one to three years, but it could take longer.

FCC Clearance and Regulation

Because some of our products use a wireless radio frequency transmitter and receiver, they are subject to equipment authorization requirements in the United States. The U.S. Federal Communications Commission, or FCC, requires advance clearance of all radio frequency devices before they can be sold or marketed in the United States. These clearances ensure that the proposed products comply with FCC radio frequency emission and power level standards and will not cause interference. We have the required clearances from the FCC. However, any modifications to our products may require new or further FCC approval before we are permitted to market and sell these products, and it could take several months to obtain any necessary FCC approval.

Anti-Kickback and False Claims Laws

In the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services. Violations of these laws can lead to civil and criminal penalties, including exclusion from participation in federal healthcare programs. These laws constrain the sales, marketing and other promotional activities of manufacturers of medical devices like us, by limiting the kinds of financial arrangements (including sales programs) we may have with hospitals, physicians and other potential purchasers of the medical devices. Other provisions of state and federal law provide civil and criminal penalties for presenting, or causing to be presented, to third-party payors for reimbursement, claims that are false or fraudulent, or which are for items or services that were not provided as claimed.

Health Insurance Portability and Accountability Act of 1996 and Related Laws

U.S. Federal and state laws protect the confidentiality of certain patient health information, including patient records, and restrict the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services, or HHS, promulgated patient data privacy and security rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA.

The privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their protected health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose.

The HIPAA privacy rules prohibit "covered entities," such as healthcare providers and health plans, from using or disclosing an individual's protected health information, unless the use or disclosure is authorized by the individual or is specifically required or permitted under the privacy rules. Under the HIPAA security rules, covered entities must establish administrative, physical and technical safeguards to protect the confidentiality, integrity and availability of electronic protected health information maintained or transmitted by them or by others on their behalf. While we do not believe that we are a covered entity under HIPAA, many of our customers are covered entities subject to HIPAA. Such customers may require us to enter into business associate agreements, which obligate us to safeguard certain health information we obtain in the course of our relationship with them, restrict the manner in which we use and disclose such information and impose liability on us for failure to meet our contractual obligations.

In addition, under The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, which was signed into law as part of the U.S. stimulus package in February 2009, certain of HIPAA's privacy and security requirements are now also directly applicable to "business associates" of covered entities and subject them to direct governmental enforcement for failure to comply with these requirements. We may be deemed as a "business associate" under HIPAA of some of our customers, even in the absence of a business associate agreement. As a result, we may be subject as a "business associate" to civil and criminal penalties for failure to comply with applicable privacy and security rule requirements. Moreover, HITECH created a new requirement obligating covered entities and business associates to report any breach of unsecured, individually identifiable health information and imposes penalties for failing to do so.

In January 2013, HHS issued final HITECH omnibus rules implementing significant changes to the HIPAA regulations, which new regulations include increased liability for violations of the regulations by business associates. Most of the new requirements go into effect by September 23, 2013.

In addition to HIPAA, most U.S. states have enacted patient confidentiality laws that protect against the disclosure of confidential medical information, and many U.S. states have adopted or are considering adopting further legislation in this area, including privacy safeguards, security standards, and data security breach notification requirements.

Regulation in Europe

Commercialization of medical devices in member countries of the European Union is regulated by directives adopted by the European Union. The European Union presently requires that all medical products bear the CE mark, an international symbol of adherence to quality assurance standards and demonstrated clinical effectiveness. Compliance with the Medical Device Directive, as certified by a recognized European Notified Body, permits the manufacturer to affix the CE mark on its products. We have authority to affix the CE mark to all our products that are currently commercially available in the European Union.

If we modify any of our products, we may need to apply for permission to affix the CE mark to the modified product. Additionally, we will need to apply for a CE mark for any new products that we may develop in the future. We cannot be certain that we will be able to obtain permission 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 that we receive. If we are unable to maintain 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.

In Europe, the frequency range in which our products operate is subject to technical standards for radio frequency use developed by the Short Range Device Maintenance Group of the European Conference of Postal and Telecommunications Administrations. We currently have clearance to operate our products in Europe based on the current product design and specifications; however, modifications to these products may require new or further approvals before we are permitted to market and sell a modified product, and it could take several months to obtain any necessary approvals.

Regulation in Japan and in Other Countries

In Japan, we have regulatory clearance to market our capsule endoscopy system with our second-generation PillCam SB capsule and our manometry and catheter-based pH monitoring systems. In March 2012, Japan's Ministry of Health, Labor and Welfare, or MHLW, cleared the PillCam Patency Capsule for use with PillCam SB and expanded the indications for use of the PillCam SB video capsule to include patients with any known or suspected small bowel disease, including the visualization and diagnosis of Crohn's disease.

Marketing our other products in Japan will require additional, product-specific regulatory clearances. Generally, the process for obtaining marketing clearance for medical devices in Japan could range from twelve months for products with only very minor modifications from previous cleared product versions, to a few years in the case of a completely new device. In September 2012, we filed an application with the Pharmaceutical and Medical Device Agency, or PMDA, to approve our PillCam COLON capsule for marketing and sale in Japan. We expect the application review process to last approximately one year.

To date, our Bravo and SmartPill systems do not have regulatory clearance in Japan and are not marketed there. We do not have immediate plans to submit these systems for clearance in Japan.

In order for us to market our products in countries other than the United States, the European Union and Japan (which were described above), we must obtain regulatory approvals and comply with extensive safety and quality regulations in these countries. These regulations, including the requirements for approvals or clearance and the time required for regulatory review, vary from country to country. Failure to obtain regulatory approval or clearance in any foreign country in which we plan to market our product may harm our ability to generate revenue and harm our business.

In all of the countries in which we are currently selling our products we have either received regulatory approval or clearance or been informed that approval or clearance is not required. Renewals or updates of the regulatory status of our products in all these countries are done as required.

In many of the countries in which we sell our products through distributors, the regulatory clearance for our products, often referred to as the product registration, is issued in the name of our local distributor. Applying, maintaining, extending or renewing regulatory clearances to our products in these countries may require actions by our distributors. We therefore depend on our distributors to be able to sell our products in these countries.

Third-Party Reimbursement

Reimbursement in the United States

In the United States, healthcare providers that purchase medical devices generally rely on third-party payors, such as Medicare, Medicaid, private health insurance plans and health maintenance organizations, to reimburse all or a portion of the cost of the devices, as well as any related healthcare services utilizing the devices. FDA clearance does not result in coverage and reimbursement by third-party payors.

Coding. Generally, a current procedural terminology, or CPT, code is necessary to facilitate claims for reimbursement. If a procedure is not covered by an appropriate existing code, an application for a new code can be made to the American Medical Association, or AMA. However, this process can be lengthy, typically taking two or more years before the new code is effective. In the meantime, claims may be submitted using a miscellaneous CPT code or using a temporary G-code, if one is established by the Department of Health and Human Services' Centers for Medicare and Medicaid Services, or CMS.

For capsule endoscopy of the small bowel performed in a physician's office, the CPT code includes a global value for both the technical and the professional components of the procedure. In the outpatient hospital setting, claims are submitted using the CPT code and paid by Medicare under the Ambulatory Payment Classification, or APC, which covers the technical component and includes the cost of the facility and supplies related to the procedure. The physician is paid separately for the interpretation.

For capsule endoscopy of the esophagus performed in a physician's office, the CPT code includes a global value for both the technical and the professional components of the procedure. In the outpatient hospital setting, claims are submitted using the CPT code and paid by Medicare under the APC, which covers the technical component and includes the cost of the facility and supplies related to the procedure. The physician is paid for the interpretation separately. In November 2006, CMS assigned an upper gastrointestinal diagnostic category APC for capsule endoscopy of the esophagus in the hospital outpatient setting effective January 2007. Since January 2012, , capsule endoscopy of the esophagus is classified as a Level II upper gastrointestinal diagnostic APC category.

For Bravo and catheter-based pH monitoring and esophageal manometry procedures performed in a physician's office, the CPT code includes a global value for both the technical and the professional components of the procedure. In the outpatient hospital setting, claims are submitted using the CPT code and paid by Medicare under the APC, which covers the technical component and includes the cost of the facility and supplies related to the procedure. The physician is paid for the interpretation separately.

Effective January 1, 2013, a permanent Category I CPT Code was established for the SmartPill procedure. For SmartPill procedures performed in a physician's office, the CPT code includes a global value for both the technical and the professional components of the procedure. In the outpatient hospital setting, claims are submitted using the CPT code and paid by Medicare under the APC, which covers the technical component and includes the cost of the facility and supplies related to the procedure. The physician is paid for the interpretation separately.

Reimbursement Coverage. A third-party payor's decision to cover a device or medical procedure is independent of the coding process, although the existence of an appropriate CPT code and APC may assist in obtaining coverage. Generally, third-party payors may deny coverage if they determine that a procedure was not reasonable or necessary as determined by the payor, was experimental or was used for an unapproved indication. During the past several years, the major third-party payors have substantially revised their reimbursement methodologies in an attempt to contain or reduce their healthcare reimbursement costs.

Third-party payors in the United States began issuing coverage policies for capsule endoscopy in early 2002. Initially, all reimbursement policies provided coverage for capsule endoscopy of the small bowel only for the diagnosis of obscure gastrointestinal bleeding. Subsequently, reimbursement coverage has been expanded to include other indications and, as of December 31, 2012, most Medicare carriers and private third-party payors, with a total insured population in the United States of approximately 220 million individuals, also cover capsule endoscopy of the small bowel for suspected Crohn's disease, suspected small bowel tumors and other small bowel pathologies.

We continuously attempt to improve reimbursement coverage for the PillCam SB capsule. Most of the reimbursement policies currently in effect require that a previous procedure, such as endoscopy or radiology, be performed prior to using capsule endoscopy and some may require prior authorization. We are continuously seeking to convince third-party payors, through economic and health outcomes analyses, that capsule endoscopy of the small bowel should be used earlier in the typical diagnostic process for patients with inflammatory bowel diseases such as Crohn's disease, and be entitled to reimbursement coverage without requiring upper endoscopy or radiology procedures to be performed prior to administering the capsule. As a result of these efforts, as of December 31, 2012, out of the 220 million individuals who have coverage in the United States for small bowel capsule endoscopy for suspected Crohn's, approximately 51 million individuals have coverage that no longer requires an upper endoscopy and require only a colonoscopy as an endoscopic procedure to be performed prior to a small bowel capsule endoscopy procedure for detecting suspected Crohn's , approximately 18 million individuals have coverage for a small bowel capsule endoscopy procedure in cases of known Crohn's of the large bowel that require small bowel evaluation and 26 million individuals have coverage with no restrictions or limitations from their payers for capsule endoscopy. As of December 31, 2012, approximately 53 million individuals have coverage for capsule endoscopy of the small bowel for diagnostic re-evaluation of Crohn's disease if patients remain symptomatic after receiving treatment and there is no suspected or confirmed gastrointestinal obstruction, stricture or fistula. This coverage supports the latest regulatory clearance to use PillCam SB to monitor inflammatory bowel disease, such as Crohn's. The only pre-condition is for patients who remain symptomatic after receiving treatment; timeframes are not specified.

As of December 31, 2012, approximately 60 million individuals in the United States had reimbursement coverage for capsule endoscopy of the esophagus using our PillCam ESO capsule to evaluate esophageal varices in patients diagnosed with cirrhosis of the liver, a chronic liver disease.

As of December 31, 2012, approximately 220 million individuals in the United States had reimbursement coverage for catheter-based pH monitoring procedure and Bravo pH monitoring procedure. The most common accepted indications for coverage are for patients with esophageal reflux who are being considered for surgical anti-reflux repairs and patients with normal endoscopic findings and reflux symptoms who are unresponsive to therapy.

As of December 31, 2012, approximately 220 million individuals in the United States had reimbursement coverage for esophageal manometry. Esophageal manometry is a procedure for determining how well the muscle of the esophagus works when diseases of the muscle are suspected by measuring pressures generated by the esophageal muscles. The most common accepted indications for coverage are evaluation of the esophagus when there is reflux of the stomach acid and contents back into the esophagus, evaluation of swallowing disorders (dysphagia) and evaluation of chest pain that may be coming from the esophagus.

As of December 31, 2012, approximately 42 million individuals in the United States had reimbursement coverage for the diagnosis of motility problems using our SmartPill system. The most common accepted indications for coverage are for the evaluation of gastroparesis, or delayed emptying of the stomach, and chronic constipation.

In addition to established reimbursement coverage, numerous third-party payors are reimbursing various procedures with our products on a case-by-case basis. We have established a toll-free reimbursement help-line whereby reimbursement specialists assist our customers with general information about the process of submitting prior authorizations, claims and appeals in the event of a denial.

Reimbursement Rates. Even if a device or medical procedure is covered, reimbursement rates must be adequate for most providers to use it routinely. Reimbursement rates vary depending on the third-party payor and individual insurance plan involved, the procedure performed and other factors. Medicare reimbursement for inpatient hospital services is based on a fixed amount per admission based on the patient's specific diagnosis and the procedure performed during the hospital stay. As a result, any illness to be treated or procedure to be performed in an inpatient setting will be reimbursed only at a prescribed rate set by the government. However, many procedures using our products are not subject to these restrictions for hospital inpatient services whenever they are performed on an outpatient basis and reimbursed by Medicare under the outpatient regulations, which allows for separate reimbursement. For example, Medicare is covering the capsule endoscopy procedure under the outpatient regulations because our PillCam platform is purchased for placement in an outpatient setting, where patients are not admitted to a hospital as an in-patient for the capsule endoscopy procedure.

In 2012, for procedures performed in a physician's office, the national average global fee paid by Medicare under the CPT code for capsule endoscopy of the small bowel was $940, an increase of $20 compared to 2011. For procedures performed in an outpatient hospital setting, the national average physician fee paid by Medicare was $197, similar to 2011, and the national average payment rate to the hospital for the technical component was $724. These payment rates are modified annually. Effective January 1, 2013, the national average global fee paid by Medicare for a procedure in a physician's office was increased to $971, the national average physician fee for the professional component of a hospital outpatient procedure remained at $197 and the national average payment rate to the hospital for the technical component increased to $751 due to an increase in the APC rate for gastrointestinal small bowel procedures classified under APC 142.

For capsule endoscopy of the esophagus, in 2012, the national average global fee paid by Medicare for a procedure in a physician's office was $766. The national average physician fee paid by Medicare in an outpatient hospital setting was $54 and the national average payment rate to the hospital for the technical component was $885, under the APC 419 for Level II upper gastrointestinal procedures. Effective January 1, 2013, the national average global fee paid by Medicare for a procedure in a physician's office increased to $812, the national average physician fee paid by Medicare in an outpatient hospital setting remained at $54 and the national average payment rate to the hospital for the technical component increased to $927.

For Bravo pH monitoring, in 2012, the national average global fee paid by Medicare for a procedure in a physician's office was $503 compared to $485 in 2011. The national average physician fee paid by Medicare in an outpatient hospital setting was $84, the same as in 2011, and the national average payment rate to the hospital for the technical component was $286, compared to $282 in 2011, under the APC 361 for Level II alimentary tests. Effective January 1, 2013, the national average global fee paid by Medicare for a procedure in a physician's office increased to $526, the national average physician fee paid by Medicare in an outpatient hospital setting remained at $84 and the national average payment rate to the hospital for the technical component increased to $303 under the APC 361 for Level II alimentary tests.

For catheter-based pH monitoring, in 2012, the national average global fee paid by Medicare for a procedure in a physician's office was $200 compared to $198 in 2011. The national average physician fee paid by Medicare in an outpatient hospital setting was $52, the same as in 2011, and the national average payment rate to the hospital for the technical component was $286, compared to $282 in 2011, under the APC 361 for Level II alimentary tests. Effective January 1, 2013, the national average global fee paid by Medicare for a catheter-based pH monitoring procedure in a physician's office increased to $202, the national average physician fee paid by Medicare in an outpatient hospital setting decreased to $51, and the national average payment rate to the hospital for the technical component increased to $303 under the APC 361 for Level II alimentary tests.

For esophageal manometry in 2012, the national average global fee paid by Medicare for a procedure in a physician's office was $187 compared to $188 in 2011. The national average physician fee paid by Medicare in an outpatient hospital setting decreased to $68 from $69 in 2011, and the national average payment rate to the hospital for the technical component was $286, compared to $282 in 2011, under the APC 361 for Level II alimentary tests. Effective January 1, 2013, the national average global fee paid by Medicare for an esophageal manometry procedure in a physician's office increased to $188, the national average physician fee paid by Medicare in an outpatient hospital setting remained at $68 and the national average payment rate to the hospital for the technical component increased to $303 under the APC 361 for Level II alimentary tests.

In 2012, for procedures performed in a physician's office, the national average global fee paid by Medicare under the Category III CPT code for the SmartPill procedure averaged $1,200. For procedures performed in an outpatient hospital setting, the national average physician fee paid by Medicare was approximately $300, and the national average payment rate to the hospital for the technical component was approximately $900. Effective January 1, 2013, the SmartPill product has been classified as a Category I CPT code and the national average global fee paid by Medicare for a procedure in a physician's office was set at $1,189, the national average physician fee for the professional component of a hospital outpatient procedure was $112 and the national average payment rate to the hospital for the technical component was $303.

Coverage Outside the United States

In countries outside the United States, coverage is obtained from various sources, including governmental authorities, private health insurance plans, and labor unions. In some countries, private insurance systems may also offer payments for some therapies. Although not as prevalent as in the United States, health maintenance organizations are emerging in certain European countries. Coverage systems in international markets vary significantly by country and, within some countries, by region. Coverage approvals must be obtained on a country-by-country or region-by-region basis. In general, the process of obtaining coverage approvals has been slower outside of the United States.

In Europe, the population with reimbursable access to small bowel capsule endoscopy at the end of 2012 was approximately 226 million, similar to the situation at the end of 2011. The number of people in Europe with reimbursement for indications in addition to OGIB at the end of 2012 was approximately 161 million. In January 2011, the German Ministry of Health has announced its intention to create an outpatient reimbursement code for PillCam SB capsule endoscopy for obscure gastrointestinal bleeding. The declaration began a process for establishing a medical code, after which the 73 million Germans covered by the public health system, or about 90% of the entire German population, will have access to the PillCam SB procedure, with full reimbursement under the German statutory health insurance system. This process is out of our control and the timing to receive the medical code is unpredictable. Approximately eight million Germans, or 10% of the population, already have coverage for PillCam SB capsule endoscopy through private health insurers. PillCam SB capsule endoscopy has been covered for inpatient use in Germany since 2004. In addition, in January 2011, Germany's Institut fuer das Entgeltsystem im Krankenhaus (INEK, Institute for Reimbursement in Hospitals) published the 2011 update of the Diagnosis Related Group , or DRG, Codes and Grouper algorithm, which includes an inpatient reimbursement pathway for PillCam® COLON capsule endoscopy. The Grouper algorithm assists in determining the reimbursement value of a particular use of this capsule. Any publicly insured individual, or approximately 90% of the German population, will have coverage under this updated scheme, which establishes a reimbursement framework for PillCam COLON capsule endoscopy as an inpatient hospital procedure for a number of cases, enabling hospitals to seek reimbursement for such cases.

In Japan, the entire adult population has been eligible for reimbursement of the PillCam SB capsule procedure for small bowel indications with obscure gastrointestinal bleeding since October 2007. In March 2012, Japan's MHLW cleared the PillCam Patency Capsule for use with PillCam SB and expanded the indications for use of the PillCam SB video capsule for patients with any known or suspected small bowel disease, including the visualization and diagnosis of Crohn's disease. We received reimbursement for this expanded indication in July 2012.

In Australia, reimbursement coverage for use of capsule endoscopy in the detection of gastrointestinal bleeding and for the surveillance of patients with Peutz Jeghers Syndrome exists for all permanent residents, including those holding Australian and/or New Zealand citizenship, providing coverage for approximately 20 million residents. In May 2008, the Department of Health and Ageing in Australia approved permanent government funding and reimbursement for capsule endoscopy of the small bowel.

In December 2010, Brazil's Medical Association issued a reimbursement code for capsule endoscopy of the small bowel. We are working with national and private health agencies in Brazil to include capsule endoscopy on their approved list of procedures under this code so that Brazilians can have access to this reimbursement coverage. We expect that all of Brazil's 190 million citizens will gradually obtain access to capsule endoscopy with our PillCam SB capsule. However, this process is unpredictable, is out of our control and could take a few years.

While coverage in Austria, Switzerland, Spain, Germany, Australia and Japan is generally limited to the indication of suspected small intestinal bleeding, the public healthcare systems in the Czech Republic, Denmark, France, some Italian regions, Israel, Portugal, Sweden and the United Kingdom cover capsule endoscopy for broader indications, including suspected Crohn's disease. We may be unable to obtain additional approvals in a timely manner or at all.

Outside the United States, reimbursement coverage for our esophageal motility or pH monitoring products varies significantly country by country. In many countries it exists for manometry and catheter-based pH monitoring, in others it does not exist at all and in others still it is insufficient to cover the cost of the procedure. There is no reimbursement outside the United States for our SmartPill product.

C. Organizational Structure

Given Imaging Ltd. is organized under the laws of the State of Israel and, as of the date of this annual report, held directly or indirectly the outstanding capital stock of the following subsidiaries and in the following ownership percentages:

Name of Subsidiary	Country of Incorporation	Percentage Ownership
Given Imaging Pty. Ltd.	Australia	100
Given Imaging, Inc.	Delaware	100
Given Imaging s.a.s.	France	100
Given Imaging GmbH	Germany	100
Given Imaging B.V.	Netherlands	100
Given Imaging K.K.	Japan	100
Given Imaging (Asia-Pacific) PTE Ltd.	Singapore	100
Given Imaging (Asia) Company Ltd.	Hong Kong	100
Given Imaging do Brazil Ltda.	Brazil	100
Given Imaging (Los Angeles) Holding Corporation	Delaware	100
Given Imaging (Los Angeles) LLC	Delaware	100
Given Imaging Vietnam Co., Ltd.	Vietnam	100
Endonetics, Inc.	California	100

D. Property, Plants and Equipment

We lease a total of approximately 12,000 square meters (approximately 129,166 square feet) in Yoqneam, Israel, hosting our corporate headquarters and a number of production lines, under a lease that expires on December 31, 2018.

We believe that our existing facilities will be adequate to meet our production and other needs in Israel for the foreseeable future.

Our subsidiaries are party to the following leases:

- Given Imaging, Inc. leases 3,363 square meters (35,579 square feet) of office and warehouse space in Duluth, Georgia under a lease that expires in May 2015;
- Given Imaging GmbH leases approximately 1,217 square meters (13,094 square feet) of office space in Hamburg, Germany, pursuant to a lease for an indefinite term that may be terminated by us or the landlord with an advance notice of six months;

- Given Imaging Pty. Ltd. leases 560 square meters (6,023 square feet) of office space in North Ryde, Australia, pursuant to a lease that expires on January 31, 2017;
- Given Imaging s.a.s. leases a total of 460 square meters (4,951 square feet) of office space in Maisons-Laffitte, France pursuant to a lease that expires in December 2015;
- Given Imaging K.K. leases 443 square meters (4,765 square feet) of office space in Tokyo, Japan pursuant to a lease that expires in August 2013;
- Given Imaging (Asia) Company Ltd. leases 110 square meters (1,183 square feet) of office space in Hong Kong, pursuant to a lease that expires on August 31, 2013;
- Given Imaging do Brazil Ltda. leases 20 square meters (215 square feet) of office space in Sao Paulo, Brazil, pursuant to a lease for an indefinite term that may be terminated by us or the landlord with an advance notice of one month.
- Given Imaging (Los Angeles), LLC leases 2,341 square meters (25,200 square feet) of office space and manufacturing facilities in Los Angeles, California pursuant to a lease that expires on September 30, 2020; and
- Given Imaging Vietnam Co. Ltd leases 1,091 square meters (11,739 square feet) of factory and office space in Ho-chi-minh City, Vietnam pursuant to a lease expiring February 28, 2014.

Item 4A. Unresolved Staff Comments

None.

Item 5. Operating and Financial Review and Prospects

A. Operating Results

Overview

We develop, manufacture and market innovative diagnostic products for disorders of the gastrointestinal tract. Our principal product, which incorporates our core technology, is the PillCam capsule endoscopy system, a proprietary wireless imaging system that represents the standard of care in visual examination of the small bowel and a new approach in visualization of other parts of the gastrointestinal tract. The system uses a miniaturized video camera contained in a disposable capsule, which we refer to as the PillCam capsule, that is ingested by the patient and delivers high quality color video in a noninvasive manner. Our main objective, subject to further development and receipt of regulatory clearances and/or approvals, is to establish the PillCam capsule endoscopy system as a leading patient-friendly platform for visualizing and detecting disorders in all parts of the gastrointestinal tract. We believe that each segment of the gastrointestinal tract presents meaningful opportunities for patient-friendly medical procedures.

We commenced marketing of the PillCam SB capsule for detection of disorders of the small bowel in 2001. We later developed and began marketing PillCam ESO for visualizing the esophagus and PillCam COLON for visualizing the colon. As of December 31, 2012 we had sold more than 1.9 million capsules, mostly PillCam SB capsules, in more than 75 countries worldwide and had approximately 5,500 active customers. We have also developed a patency capsule, which is a dissolvable capsule that enables physicians to determine whether there are obstructions or strictures in the gastrointestinal tract that may prevent passage of our PillCam capsules.

In December 2008, we acquired the Bravo pH monitoring business from Medtronic. This was our first acquisition since our inception. The Bravo pH monitoring system is the only wireless, catheter-free pH test for GERD, and uses a disposable capsule temporarily placed in the esophagus that measures pH levels and transmits the data to an external receiver.

On April 1, 2010, we acquired Sierra Scientific Instruments, or Sierra. Sierra was a leading provider of specialty diagnostic devices for the gastrointestinal tract. With this acquisition, we advanced our goal of providing comprehensive diagnostic solutions to our customers in the field of gastroenterology. From a financial perspective, this acquisition has contributed to the growth of our revenue and profitability. This acquisition enabled us to diversify our product and geographic revenues through access to additional products, people, and manufacturing assets. In 2012, we changed the name of Sierra to Given Imaging (Los Angeles) LLC, or GILA.

In October 2012, we acquired the SmartPill business for $6 million plus an earn-out. The SmartPill® is an ingestible capsule that uses sensor technology to measure pH, pressure and temperature in the gastrointestinal tract. The SmartPill system measures gastric emptying and the transit time of solid and liquid content through the entire gastrointestinal tract and is used to evaluate motility disorders like gastroparesis and constipation.

We were incorporated in Israel in January 1998. We raised approximately $53.2 million of net proceeds in our initial public offering in October 2001 and have been listed since then on the Nasdaq Global Select Market. We completed a follow-on offering in June 2004 in which we raised additional net proceeds of $44.3 million. Since March 2004, our shares have also been listed on the Tel-Aviv Stock Exchange. We devote substantially all of our resources to developing and marketing devices to detect gastrointestinal disorders, acquiring new products and technologies in the field of gastroenterology, performing clinical trials and selling our products worldwide.

Revenues

We derive most of our revenues from recurring sales of our PillCam SB capsules to our existing installed base, from sales of our Bravo system and sales of our high resolution manometry systems, known as the ManoScan family of equipment, and catheter-based pH and pH and impedance monitoring systems. To a lesser extent, we derive our revenues from sales of capsule endoscopy capital equipment, such as RAPID workstations and data recorders, and software, such as RAPID Access. We also derive a small portion of our revenues from post-sale customer support contracts entered into by customers at the end of the warranty period for the computer workstation and data recorders. We also derive limited revenues from sales of our Agile patency system.

Revenue Breakdown. A majority of our revenues is generated from sales of our PillCam capsules, particularly PillCam SB capsules. In 2012, we derived approximately 65% of our revenues from sales of our PillCam SB capsules, compared to 66% of our revenues in 2011 and 70% of our revenues in 2010. Sales of each of the PillCam ESO capsule and the PillCam COLON capsule were insignificant in these periods. The percentage of PillCam SB capsules revenues out of total revenues has declined primarily due to the increased sales of our manometry and catheter-based pH products.

In 2012, we derived approximately 10% of our revenues from sales of the Bravo system and its components, compared to 11% of our revenues in 2011 and 12% of our revenues in 2010. In 2012, we derived approximately 19% of our revenues from sales of our ManoScan and Digitrapper products, compared to 16% of our revenues in 2011 and 11% during the last three quarters of 2010, following our acquisition of Sierra in April 2010. We expect that sales of the Bravo system and our Digitrapper and ManoScan products will continue to contribute significantly to our revenues, particularly in the United States. We also expect that a majority of our revenues in the future will continue to come from recurring sales of our capsules.

Following the acquisition of the SmartPill business, we began generating revenues from sales of the SmartPill system. We recorded revenues of $0.6 million from sales of SmartPill during the fourth quarter of 2012.

The following table sets forth information for the periods indicated regarding the breakdown of our revenues:

	$			% of Annual Revenues		
	2012	2011	2010	2012	2011	2010
	(U.S. Dollar in Thousands)					
Workstations, RAPID Access and data recorders	$ 7,533	$ 9,060	$ 8,120	4.2%	5.1%	5.0%
PillCam SB capsule	116,618	117,561	110,189	64.6	66.1	70.0
PillCam COLON capsule	1,981	1,798	1,291	1.1	1.0	1.0
Other capsule endoscopy products (ESO & Patency capsules and scanners)	1,175	1,217	1,205	0.7	0.7	0.7
Bravo business	17,677	19,746	18,603	9.8	11.1	11.7
Manometry, catheter-based pH and Impedance	34,704	28,460	17,913*	19.2	16.0	11.3
SmartPill business	594**	--	--	0.3	--	--
Service and accessories	219	113	488	0.1	--	0.3
Total	$ 180,501	177,955	$ 157,809	100%	100%	100%

* Represents revenues from April 1, 2010

** Represents revenues since October 2012

Capsule Endoscopy Products

Workstations and Data Recorders. In 2012, our revenues from the sale of capsule endoscopy workstations and data recorders decreased compared to our revenues from the sale of these products in 2011. Typically, sales of capital equipment are more significant in new markets or in areas where a major reimbursement announcement occurs. In the more mature markets, such as Europe and the United States, our revenues from the sale of workstations and data recorders are decreasing compared to prior periods. The decrease in revenues from sale of capital equipment in these markets is attributable to both lower quantities of workstations and data recorders sold and lower average selling price. We believe this decrease in revenues from sale of capital equipment is due in part to our already existing large installed based in the major markets, in part to the global economic crisis that has caused customers to delay capital investment decisions and in part due to competitive pressure.

In addition, with the introduction of new products or newer versions of existing products or as part of our promotional activities, we place our capital equipment, or replace older equipment of many customers with newer versions of our capital equipment, at a reduced price. This resulted in a lower average selling price for our capital equipment.

RAPID Access. RAPID Access is a version of our capsule endoscopy software that can be installed on customers' hardware and enables PillCam capsule endoscopy study management to be performed in a network environment. RAPID Access supports a variety of customized workflow models to best suit the customers' unique needs, including import of patient demographic data and export of procedure reports, in addition to accessing network resources such as storage drives and printers. Most customers prefer this version of our software over the stand-alone RAPID workstations due to the customers' reluctance to invest in capital equipment and the operational convenience afforded by working in a network environment.

PillCam SB. Substantially all of our revenues from capsule sales were attributable to sales of the PillCam SB capsule. We believe this is primarily because the market for the PillCam SB capsule is currently a more developed market, including in terms of the scope of reimbursement coverage around the world, the large amount of clinical data to support the use of this capsule and the lack of other accepted imaging modalities of the small bowel.

In 2012, worldwide PillCam SB sales were $116.6 million, compared to $117.6 million in 2011. We expect recurring sales of the PillCam SB capsule to continue to account for a substantial majority of our revenues from capsule sales in 2013. In March 2011, we received updated clearance from the FDA for our PillCam SB capsule. The PillCam SB capsule has been cleared since 2001 for the visualization of the small bowel mucosa and may be used as a tool in the detection of abnormalities of the small bowel in adults and children from two years of age. The updated labeling allows us to promote the use of this capsule for monitoring inflammatory bowel disease, such as Crohn's disease. We have increased our sales and marketing activities for this indication; however, we believe that impact on revenues has been limited, primarily due to limited reimbursement for the "monitoring" indication and to a lesser extent due to established habits and conceptions of medical practitioners that take time to change. It is difficult for us to determine with certainty the indications for which physicians use the PillCam SB capsule because we have no standard tool that tracks this data. Gradual implementation of reimbursement coverage for PillCam SB in Germany and Brazil, which we describe in more details below in this section under the heading "Reimbursement," are also expected to contribute to increased sales of PillCam SB over the next few years, but did not have an impact in 2012. The effective date of such reimbursement coverage is a matter of governmental decision and is uncertain, difficult to predict and outside of our control.

There are factors that have had a negative impact on the growth rate of sales of our PillCam SB capsule, including maturation of the market for the OGIB indication in the United States, slow adoption of new indications of use beyond OGIB, intense competition, a decrease in endoscopic procedures in the United States, which usually precede the use of capsule endoscopy, and a decrease in sales in certain European countries due to a difficult macroeconomic environment.

For more information on PillCam SB sales see in this Item 5 under "geographical breakdown."

PillCam ESO. We have marketed the PillCam ESO in the United States since November 2004. Since then, sales of our PillCam ESO were insignificant due primarily to the lack of favorable reimbursement coverage, as well as limited clinical data to support widespread use of the PillCam ESO capsule compared to other available alternatives to visualize the esophagus and detect esophageal disorders.

As of December 31, 2012, approximately 45 million individuals in the United States had reimbursement coverage for using the esophageal capsule endoscopy procedure in the detection of esophageal varices, a common condition in patients diagnosed with cirrhosis of the liver, a chronic liver disease. Reimbursement coverage for the use of PillCam ESO in the detection of Gastro-Esophageal Reflux Disease, or GERD, which is more prevalent in the general population than esophageal varices, is not expected before additional clinical data supporting such use is available. Because esophageal varices is not a common condition in the general population, we expect that sales of PillCam ESO for the foreseeable future will continue to be immaterial to our total revenues. We believe that sales of the PillCam ESO capsule could increase when and if there is clinical data and reimbursement coverage to support and cover the use of this capsule in GERD patients; however, significant market development, planning and other resources are required to achieve these results and there is no assurance that we will be able to do so.

PillCam COLON. PillCam COLON is the third capsule we developed. To date, sales of our PillCam COLON capsule have been insignificant. This capsule is cleared for marketing in the European Union, Canada and parts of Latin America and Asia; however, sales have been limited primarily due to lack of reimbursement and the existence of other established diagnostic modalities and perceptions among healthcare professionals that are difficult to change without significant clinical evidence to support the use of PillCam COLON. We expect clinical evidence to accumulate over time as the use of this capsule becomes more prevalent. PillCam COLON has not yet received FDA marketing clearance in the United States or PMDA approval in Japan.

In 2012, we filed for regulatory clearance of the PillCam COLON capsule in the United States and Japan. In the United States, we completed an 885-patient, multi-center pivotal clinical trial with our PillCam COLON capsule and submitted an application to the FDA for clearance to market our PillCam COLON capsule for visualization of the lower gastrointestinal tract to detect polyps in patients unable to undergo colonoscopy or in case of incomplete colonoscopy. The trial had a unique and complex design and to our knowledge was the first to directly compare an imaging tool against colonoscopy for the purpose of obtaining regulatory clearance. Colonoscopy is the standard colorectal cancer screening and diagnostic procedure in the United States. At the outset of the trial, we expected the results to support regulatory clearance of the PillCam COLON capsule for colorectal cancer screening. However, based on the results of the trial, discussions with the FDA and the existence of a well-established gold standard, it became clear to us that obtaining clearance for a screening indication would not be likely at this time and that we should first submit for a more limited indication.

As of the date of this annual report, we remain in discussion with the FDA regarding its review of our submission for clearance, including concerning the proposed indication for use. We expect to obtain FDA clearance for this capsule in 2013. However, there can be no assurance that the FDA will clear the PillCam COLON for marketing in the United States under our proposed indication for use or at all.

The growth opportunity associated with our PillCam COLON capsule will depend on the indication of use ultimately cleared by the FDA, if any clearance occurs. In addition, before we can realize any such growth opportunity, we will need to obtain reimbursement to cover the procedure. Until we are able to do this, we do not expect significant revenues from this product in the United States.

The submission to the Japanese PMDA included the results of the PillCam COLON clinical trial which was designed to evaluate the PillCam COLON as a tool to visualize the mucosal layer of the colon for pathologies, including colorectal cancer. A total of 72 patients aged 40-75 years were enrolled at three sites. In Japan, the primary modality for colorectal screening cancer is fecal occult blood test, or a stool test. Patient compliance with guidelines related to a stool test is low. In addition, only approximately 50% of patients proceed to colonoscopy following a positive stool test. We therefore believe that PillCam COLON can be a useful tool for physicians in Japan to visualize and diagnose colon polyps following a screening stool test. We estimate the addressable market in Japan to be approximately one million procedures each year. Also, we believe that PMDA and the medical community in Japan recognize the need for the PillCam COLON capsule as described here and based on our discussions with regulators in Japan to date we are optimistic that we can obtain approval for this product in Japan in 2013. This represents a significant revenue opportunity for us in the coming years. However, the regulatory review process is out of our control and there can be no assurance that we will be able to obtain the desired approval in Japan. Also, reimbursement coverage will be needed before significant growth can be expected.

We may be unable to obtain FDA clearance or PMDA approval for this capsule. Even if we do, this capsule may not achieve widespread market acceptance as superior to existing technologies for visualization or screening of the colon.

We believe the following are important factors in determining the success of our PillCam COLON capsule for the foreseeable future:

- Receipt of FDA marketing clearance in the United States or regulatory approvals in Japan.
- The existence of clinical data sufficient to support the use of our PillCam COLON for visualization of the colon as compared to other colon visualization methods. Physicians may be reluctant to use this product without supportive clinical data and literature.
- The time it takes the physician to read the video captured by the PillCam COLON capsule.
- The level of professional education and hands-on training of medical staff in performing the PillCam COLON procedure and reading and interpreting the images captured by the capsule, since the procedure and the reading are different than what many medical staff is used to with colonoscopy.
- The availability of sufficient clinical and cost-effectiveness data for physicians to use this product in their practice, for the American Medical Association, or AMA, to provide a favorable permanent "current procedural terminology," or CPT, code, and for private third-party payors to make an adequate reimbursement decision to provide coverage for the PillCam COLON procedure.
- The availability of a reliable colon cleansing and preparation procedure for the PillCam COLON capsule that is accepted by physicians and patients.
- The absence of other safe and effective colon cancer screening products, which, if brought to market by a third party, may make the PillCam COLON capsule obsolete.

We believe that the PillCam COLON procedure will eventually provide a non-invasive alternative to visualize the colon and detect polyps. However, further procedure development as well as significant additional data to support the use of this capsule is necessary before we can realize this market opportunity.

Manometry and pH Monitoring Products

Bravo pH Monitoring. In 2012, sales of the Bravo products were approximately $17.7 million, or 10% of our total sales, compared to $19.8 million, or 11% of our total sales, in 2011 and $18.6 million, or 12% of our total sales, in 2010. Almost all of the revenues from the Bravo product were generated from sales in the United States, where the use of this product has broad and favorable reimbursement coverage. Outside the United States, the Bravo pH monitoring system has not been widely used, primarily due to lack of market development. We believe there is limited potential for revenue growth of this product outside the United States.

In January 2012, the Company conducted a voluntary recall of certain lots of our Bravo product. The recall was related to reports that, in some cases, the Bravo capsules were not attaching or detaching from the esophagus as intended. The Company developed a root cause analysis of this issue and developed a plan to remediate the problem. In accordance with this recall and remediation plan, we replaced affected product lots with new products manufactured according to newly defined product specifications and tolerances. In February 2012, we initiated a second voluntary recall of certain additional lots of the Bravo product due to continued reports of failures to attach to the esophagus. All recalled lots have been replaced with new products manufactured according to the most updated product specifications and tolerances.

We believe that these recalls are the primary reason for the lower sales of this product in 2012 compared to 2011. These recalls have been resolved and we believe the quality of this product is high with complaint rates being at historically low levels. We are working to regain customer confidence in using this product and expect revenue to grow again in 2013 compared to 2012. However, if we need or are required to recall the Bravo product from the market again, on a temporary or permanent basis, make changes to this product or shut down our manufacturing operations due to quality issues, our sales of the Bravo product may decline, our financial results could be materially adversely affected and we may suffer damage to our reputation that could adversely affect sales of our other products. It is also possible that we could be subject to lawsuits relating to the product failures.

In addition, as part of the implementation of the various parts of the U.S. Patient Protection and Affordable Care Act of 2010, there is a work instruction issued by the federal government due to take effect in the second quarter of 2013 that will limit physicians' ability to receive payment for services and procedures that are performed with our products in an Ambulatory Surgical Center, or ASC. If this work instruction does not change, it may directly affect physicians' ability to get reimbursed for the placement of Bravo pH monitoring at ASCs and could negatively impact sales of this product in the U.S.

Catheter-based Products. The manometry, impedance and catheter-based pH monitoring products and technologies we acquired from Sierra in April 2010, have advanced our goal of providing comprehensive solutions to our customers. This acquisition strengthened our position as a global leader in the gastro-esophageal diagnostic market. From a financial perspective, this acquisition has been our main revenue growth driver in 2011 and 2012. This acquisition enabled us to diversify our product and geographic revenues through access to additional products, people, and manufacturing assets.

The primary technology we acquired from Sierra is esophageal manometry. Esophageal manometry is a test to measure the pressure inside the esophagus. Sierra pioneered the development of high-resolution solid state manometry in which motility physiology is clearly visualized through the length of the esophagus. This technology is embodied in our industry-leading ManoScan family of equipment. It represents the primary innovation and our competitive strength in this field. We also market and sell catheter-based reflux monitoring products for measurement of pH or a combination of pH and impedance in the esophagus. In 2012, we sold approximately $34.7 million of manometry and catheter-based pH monitoring products, compared to approximately $28.5 million in 2011 and $17.9 million in the last three quarters of 2010 (following acquisition of these products from Sierra in April 2010).

We design and manufacture various disposable sheaths for use with our high resolution and three dimensional high resolution catheters under the name ManoShield. The purpose of this product is to eliminate or reduce the need for the disinfection of the catheters between uses, which increases the operational efficiency for our customers. In 2012, we conducted a voluntary recall of this product due to defects in the manufacturing process of this product in our Vietnam facility. The recall has been completed successfully and sales of this product resumed in late 2012. However, following the recall we have decided to change the indication of use statement of this product from "viral barrier" to "sanitary sheath." While this product reduces gross contamination of our equipment, we now recommend that customers clean and disinfect products between uses. This change in the use of the ManoShield product could impact the use by our customers of our manomatry catheters and the sales growth of these products.

We expect that our future revenue growth will continue to depend, in part, on our ability to grow the Bravo pH monitoring business and our manometry and catheter-based pH and pH impedance monitoring businesses, in particular in light of the fact that the growth rate of sales of the PillCam SB capsule, our primary selling product, has declined from 2008 through 2012 compared to prior years.

SmartPill. We acquired the assets of the SmartPill business in October 2012, and have recorded revenues of $0.6 million from sales of SmartPill during the fourth quarter of 2012. We do not have reliable comparable data from prior years. We plan to invest in clinical trials to expand the clinical data available with this product to increase physician awareness of this product and support reimbursement coverage decisions. We expect our revenues from sales of this product in 2013 to be several million dollars and to occur primarily in the United States.

Geographical Breakdown

The following table sets forth the geographic breakdown of our revenues for the periods indicated:

	2012	2011	2010
Americas	64%	61%	64%
EMEA	24%	26%	25%
AP/J	12%	13%	11%

Sales in the Americas region were $115.2 million in 2012, compared to $108.8 million in 2011 and $100.6 million in 2010.

PillCam SB sales in the Americas in 2012 were $68.6 million, compared to $66.9 million in 2011 and $67.6 million in 2010. We believe that the modest increase in sales of PillCam SB in the United States is due in part to the use of the PillCam SB for diagnostics and monitoring of Crohn's disease as well as for the most common use of the PillCam SB capsule, namely the detection of obscure gastrointestinal bleeding, or OGIB. Expanding the use of the PillCam SB capsule beyond OGIB, particularly in the United States, is important to our future growth of the PillCam SB. Our growth in of the sales of the PillCam SB is despite a decline in the number of upper and lower endoscopy procedures, which are often performed by physicians prior to prescribing capsule endoscopy or are required by third-party payors as a preceding condition for covering capsule endoscopy procedures. The decline in the number of endoscopic procedures may be attributable to the economic slowdown in the United States and may continue in 2013.

Sales of our high resolution manometry products increased to $22.9 million, or by approximately 30%, compared to $17.6 million in 2011. We believe this increase is the result of our ability to leverage our sizable sales force and marketing resources along with the customer base of our capsule endoscopy products to capture cross-selling opportunities and increase the number of physicians using high-resolution manometry following our acquisition of Sierra Scientific in April 2010. It is uncertain that we will be able to maintain this growth rate. Sales of the Bravo products declined to $16.3 million, or by 11%, compared to $18.3 million in 2011. The decline in Bravo revenues in 2012 is attributable to a recall we had for the product during 2012. The recall was resolved during the second half of the year and we expect growth in sales to resume as customer confidence in the product returns. In October 2012, we acquired the assets of SmartPill and recorded revenues of $0.4 million from sales of this product in the United States during the fourth quarter of 2012. We plan to continue to take advantage of cross selling opportunities among our various product lines to further increase the sales of our functional diagnostic products.

In January 2012, we began operating directly in Brazil through a wholly-owned subsidiary. We expect this new direct market to contribute to revenue growth in the Americas region, in particular in light of the December 2010 reimbursement announcement in Brazil, which is described below, and is expected to gradually enable all of Brazil's 190 million citizens to have access to capsule endoscopy with our PillCam SB capsule over the next few years, although the exact timing is not in our control and is unpredictable.

In EMEA, sales in 2012 decreased by 5% to $42.9 million, compared to $45.1 million in 2011. This decline is attributable primarily to the ongoing economic downturn in Europe, in particular in the southern part of Europe. PillCam SB sales in the EMEA region declined to $30.9 million, or by 7%, from $33.1 million in 2011. This decline is primarily attributable to the economic environment in Europe which is still volatile and uncertain, resulting in decreased healthcare spending by governments in the region, more conservative purchasing patterns by customers in the region and financial difficulties to a few of our European distributors. Consequently, our ability to accurately predict and estimate our financial results in Europe has been adversely affected. The reimbursement coverage announcements in January 2011 in Germany, our single largest market in EMEA, for the use of PillCam SB for obscure gastrointestinal bleeding in an outpatient setting, which we describe in more details below in this section under the heading "Reimbursement," are expected to contribute to the growth of our capsule endoscopy product sales in Germany over the next few years. However, the date on which this reimbursement becomes effective is not in our control and unpredictable.

Sales in the AP/J region decreased by 6% to $22.5 million in 2012, compared to $24.0 million in 2011. This decline is due to lower sales of capital equipment related to our capsule endoscopy platform, a decline in sales of PillCam SB capsules, and a decline of sales of our functional diagnostic products. Sales of PillCam SB capsules in the AP/J region decreased to $17.2 million, or by 2%, compared to $17.6 million in 2011. This decline was primarily due to a decline of 19% in sales of our PillCam SB capsule in Australia/New Zealand to $6.6 million in 2012, compared to $ 8.1 million in 2011. This decline is primarily due to market saturation and turnover of sales personnel. This decline in sales of PillCam SB capsules in Australia and New Zealand was partially offset by an increase of $0.3 million in Japan and an increase of $0.8 million in other countries in the Far East. In addition, sales of our functional diagnostic products in the AP/J region declined by 15% to $2.8 million in 2012, compared to $3.3 million in 2011 and sales of capital equipment for our capsule endoscopy system declined by $0.5 million. Any difficulties in our business in Japan and China could have a material adverse effect on our revenue growth plans. We do not have regulatory clearance to sell our Bravo system and high resolution manometry products in Japan and sales of these products in other countries in this region were insignificant.

We expect that a majority of our revenues for the foreseeable future will continue to come from the United States, mainly due to the size of the market, the size of our direct sales force, our ability to leverage existing market share to generate additional sales, a favorable reimbursement system and general acceptance of new technologies among physicians.

Seasonality

We believe that demand for our products may be affected by seasonal factors, mainly during the summer months when physicians and administrators are more likely to postpone purchasing decisions relating to our products due to summer vacations, and patients are more likely to postpone less urgent diagnostic procedures until later in the year.

Reimbursement

Capsule endoscopy

We believe that the existence of reimbursement coverage and the amount of reimbursement will continue to significantly affect our revenues. Availability of reimbursement is a key factor in the decision of physicians and healthcare providers to purchase our products and perform medical procedures with them. Once a payor has decided to provide reimbursement for use of our products, the level of reimbursement coverage provided also becomes a key factor in a physician's decision. We estimate that as of December 31, 2012, reimbursement for small bowel capsule endoscopy was available worldwide to approximately 600 million people. In the United States approximately 220 million people are covered with most reimbursement policies providing coverage for a number of small bowel indications, including obscure gastrointestinal bleeding, suspected Crohn's disease, suspected small bowel tumors and other small bowel pathologies.

We continue to seek to improve reimbursement coverage for the PillCam SB capsule and to reduce or eliminate any conditions or limitations on such coverage. As of December 31, 2012, out of the 220 million individuals who have coverage in the United States for small bowel capsule endoscopy for suspected Crohn's, approximately 51 million individuals have coverage that does not require an upper endoscopy and requires only a colonoscopy as an endoscopic procedure to be performed prior to a small bowel capsule endoscopy procedure for detecting suspected Crohn's, approximately 18 million individuals have coverage for a small bowel capsule endoscopy procedure in cases of known Crohn's of the large bowel that require small bowel evaluation, and 26 million individuals have coverage with no restrictions or limitations from their payers for capsule endoscopy.

As of December 31, 2012, approximately 53 million individuals had coverage for using capsule endoscopy of the small bowel for diagnostic re-evaluation of Crohn's disease if patients remain symptomatic after receiving treatment and there is no suspected or confirmed gastrointestinal obstruction, stricture or fistula. This coverage supports the revised clearance to use PillCam SB to monitor inflammatory bowel disease, such as Crohn's. The only pre-condition is for patients who remain symptomatic after receiving treatment; timeframes are not specified. In December 2010, Brazil's Medical Association issued a reimbursement code for capsule endoscopy of the small bowel. As of December 31, 2012, approximately 9 million people had reimbursement coverage for capsule endoscopy in Brazil. We are working with national and private health agencies in Brazil to include capsule endoscopy on their approved list of procedures under this code so that Brazilians can have access to this reimbursement coverage. We expect that all of Brazil's 190 million citizens will gradually obtain access to capsule endoscopy with our PillCam SB capsule. However, this process is unpredictable, is out of our control and could take a few years.

In Europe, reimbursement coverage for small bowel capsule endoscopy was available for approximately 226 million people as of December 31, 2012, and reimbursement coverage for expanded indications, such as Crohn's disease and other small bowel disorders was available for approximately 161 million people at the end of 2012. This includes approximately 60 million people in France. In January 2011, the German Ministry of Health has announced its intention to create an outpatient reimbursement code for PillCam SB capsule endoscopy for obscure gastrointestinal bleeding. The declaration began a process for establishing a medical code, which is out of our control and may take a few years. After establishment of this medical code, the 73 million Germans covered by the public health system, or about 90% of the entire German population, will have access to the PillCam SB procedure, with full reimbursement under the German statutory health insurance system. Approximately eight million Germans, or 10% of the population, already have coverage for PillCam SB capsule endoscopy through private health insurers. PillCam SB capsule endoscopy has been covered for inpatient use in Germany since 2004. The establishment of an outpatient reimbursement code for PillCam SB capsule endoscopy represents an important milestone for us, potentially enabling us to significantly increase our annual sales in Germany from the current level of several million dollars after receipt of the medical code. There is very limited reimbursement in Europe for procedures with our PillCam COLON capsule and, as a result, we expect only limited sales growth of this capsule in Europe until reimbursement is widely available.

In Japan, the entire adult population (approximately 105 million people) is eligible for reimbursement of the PillCam SB capsule procedure for small bowel, including procedures with our PillCam Patency capsule for patients with any known or suspected small bowel disease, such as the visualization and diagnosis of Crohn's disease.

Reimbursement coverage for use of the PillCam SB capsule in the detection of gastrointestinal bleeding is available for approximately 20 million individuals in Australia and New Zealand.

In addition to continuing our efforts to expand reimbursement coverage, we have made significant efforts to educate our customers regarding coverage conditions and rates. For example, we maintain frequent contact with existing and potential third-party payors on the one hand, and with our customers on the other hand. We believe that increased customer awareness and knowledge is important to remove any misunderstandings that may exist among physicians regarding the availability of reimbursement or coverage rates and to allow more patients to access the benefit of our technology. We also maintain a reimbursement telephone support line in the United States to respond directly to inquiries from customers.

As of December 31, 2012, 60 million individuals in the United States have coverage for using our PillCam ESO for the diagnosis of esophageal varices.

To date, other than limited coverage in Germany for inpatient hospital use, there is no reimbursement coverage for procedures with our PillCam COLON capsule. This capsule is new to the market and more clinical evidence will be necessary to support reimbursement. Reimbursement coverage for this capsule in the United States and Japan is not expected for the foreseeable future.

Motility and pH monitoring

As of December 31, 2012, approximately 220 million individuals in the United States had reimbursement coverage for catheter-based pH monitoring, Bravo pH monitoring and esophageal manometry procedures. The most common accepted indications for coverage for pH monitoring are for patients with esophageal reflux who are being considered for surgical anti-reflux repairs and patients with normal endoscopic findings and reflux symptoms who are unresponsive to therapy and those patients that are refractory to PPI therapy. The most common accepted indications for coverage of esophageal manometry is when there is reflux of stomach acid and contents back into the esophagus, to determine the cause of swallowing problems (dysphagia) and to evaluate chest pain that may be coming from the esophagus.

Outside the United States, reimbursement coverage for our esophageal motility or pH monitoring products varies significantly country by country. In many countries it exists for manometry and catheter-based pH monitoring, in others it does not exist at all and in others still it is insufficient to cover the cost of the procedure.

As of December 31, 2012, approximately 42 million individuals in the United States had reimbursement coverage for the diagnosis of motility problems using our SmartPill system. The most common accepted indications for coverage are for the evaluation of gastroparesis, or delayed emptying of the stomach, and chronic constipation. Effective January 1, 2013, the SmartPill product was classified as a Category I CPT code, which could result in an increase in individuals covered by both commercial and Medicare providers for the SmartPill procedure and in turn an increase in the sales of this product in the United States in 2013. As of December 31, 2012, there was no reimbursement coverage for the SmartPill capsule outside the United States.

For discussion of the reimbursement rates applicable to various procedures with our products see in Item 4 — "The Business of the Company — Business Overview — Third-Party Reimbursement — Reimbursement Rates." Reimbursement rates may also be modified in the future. Based on recent history, we do not expect that modest changes to reimbursement rates will have a material effect on our business.

Competition

For discussion of competition see in Item 4 — "The Business of the Company — Business Overview — Competition."

Customers and Customer Concentration

We market and sell our products through a direct sales force in the United States, Germany, France, Canada, Australia, Brazil, Hong Kong and Israel. We rely on third-party distributors in international markets outside these countries. We sell our products primarily to hospitals, gastroenterology offices and gastroenterology outpatient facilities. In 2012, we derived $42.4 million, or 23.4%, of our revenues from sales to local distributors, compared to $43.6 million, or 25%, in 2011. Our direct sales revenues are derived from a large number of individual customers and have higher gross margins. In 2012, no single direct sales customer accounted for more than 0.3% of our revenues and no single distributor accounted for more than 3% of our revenues. It is our policy to require pre-payment or collateral or security in connection with sales to most distributors. Due to these factors, the geographical dispersion of our customers and certain trade insurance tools that we use, we believe that we adequately control our exposure to credit risks associated with accounts receivable. To date, we have not experienced any material bad debts and we have collected substantially all of our receivables.

Cost of Revenues and Gross Margins

Cost of revenues consists primarily of materials and components, as well as manufacturing costs and related depreciation of our production facilities, the salary and related costs of our technical staff assembling our products, warranty costs and product liability insurance.

The principal factors affecting our gross margins are related to the volume of sales of our disposable products, the sale prices, the product mix (namely, the proportion of our revenues derived from sales of capital equipment compared to sales of capsules and the proportion of sales of esophageal manometry and pH measurement products compared to sales of capsule endoscopy products), as well as the percentage of our sales made as direct sales. In general, our gross margins from capsule sales are higher than our average gross margins from sales of capital equipment, such as workstations and data recorders. A primary reason for the lower gross margins of capital equipment is that from time to time, with the introduction of new products or newer versions of existing products or as part of our promotional activities, we place our capital equipment, or replace older equipment of many customers with newer versions of our capital equipment, at a reduced price or at no charge. In addition, our gross margins in territories in which we use our direct sales force are generally higher than our gross margins in territories in which we market and sell our products through third-party distributors. Our gross margins from sales of the Bravo system and of our manometry and catheter-based pH monitoring products are lower than our gross margins related to our capsule endoscopy products. Generally, our gross margins may also be negatively impacted as a result of increasing direct competition in our field.

Our average gross margins over the last three fiscal years were 76.4%. Our gross margins in 2012 were 76.2%, compared to 76.7% in 2011 and 76.2% in 2010. Gross margins in 2010 were adversely impacted by a one-time charge and ongoing purchase price allocation expenses related to the acquisition of Sierra and positively impacted by reduced material costs of PillCam SB, improved efficiencies in the manufacturing process and the transition of the Bravo manufacturing activities to Israel. Gross margins were also adversely affected in 2010 by the mix of products sold. In 2011 gross margins were impacted by improvement to the gross margins of our manometry products after we completed the integration of the operational and manufacturing functions of the Sierra business. Gross margins in 2012 were primarily impacted by transaction expenses related to the acquisition of the assets of SmartPill and by expenses related to the Bravo recall.

Operating Expenses

Research and Development. Our research and development expenses consist primarily of costs associated with the design, development, pre-manufacture and testing of, and enhancements to, our products, clinical studies and obtaining regulatory approvals, patent costs, sponsored research costs and other expenses related to our product development and research program. We expense our research and development costs as they are incurred. “Research and development expenses, net” are net of grants received from the Israeli Government through the OCS or from other sources. We plan to continue investing in research and development, as we enhance our various product lines, pursue the development of new products and perform more clinical trials to drive continued expansion of reimbursement for our products worldwide.

Sales and Marketing. Our sales and marketing expenses consist primarily of salaries, commissions to our sales force, travel and related costs for our internal sales staff and costs related to marketing activities such as medical meetings, medical training and education, trade shows, and promotional and public relations activities, as well as costs associated with development of our website. We expect that our selling and marketing expenses will increase gradually in the future as we increase sales of our products, further expand our sales and marketing team, expand our educational activities and expand our promotional efforts.

General and Administrative. Our general and administrative expenses consist primarily of salaries and related costs for our executive and administrative staff, insurance premiums, and legal, accounting and consulting expenses.

Equity-Based Compensation. Our operating expenses also include amortization of stock-based compensation, which is allocated among research and development expenses, marketing expenses and general and administrative expenses based on the division in which the recipient of the option grant is employed. Under Accounting Standard Codification, or ASC 718-20, we recognize as an expense the grant-date fair value of stock options and other equity-based compensation to employees based on the valuation of our equity-based compensation. The application of this accounting standard has a material impact on our earnings per share. In 2012, we recognized $6.2 million in equity-related compensation expense, compared to $7.4 million of equity-related compensation expense in 2011. We expect to continue our practice of granting equity awards to our directors, officers, employees and consultants. The resulting compensation expenses in 2012 and 2011 were impacted by various factors, primarily the number of equity awards we granted and their fair value at the date of grant.

Financial Income, Net. Financial income, net consists primarily of interest earned on our cash balances, interest income from marketable securities and foreign exchange gains or losses, net of financing expenses.

Taxes. In 2012, Israeli companies were generally subject to income tax at the corporate tax rate of 25%. However, our investment program in leasehold improvements and equipment at our manufacturing facility in Yoqneam, Israel has been granted approved enterprise status and, therefore, we are eligible for the reduced tax benefits described later in this section in "Corporate Tax." These benefits should result in income recognized by us from our investment program being tax exempt for a specified period. However, these benefits may not be applied to reduce the tax rate for any income that is not derived from sales of our product manufactured at our facility in Yoqneam, Israel.

As of December 31, 2012, we have recorded a net deferred tax asset of $2.6 million. On a regular basis, we estimate our actual current tax exposures and assess 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. The deferred tax asset represents our assessment of accumulated losses that could be carried forward to future years to reduce taxable income in those future years and other expenses that were already recognized for accounting purposes but will be recognized for tax purposes only in future years. We consider projected future taxable income and tax planning strategies in making this assessment. We must then assess the likelihood that our deferred tax assets will be recovered and, to the extent we believe that recovery is not more likely than not, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we cannot record a tax benefit, or must include an expense within the tax provision in the statement of income. The deferred tax asset may be realized over time, depending upon the generation of future taxable income during the periods in which those accumulated losses become deductible.

Significant management judgment is required in determining our deferred tax assets and any related valuation allowance. Based upon our projections for future taxable income of our subsidiaries over the periods in which the deferred tax assets are deductible, we believe that it is more likely than not that we will realize the benefits of these deferred tax assets. However, the amount of the deferred tax asset considered realizable could be reduced in the near term if estimates of future taxable income during the carry-forward period are reduced. Significant management judgment is also required in determining our tax liability under ASC 740-10, "Accounting for Uncertainty in Income Taxes."

Net Loss Attributable to Non-Controlling Interests in Subsidiary. Net loss attributable to non-controlling interests in subsidiary consists of the losses attributed to the minority shareholders in our Japanese subsidiary, Given Imaging K.K.

Critical Accounting Policies

Our significant accounting policies are more fully described in Note 1 of the notes to our consolidated financial statements. 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.* We recognize revenues from sales of our products upon shipment, provided that collection of payment is probable, there is persuasive evidence of an arrangement, no significant obligations in respect of installation remain and the price is fixed or determinable. In any case, revenues are not recognized for an initial sale of a system until all equipment has been delivered so that the customer may use and operate the system as a whole for its intended purpose. Our arrangements with customers and distributors do not contain product return rights. Certain of our sales contracts include a post-contract customer support, or PCS, component. We defer recognition of the revenue attributed to the PCS component of the sale and recognize revenue based on the term of the support period, which is generally a one-year period following the sale. The fair value of the PCS component is based on the price at which we sell customer support contracts separately following the expiration of the standard warranty period for our products. In 2010, we elected to early adopt ASU 2009-13, "Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements," and therefore for multi-element arrangements that include tangible products that contain software that is essential to the tangible product's functionality and undelivered software elements that relate to the tangible product's essential software, we allocate revenue to all deliverables based on their relative selling prices. In such circumstances, we use a hierarchy to determine the selling price to be used for allocating revenue to deliverables: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price, and (iii) best estimate of the selling price. The adoption of this standard did not have a material effect on our financial position, results of operations or cash flow.

- *Inventories.* Inventories are stated at the lower of cost or market, cost being determined on the basis of the average cost method for raw materials and finished goods and on the basis of actual manufacturing costs for work-in-progress and sub-contractors. In addition, we add to the cost of finished products held in inventory the overhead from our manufacturing process. Inventory that is not expected to be consumed in the subsequent year based upon sales forecast is classified as a non-current asset. Management regularly evaluates the necessity of provisions for obsolescence, which may result from excess, slow-moving or obsolete inventories.

- *Foreign Currency Translation.* In preparing our consolidated financial statements, we are required to translate non-U.S. dollar amounts in our financial statements and the financial statements of our subsidiaries into U.S. dollars. Under the relevant accounting guidance the treatment of any gains or losses resulting from this translation is dependent upon our management's determination of the functional currency of each subsidiary. The functional currency is determined based on management's judgment and involves consideration of all relevant economic facts and circumstances affecting the subsidiary. Generally, the currency in which the subsidiary transacts a majority of its transactions, including billings, financing, payroll and other expenditures would be considered the functional currency. However, any dependency upon the parent and the nature of the subsidiary's operations must also be considered. If any subsidiary's functional currency is deemed to be the local currency, then any gain or loss associated with the translation of that subsidiary's financial statements into U.S. dollars would be included as other comprehensive income. However, if the functional currency of a subsidiary is deemed to be the U.S. dollar, then any gain or loss associated with the translation of that subsidiary's financial statements would be included within statement of income. Based on our assessment of the factors discussed above, we consider the U.S. dollar to be the functional currency for us and each of our subsidiaries. All translation gains and losses derived from transactions in currencies other than the U.S. dollar are recorded in our statement of income and are included in determining our net income. In the event that we determine that the functional currency of these or any future subsidiaries is not the U.S. dollar, any translation gains or losses from transactions in currencies other than the U.S. dollar would not affect our net income for the year presented.

- *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. We must then assess the likelihood that our deferred tax assets will be recovered and, to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within the tax provision in the statement of income. Significant management judgment is required in determining our deferred tax assets and any related valuation allowance. We have recorded a net deferred tax asset of $2.6 million as of December 31, 2012. Based upon our projections for future taxable income in our U.S. subsidiary over the periods in which the deferred tax assets are deductible, we believe that it is more likely than not that we will realize the unreserved benefits of these deductible differences. The amount of the deferred tax asset considered realizable, however, could be reduced in the near term if estimates of future taxable income during the carry forward period are reduced.

  We follow the guidance in ASC Sub-topic 740-10, which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. We follow a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit. The second step is to measure the tax benefit as the largest amount that is more likely than not to be realized upon ultimate settlement. We performed our evaluation mainly in respect of tax years that may still be subject to, or are currently under examination by local tax authorities in some tax jurisdictions.

We may incur additional tax liability in the event we decide to distribute intercompany dividends from some of our non-Israeli subsidiaries; however we do not expect these subsidiaries to distribute dividends in the foreseeable future.

- *Accounting for Equity Awards.* We account for equity awards according to SFAS ASC 718-20. ASC 718-20 requires all equity-based payments to employees, including grants of employee stock options, to be recognized in the statement of income based on their fair values. In 2012, we recognized equity-based compensation expense in the amount of $6.2 million. Compensation costs recognized in 2012 also include compensation costs for all share-based payments granted in prior years, but have not vested in prior years. When calculating this equity-based compensation expense we took into consideration awards that are ultimately expected to vest. Therefore, this expense has been reduced for estimated forfeitures. The compensation cost for the fixed plans was recorded over the period the employee performs the service to which the stock compensation relates.

- *Accounting for Business Combinations.* The acquisitions of the Bravo product line, the business of Sierra and the SmartPill business were accounted for by the purchase method. The results of operations of the Bravo business were included in the consolidated financial statements of the Company commencing December 2008. The results of operations of the Sierra business were included in the consolidated financial statements of the Company commencing April 2010. The results of operations of the SmartPill business were included in the consolidated financial statements of the Company commencing October 2012. The consideration for each acquisition was attributed to net assets on the basis of fair value of assets acquired as determined by management. In making such determinations, management has considered and relied in part upon a report of a third party appraiser. Identifiable intangible assets, including purchased in-process research and development, were valued utilizing a forecast of expected cash inflows (including adjustments, as appropriate, for regulatory and commercial risks), cash outflows and contributory charges for economic returns on tangible and intangible assets employed. The purchase price allocated to patents of the existing core technology, customer relationships, trade names and trademarks is being amortized using the straight line method over a period of eight years to twenty years, which approximates their expected useful lives. These definite life intangible assets will be evaluated for recoverability whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. In the Bravo acquisition, amounts assigned to tangible and intangible assets to be used in a particular research and development project that has not reached technological feasibility and have no alternative future use, were charged to “in-process research and development acquired in a business combination” among operating expenses at the acquisition date. In addition, in the Bravo acquisition, transaction costs were included in consideration paid and consequently attributed to net assets as part of the purchase price allocation. As to the Sierra and SmartPill acquisitions, revised accounting guidelines for business combinations were implemented. Accordingly, amounts assigned to tangible and intangible assets to be used in a particular research and development project that has not reached technological feasibility and have no alternative future use, which existed in the Sierra acquisition, were recognized as an intangible asset, which will be amortized once the project reaches technological feasibility. Applying the revised guidance, transaction costs were expensed and not included in consideration paid for the purpose of the purchase price allocation. In addition, applying the revised guidance, future earn-out consideration that was agreed upon in the SmartPill acquisition was valued at its present value and added on to the purchase price. Any future adjustment to the earn-out consideration will be recorded as an expense or as income in the statement of income data. Goodwill reflects the excess of the purchase price paid in each acquisition over the fair value of net assets as of the date of the acquisition. Goodwill is not amortized but rather tested for impairment at least annually.

Results of Operations

Our consolidated statements of income data for the years ended December 31, 2012, 2011 and 2010 are set forth below:

	Year Ended December 31,		
	2012	2011	2010
		(In Thousands)	
Statements of Income Data:			
Revenues	$ 180,501	$ 177,955	$ 157,809
Cost of revenues	(42,971)	(41,466)	(37,629)
Gross profit	137,530	136,489	120,180
Operating expenses:			
Research and development, gross	(25,627)	(26,129)	(21,695)
Government grants	1,439	1,113	1,477
Research and development, net	(24,188)	(25,016)	(20,218)
Sales and marketing	(76,272)	(75,014)	(67,114)
General and administrative	(22,746)	(23,078)	(25,138)
Other, net	(455)	(397)	(759)
Total operating expenses	(123,661)	(123,505)	(113,229)
Operating profit	13,869	12,984	6,951
Financial income, net	847	1,343	2,599
Profit before taxes on income	14,716	14,327	9,550
Income tax benefit (expense)	(459)	(2,158)	(1,362)
Net profit	14,257	12,169	8,188
Net loss (profit) attributable to non-controlling interest	93	(191)	(290)
Net profit attributable to shareholders	$ 14,350	11,978	$ 8,478
Net change in respect of available for sale securities	1,151	(980)	(304)
Total comprehensive profit attributable to shareholders	$ 15,501	$ 10,998	$ 7,884

Our historical operating results as a percentage of net revenues for the years ended December 31, 2012, 2011 and 2010 are set forth below:

	Year Ended December 31,		
	2012	2011	2010
Statements of Income Data:			
Revenues	100%	100%	100%
Cost of revenues	(23.8)	(23.3)	(23.8)
Gross profit	76.2	76.7	76.2
Operating expenses:			
Research and development, gross	(14.2)	(14.7)	(13.7)
Government grants	0.8	0.6	0.9
Research and development, net	(13.4)	(14.1)	(12.8)
Sales and marketing	(42.3)	(42.1)	(42.6)
General and administrative	(12,6)	(13.0)	(15.9)
Other, net	(0.3)	(0.2)	(0.4)
Total operating expenses	(68.5)	(69.4)	(71.7)
Operating profit	7.7	7.2	4.4
Financial income, net	0.5	0.8	1.6
Profit before taxes on income	8.2	8.0	6.0
Income tax benefit (expense)	(0.3)	(1.2)	(0.8)
Net profit	7.9	6.8	5.2
Net loss (profit) attributable to non-controlling interest	0.1	(0.1)	0.2
Net profit attributable to shareholders	8.0%	6.7%	5.4%

Non-GAAP Financial Measures

In our earnings press releases and conference calls we discuss non-GAAP gross profit, operating profit, net income and earnings per share which are not calculated in accordance with U.S. GAAP. Our management uses non-GAAP financial measures in assessing our results and in planning, forecasting and analyzing future trends. We also use non-GAAP financial measures internally to evaluate our performance, to compare against work plans and budgets and ultimately to evaluate the performance of management and management compensation. In arriving at our non-GAAP presentation, we have in the past factored out items, and would expect in the future to continue to factor out items, that have a non-recurring impact on our financial statements, or which, in the judgment of management, are items that as a result of their nature or size could, had they not been singled out, potentially cause investors to extrapolate future performance from an improper base. While not all-inclusive, examples of these items primarily include non-cash charges related to employee stock based compensation expenses, charges related to amortization of purchase price allocation, or PPA, and tax benefits. We believe these non-GAAP measures, when taken together with the corresponding U.S. GAAP financial measures, provide meaningful and useful supplemental information to investors regarding our performance. However, these non-GAAP financial measures should be considered in addition to, and not as a substitute for or preferable to, financial measures prepared in accordance with U.S. GAAP. Also, investors are cautioned that, unlike financial measures prepared in accordance with U.S. GAAP, non-GAAP measures may not be comparable with the calculation of similar measures of other companies. The limitations of using these non-GAAP financial measures as performance measures are that they provide a view of our results of operations without including all events during a period, such as the effects of acquisition and other charges, and may not provide a comparable view of our performance to other companies in our industry.

The following table provides supplemental non-GAAP income data for the years 2010 through 2012:

	Year ended December 31,		
	2012	2011	2010
	(in thousands of U.S dollars, except per share data)		
Supplemental non-GAAP income data:			
Gross profit	$ 137,530	$ 137,437	$ 122,162
Operating profit	23,142	21,619	18,991
Profit before taxes on income	23,989	22,962	21,590
Income tax	(1,498)	(2,667)	(2,250)
Net profit attributable to shareholders	22,584	20,104	19,340
Diluted earnings per ordinary share	$ 0.72	$ 0.65	$ 0.64

A reconciliation of these non-GAAP measures to the most directly comparable U.S. GAAP measures for 2012 and 2011 is as follows:

	Year ended December 31, 2012			Year ended December 31, 2011		
	U.S. GAAP	Excluded Items	Non GAAP	U.S. GAAP	Excluded Items	Non GAAP
Revenues	$ 180,501	$ —	$ 180,501	$ 177,955	$ —	$ 177,955
Cost of revenues	(42,971)	1,777	(41,194)	(41,466)	948	(40,518)
Gross profit	137,530	1,777	139,307	136,489	948	137,437
Gross profit as a% of revenues	**76.2%**	—	**77.2%**	**76.7%**	—	**77.2%**
Operating expenses						
Research and development, net	(24,188)	724	(23,464)	(25,016)	708	(24,308)
Sales and marketing	(76,272)	2,998	(73,274)	(75,014)	2,499	(72,515)
General and administrative	(22,746)	3,774	(18,972)	(23,078)	4,480	(18,598)
Other, net	(455)	—	(455)	(397)	—	(397)
Total operating expenses	(123,661)	7,496	(116,165)	(123,505)	7,687	(115,818)
Operating profit	13,869	9,273	23,142	12,984	8,635	21,619
Operating profit as a% of revenues	7.7%		12.8%	**7.3%**		**12.1%**
Financing income, net	847	—	847	1,343	—	1,343
Profit before taxes on income	14,716	9,273	23,989	14,327	8,635	22,962
Income tax	(459)	(1,039)	1,498	(2,158)	(509)	(2,667)
Net Profit	14,257	8,234	22,491	12,169	8,126	20,295
Net loss (profit) attributable to non-controlling interest	93	—	93	(191)	—	(191)
Net profit attributable to shareholders	$ 14,350	$ 8,234	$ 22,584	$ 11,978	$ 8,126	$ 20,104
Net profit attributable to shareholders as a% of revenues	**8.0%**		**12.5%**	**6.7%**		**11.3%**
Earnings per share						
Basic Earnings attributable to shareholders per Ordinary Share	$ 0.47	0.27	0.74	$ 0.40	$ 0.27	$ 0.67
Diluted Earnings attributable to shareholders per Ordinary Share	$ 0.45	$ 0.27	$ 0.72	$ 0.39	$ 0.26	$ 0.65

A reconciliation of these non-GAAP measures to the most directly comparable U.S. GAAP measures for 2011 and 2010 is as follows:

	Year ended December 31, 2011			Year ended December 31, 2010		
	U.S. GAAP	Excluded Items	Non GAAP	U.S. GAAP	Excluded Items	Non GAAP
Revenues	$ 177,955	$ —	$ 177,955	$ 157,809	—	$ 157,809
Cost of revenues	(41,466)	948	(40,518)	(37,629)	1,982	(35,647)
Gross profit	136,489	948	137,437	120,180	1,982	122,162
Gross profit as a% of revenues	**76.7%**	—	**77.2%**	**76.2%**	—	**77.4%**
Operating expenses						
Research and development, net	(25,016)	708	(24,308)	(20,118)	428	(19,790)
Sales and marketing	(75,014)	2,499	(72,515)	(67,114)	1,802	(65,312)
General and administrative	(23,078)	4,480	(18,598)	(25,138)	7,828	(17,310)
Termination of marketing agreement	(397)	—	(397)	(759)	—	(759)
Total operating expenses	(123,505)	7,687	(115,818)	(113,229)	10,058	(103,171)
Operating profit	12,984	8,635	21,619	6,951	12,040	18,991
Operating profit as a% of revenues	**7.3%**		**12.1%**	**4.4%**		**12.0%**
Financing income, net	1,343	—	1,343	2,599	—	2,599
Profit before taxes on income	14,327	8,635	22,962	9,550	12,040	21,590
Income tax benefit (expense)	(2,158)	(509)	(2,667)	(1,362)	(888)	(2,250)
Net Profit	12,169	8,126	20,295	13,444	5,143	18,587
Net loss attributable to non-controlling interest	(191)	—	(191)	290	—	290
Net profit attributable to shareholders	$ 11,978	$ 8,126	$ 20,104	$ 8,478	$ 11,152	$ 19,630
Net profit attributable to shareholders as a% of revenues	**6.7%**		**11.3%**	**5.4%**		**12.4%**
Earnings per share						
Basic Earnings attributable to shareholders per Ordinary Share	$ 0.40	$ 0.27	$ 0.67	$ 0.29	$ 0.37	$ 0.66
Diluted Earnings attributable to shareholders per ordinary share	$ 0.39	$ 0.26	$ 0.65	$ 0.28	$ 0.36	$ 0.64

The following table provides details of the excluded items for 2012, 2011 and 2010:

	Gross Profit	Research and Development	Selling And Marketing	General And Admin	Tax Expense (Benefit)	Total
Year ended December 31, 2012						
Compensation expenses	$ -	$ 724	$ 1,985	$ 3,449	$ -	$ 6,158
Transaction Expenses [1]	250	-	677	325	(352)	900
Amortization of PPA	1,527	-	336	-	(687)	1,176
Total	$ 1,777	$ 724	$ 2,998	$ 3,774	$ (1,039)	$ 8,234
Year ended December 31, 2011						
Stock-based compensation	$ —	$ 708	$ 2,175	$ 4,480	$ —	$ 7,363
Amortization of PPA	948	—	324	—	(509)	763
Total	$ 948	$ 708	$ 2,499	$ 4,480	$ (509)	$ 8,126
Year ended December 31, 2010						
Stock-based compensation	$ —	$ 428	$ 1,557	$ 6,497	$ —	$ 8,482
Amortization of PPA	1,982	—	245	645	(888)	1,984
Acquisition expenses	—	—	—	686	—	686
Total	$ 1,982	$ 428	$ 1,802	$ 7,828	$ (888)	$ 11,152

(1) Transaction expenses related to our acquisition of the SmartPill assets and our review of strategic alternatives.

Year Ended December 31, 2012 Compared to Year Ended December 31, 2011

Revenues. Revenues increased by $2.5 million, or 1.4%, to $180.5 million in 2012, compared to $178 million in 2011. This increase was primarily due to an increase of $5.4 million resulting from an increase in the number of product units sold, which was offset by a decrease in revenues of $3.0 million due to exchange rates effect. Changes in average selling prices of our products had an insignificant effect on change in revenues. Sales of our manometry and catheter-based pH measurement products we acquired from Sierra totaled $34.7 million in 2012, an increase of $6.2 million, or 21.9%, compared to 2011. Sales of PillCam SB capsules decreased by $0.9 million, or 0.8%, to $116.6 million. Sales of our other PillCam capsules increased by $0.2 million or 5.2%. Sales of workstations, data recorders and Rapid software decreased by $1.5 million, or 17%. Sales of Bravo capsules decreased by $0.1 million, or 0.9 %, and sales of Bravo systems decreased by $1.9 million, or 30.6%, compared to 2011. Sales of the SmartPill product, which we acquired in October 2012, totaled at $0.6 million.

Cost of Revenues and Gross Margins. Cost of revenues was $43.0 million in 2012, compared to $41.5 million in 2011. Gross margins in 2012 were 76.2%, compared to 76.7% in 2011. The decrease in gross margins in 2012 was attributable primarily to expenses related to the acquisition of the assets of SmartPill and to the Bravo recall.

Research and Development. Gross research and development expenses decreased by $0.5 million to $25.6 million, compared to $26.1 million in 2011. The decrease in research and development expenses in 2012 was primarily due to a decrease of $0.2 million of clinical trials expenses, a decrease of $0.7 million in labor expenses mainly due to the impact of exchange rates, offset by an increase of $0.4 million in research and development project expenses.

Research and development expenses, net of government grants, totaled $24.2 million in 2012, compared to $25.0 million in 2011. Government grants received in 2012 were $1.4 million, compared to $1.1 million received in 2011. In both years, the grants were received for new products under development.

Sales and Marketing. Sales and marketing expenses increased by $1.3 million, or 1.7%, to $76.3 million in 2012 from $75.0 million in 2011. The increase in sales and marketing expenses was primarily attributable to an increase of $0.3 million in labor and related expenses, including salaries & sales commission, an increase of $0.2 million in product management expenses, an increase of $0.7 million in one time expense related to the retention of SmartPill employees during a transition period, an increase of $0.2 million in other accounting services and a decrease of $0.4 million in marketing expense contributions from distributors. This increase was offset by a decrease of $0.4 million in education and workshop expenses and a decrease of $0.1 million in other sales and marketing expenses.

General and Administrative. General and administrative expenses decreased by $0.4 million, or 1.7%, to $22.7 million in 2012, compared to $23.1 million in 2011. This decrease was primarily attributable to a decrease in $1.0 million of equity-based compensation expenses compared to 2011, a decrease of $1.0 million in labor and related expenses due to synergy of GILA activities in the U.S., the impact of exchange rate and other compensation. This decrease was offset by an increase of $0.7 million in litigation expenses, an increase of $0.2 million in legal expenses, an increase of $0.2 million in IT expenses, and an increase of $0.4 million in other G&A expenses.

Financial Income, Net. Financial income, net, decreased by $0.5 million to $0.8 million in 2012, compared to $1.3 million in 2011. The decrease was due mainly to a decrease of $0.6 million in currency gains, net. In addition, we had an increase of $0.3 million in interest income, which was offset by an increase of $0.2 in bank charges and other financial expenses.

Taxes on Income. We had a tax expense of $0.5 million in 2012, compared to $2.2 million in 2011. The decrease in taxes on income was mainly attributable to exchange rates effect and to a tax settlement with the tax authorities in Israel.

Year Ended December 31, 2011 Compared to Year Ended December 31, 2010

Revenues. Revenues increased by $20.1 million, or 12.8%, to $178 million in 2011, compared to $157.8 million in 2010. This increase was primarily due to an increase of $17.8 million resulting from an increase in the number of product units sold and an increase of $3.4 million due to exchange rates effect. These increases were offset by a decrease of $1.1 million in revenues due to lower average selling price of our products. Sales of our manometry and catheter-based pH measurement products we acquired from Sierra totaled $28.5 million in 2011, an increase of $10.5 million, or 58.9%, compared to 2010. We acquired Sierra in April 2010. Sales of PillCam SB capsules increased by $7.4 million, or 6.7%, to $117.6 million. Sales of our other PillCam capsules increased by $0.6 million or 22.2%. Sales of workstations, data recorders and Rapid software increased by $0.5 million, or 5.7%. Sales of Bravo capsules increased by $1.4 million, or 11.0 %, offset by a decrease in sales of Bravo systems of $0.2 million, or 3.5%.

Cost of Revenues and Gross Margins. Cost of revenues was $41.5 million in 2011, compared to $37.6 million in 2010. Gross margins in 2011 were 76.7%, compared to 76.2% in 2010. The increase in gross margins in 2011 is attributable primarily to implementation of efficiency and saving measures and to the absence of certain non-recurring expenses recorded in 2010 relating to the acquisition of Sierra.

Research and Development. Gross research and development expenses increased by $4.4 million to $26.1 million, compared to $21.7 million in 2010. The increase in research and development expenses in 2011 is primarily due to $2.0 million of clinical trials expenses related to clinical trials with our PillCam COLON capsule and $0.2 million increase in other clinical trials expenses, $1.2 million increase in labor expenses mainly due to increase in headcount and impact of exchange rate, $0.7 million increase in research and development expenses related to our manometry products and $0.3 increase in equity-based compensation expenses.

Research and development expenses, net of government grants, totaled $25.0 million in 2011, compared to $20.2 million in 2010. Government grants received in 2011 were $1.1 million, compared to $1.5 million received in 2010. In both years, the grants were received for new products under development.

Sales and Marketing. Sales and marketing expenses increased by $7.9 million, or 11.8%, to $75.0 million in 2011 from $67.1 million in 2010. The increase in sales and marketing expenses is primarily due to an increase of $9.9 million in labor related expenses, including salaries, sales commission and travel expenses. This increase was offset by a decrease of $1.5 million in Sierra sales and marketing expenses and a decrease of $0.4 million in trade shows expenses.

General and Administrative. General and administrative expenses decreased by $2.0 million, or 8%, to $23.1 million in 2011, compared to $25.1 million in 2010. This decrease was primarily due to a decrease of $2.0 million of equity-based compensation expenses compared to 2010 and a decrease of $1.8 million in general and administrative expenses compared to these expenses in 2010, which included the Sierra acquisition expenses. This decrease was partially offset by an increase of $1.3 million in labor expenses mainly due to increase of salaries and impact of exchange rate, an increase of $0.3 million in travel expenses and an increase of $0.2 million in other expenses.

Financial Income, Net. Financial income, net, decreased by $1.3 million to $1.3 million in 2011, compared to $2.6 million in 2010. The decrease was due mainly to a decrease of $1.3 million in currency gains, net. In addition, we had an increase of $0.2 million in interest income, which was offset by an increase of $0.1 in bank charges and other financial expenses.

Taxes on Income. We had a tax expense of $2.2 million in 2011, compared to $1.4 million in 2010. The 2011 tax expense was partially offset by a tax benefit of $0.5 million resulting from the amortization of the deferred tax liability that was recognized against the intangible assets acquired in the Sierra acquisition. The increase in taxes on income is mainly attributed to an increase in tax expense in the United States as a result of Sierra's operations.

Impact of Currency Fluctuations

In 2012, we derived 66% of our revenues in U.S. dollars, 23% in Euro, 5% in Japanese Yen and 4% in Australian dollars, with the remainder denominated in other currencies, depending on the location of the customer or the distributor used to fulfill our customers' orders. In 2012, 25% of our expenses, principally salaries and related personnel expenses, were denominated in Shekels, and we expect this level of Shekel expenses to continue for the foreseeable future. During 2012, the U.S. dollar weakened against the Shekel by 2.4%. In addition, 55% of our expenses were denominated in U.S. dollars, 11% were denominated in Euros 6% were denominated in Japanese yen, 2% were denominated in Australian dollars and 1% was denominated in other currencies. If the value of a currency in which our revenues are denominated weakens against the value of a currency in which our expenses are denominated, there will be a negative impact on the profit margins for sales of our products. In addition, as of December 31, 2012, 33% of our cash and cash equivalents were denominated in currencies other than U.S. dollar and we are therefore subject to the risk of exchange rate fluctuations among U.S. dollar, Yen, Shekel, Australian dollar and Euro. In 2012, we have used different hedging tools in order to minimize the effect of currency fluctuations on our income and were generally able to neutralize the impact of exchange rate fluctuations on our financial results. If we wish to maintain the dollar-denominated price of our product in non-U.S. markets, devaluation in the local currencies of our customers relative to the U.S. dollar could cause our customers to cancel or decrease orders or default on payment.

B. Liquidity and Capital Resources

From our inception through December 31, 2012, we raised a total of $168 million through public and private sales of our equity securities. As of December 31, 2012, we had a balance of cash, cash equivalents and investments totaling approximately $124.1 million, consisting of $35.4 million in cash and cash equivalents, $30.2 million invested in long-term marketable securities and $58.4 million in short term investments, primarily time deposits. Our working capital, which we calculate by subtracting our current liabilities from our current assets, was $122.3 million.

In June 2009, we purchased half of the non-controlling shares of Marubeni in Given Imaging K.K., our Japanese subsidiary, for $0.4 million in cash. In October 2009, we invested $4.4 million in this subsidiary to finance its operations. In July 2010, we purchased the remaining shares of Marubeni in our Japanese subsidiary for $0.4 million in cash. In March 2012, we purchased the remaining shares in GIKK from the other minority shareholder of GIKK, Suzuken Co., Ltd., for total consideration of $658,000 in cash. As a result of these transactions, we now own 100% of the shares of GIKK. We funded these transactions out of our cash resources.

In January 2012, we paid $390,000 in a combination of cash and forgiveness of commercial debt in connection with setting up a direct sales and marketing team in Brazil. In January 2013, we made a second payment of $210,000 under our agreement to enter this market, and we may be obligated to pay up to an additional $450,000 if certain conditions and performance milestones are achieved between December 2013 and December 31, 2015.

In addition, in January 2012, we made a loan of $600,000 to a private company that had collaborated with us on a research and development project. The loan bears interest of 8% per year and is secured by the borrower's intellectual property from the business collaboration and by a personal guarantee of the principal of the borrower. The maturity date of this loan is on December 31, 2013.

In August 2012, we paid €1.0 million to a third party for a non-exclusive license to a portfolio of patents related to a research and development activity. Under our patent license agreement with such third party, we may be obligated to pay royalties of up to €8.0 million if we commercialize products in the field covered by the licensed patents. We do not anticipate royalty payments in the foreseeable future.

In October 2012, we paid $6 million in cash in connection with our acquisition of the assets of the SmartPill business. Under our agreement to acquire SmartPill, if the annual revenues from sales of the SmartPill product reach $8 million or more in any fiscal year until 2016, we are obligated to pay to the sellers an additional amount equal to 15% of the total of such annual revenues in any such year.

We believe that our cash reserves and expected cash from operations will be sufficient to meet our present working capital requirements. We do not rely on cash transfers from our subsidiaries to fund our operations. Distributions, loans and advances from our subsidiaries may be prohibited or restricted by tax regimes and statutory or contractual restrictions.

The following table sets forth the components of our cash flows for the periods indicated:

	2012	2011	2010
		(In Thousands)	
Net cash provided by operating activities	$ 27,828	$ 19,929	$ 31,684
Net cash provided by (used in) investing activities	(20,059)	(36,535)	(47,387)
Net cash provided by (used in) financing activities	3,328	6,417	3,673
Effect of exchange rate changes on cash	60	(145)	191
Increase (decrease) in cash and cash equivalents	$ 11,157	$ (10,334)	$ (11,839)

Net cash provided by operating activities was $27.8 million in 2012, compared to $19.9 million in 2011 and $31.7 million in 2010. The increase in net cash from operating activities in 2012 compared to 2011 resulted primarily from a decrease of $5.5 million dollars in trade receivables, a decrease of $2.2 million in other accounts receivable and $2.8 million in inventory, which was offset by an increase of $1.5 million in other current assets. The decrease in net cash from operating activities in 2011 compared to 2010 resulted primarily from an increase of $5.5 million in accounts receivables and $5.5 million in inventory.

Net cash used in investing activities was $20.1 million in 2012, compared to $36.5 million in 2011 and $47.4 million in 2010. Investment activities in 2012 consisted primarily of an investment of $6.5 million in marketable securities and short term deposits, an investment of $6.0 million in the acquisition of SmartPill and an investment of $7.0 million in fixed and intangible assets. Our investments in fixed and intangible assets in 2012 consisted primarily of investments of $2.0 million in manufacturing machinery and equipment, $1.5 million in computer hardware and software, $1.3 million in furniture, fixtures and leasehold improvements and $2.2 million in patents. Investment activities in 2011 consisted primarily of an investment of $25.9 million in marketable securities and short term deposits and an investment of $10.6 million in fixed and intangible assets. Our investments in fixed and intangible assets in 2011 consisted primarily of investments of $2.0 million in manufacturing machinery and equipment, $1.2 million in computer hardware and software, $0.2 million in furniture, fixtures and leasehold improvements and $7.2 million in patents. Investment activities in 2010 consisted primarily of an investment of $35 million in the acquisition of Sierra, an investment of $7.6 million in marketable securities and short term deposits, and $5.0 million in fixed and intangible assets. Our investments in fixed and intangible assets in 2010 consisted primarily of investments of $1.3 million in manufacturing machinery and equipment, $2.0 million in computer hardware and software, $0.6 million in furniture, fixtures and leasehold improvements and $1.0 million in patents.

Net cash provided by financing activities was $3.3 million, compared to $6.4 million in 2011 and $3.7 million in 2010. In 2012, net cash provided by financing activities consisted primarily of $4.1 million of proceeds from exercise of stock options, offset by $0.7 million used to purchase the entire interest held by a third party in our Japanese subsidiary. In 2011, net cash provided by financing activities consisted primarily of $6.6 million of proceeds from exercise of stock options. In 2010, net cash provided by financing activities consisted primarily of $4.2 million of proceeds from exercise of stock options, offset by $0.4 million used to purchase the entire holding of a third party in our Japanese subsidiary.

Market Risk

As of December 31, 2012, we had $35.4 million in cash and cash equivalents, which were invested in bank accounts and deposits with maturities of three months or less deposited with a number of highly-rated banks inside and outside of Israel. In addition, as of December 31, 2012, we had $30.2 million invested in long-term marketable securities and $58.4 million in short term investments, primarily time deposits. We invest these additional amounts in longer-term financial instruments in order to seek to achieve a higher yield. As of December 31, 2012, all of the marketable securities are held in corporate bonds and commercial paper that were highly-rated by rating agencies at the time of investment. All investments are made in compliance with investment policies and authorization rights approved by the audit committee of our board of directors, are focused on the preservation of capital and are monitored periodically by our audit committee.

Our cash and investments are subject to general credit, counterparty, liquidity, market and interest rate risks, which were exacerbated by the dislocation that has recently affected the financial markets and global economy and caused credit and liquidity issues for a number of reputable financial institutions.

Market acceptance of our products in the United States and other countries is dependent upon the medical equipment purchasing and procurement practices of our customers, patient demand for our products and procedures and the reimbursement of patient's medical expenses by third-party payors, including government healthcare programs. The current uncertainty surrounding world financial markets may result in the purchasers of medical equipment decreasing their medical equipment purchasing and procurement activities. In addition, tightening in world credit markets may result in our customers having increased difficulty securing the financing necessary to purchase our products which may result in decreased sales. The financial condition of our customers may deteriorate and our ability to collect payments due to us may be adversely affected. Widespread economic uncertainty may also result in cost-conscious patients making fewer trips to their physicians and specialists, which could result in reduced demand for our products and procedures. Furthermore, third-party payors, including governments, around the world facing tightening budgets could move to further reduce their offered reimbursement rates or countries may adopt healthcare reforms to reduce healthcare spending. If the current economic condition results in the occurrence of any of these events, our liquidity and financial results may be materially and adversely affected.

For more information about market risks, see Item 3 — "Risk Factors," Item 5 — "Operating and Financial Review and Prospects — Impact of Currency Fluctuations" and Item 11 — "Quantitative and Qualitative Disclosures About Market Risks."

Corporate Tax

Israeli companies were generally subject to income tax at the corporate rate of 25% in 2012. As of December 31, 2012, we had no tax loss carry-forwards in Israel except for capital losses amounting to $37 million. Under Israeli tax law, capital losses can be carried forward indefinitely and offset against future taxable capital gains.

In addition, our investments in equipment and leasehold improvements at our manufacturing facility in Yoqneam, Israel are eligible for tax benefits as an "approved enterprise" or "beneficiary enterprise" under the Law for the Encouragement of Capital Investments, 1959 (the "Investment Law"). Subject to compliance with applicable requirements, the portion of our undistributed income derived from our approved enterprise programs will be exempt from corporate tax for a period of ten years commencing in the first year in which we generate taxable income. The ten-year period may not extend beyond the later of 14 years from the year in which approval was granted or 12 years from the year in which operations or production by the enterprise began. We received approved enterprise status for investments beginning in 1999. The first year in which we generated taxable income was 2005. Accordingly, the ten-year period applicable to our initial approved enterprise program will end in 2014 and our income will be subject to corporate tax after such date; however, we have additional investments that we believe qualify for approved or beneficiary enterprise status that are expected to result in tax benefits on a portion of our income generated under these additional investments until approximately 2021. We are permitted to claim tax benefits in respect of future investments retroactively on our corporate tax returns instead of filing an application for tax benefits in advance with the Investment Center, the administrator of the Investment Law, and without prior approval and without submitting any reports to the Investment Center. Audits of any claim for tax benefits will take place by the Israeli income tax authority as part of the general tax assessments it may perform from time to time. We may be unable to receive approvals in the future for approved enterprise status and tax benefits for approved investments may not continue at current levels or at all.

We expect that a substantial portion of the income we derive in the future will be from our approved enterprise programs. These benefits should result in income recognized by us being tax exempt for a specified period as described in the preceding paragraph. These benefits may not be applied to reduce the tax rate for any income that is not derived from sales of our products manufactured at our facility in Yoqneam, Israel.

Our approved enterprise status imposes certain requirements on us, such as the location of our manufacturing facility, location of certain subcontractors and the extent to which we may outsource portions of our production process. These requirements limit our ability to pursue production arrangements that may otherwise be more favorable to us if we want to maintain these tax benefits. Therefore, we may be required to weigh the possible loss of these benefits against other benefits from pursuing arrangements which are not, or which may not be considered by the relevant Israeli authorities to be, in compliance with these requirements. If we do not meet these requirements, Israeli law permits the authorities to cancel such tax benefits retroactively.

On December 29, 2010, the Investment Law was amended to significantly revise the tax incentive regime in Israel commencing on January 1, 2011. Due to our election, this amendment is currently not applicable to us. For more information, see Item 10 – "Taxation – Taxation of Companies in Israel - Tax Benefits Under the Law for the Encouragement of Capital Investments, 1959."

As of December 31, 2012, the net operating loss carry-forwards of our subsidiaries for tax purposes amounted to $37.1 million. A subsidiary's net operating loss carry-forwards for tax purposes relating to a jurisdiction are generally available to offset future taxable income of such subsidiary in that jurisdiction, subject to applicable expiration dates.

Government Grants

Our research and development efforts are financed, in part, through grants from the Office of the Chief Scientist, or OCS, of the Israeli Ministry of Industry, Trade and Labor. From inception through 2007, we received grants totaling $7.5 million from the Office of the Chief Scientist, which we repaid in full in 2007. In 2012, we received an additional $0.7 million of royalty-bearing grants. We have applied to receive additional grants to support our research and development activities in 2013.

Under the Law for the Encouragement of Industrial Research and Development of 1984, or the R&D Law, royalties on the revenues derived from sales of products or services developed in whole or in part using these OCS grants are payable to the Israeli government, generally at the rate of between 3.0% and 5.0%. The maximum aggregate royalties paid generally cannot exceed 100% of the grants made to us, plus annual interest generally equal to the 12-month London Interbank Offered Rate, or LIBOR, applicable to dollar deposits, which is published on the first business day of each calendar year.

In addition to paying any royalty due, we must abide by other restrictions associated with receiving such grants under the R&D Law continue to apply. These restrictions may impair our ability to outsource manufacturing, engage in change of control transactions or otherwise transfer our know-how outside Israel and may require us to obtain the approval or the OCS for certain actions and transactions and pay additional royalties to the OCS. In particular, any change of control and any change of ownership of our ordinary shares that would make a non-Israeli citizen or resident an "interested party," as defined in the R&D Law, requires a prior written notice to the OCS in addition to any payment that may be required of us for transfer of manufacturing or know-how outside Israel. If we fail to comply with the R&D Law, we may be subject to criminal charges. For more information on the R&D Law, see Item 10 – "Taxation – Taxation of Companies in Israel - Grants Under the Law for the Encouragement of Industrial Research and Development, 1984."

We continue to be involved in non-royalty bearing government-funded research programs inside and outside of Israel. One example is our leadership of a consortium of Israeli companies, academic and healthcare institutions that is partially funded by the OCS. The goal of this Israeli consortium was to develop new technologies based on light that could be used for medical and biological applications particularly relevant to diagnosis and therapy of diseases of the gastrointestinal tract. This consortium began its work in late 2007 and ended its activity at the end of 2012.

C. Research and Development

Our gross research and development expenditures were $25.6 million in 2012, compared to $26.1 million in 2011 and $21.7 million in 2010. Our research and development activities are conducted by our research and development staff primarily at our headquarters in Israel and to a lesser extent in the facility in Los Angeles. Our research and development efforts are focused primarily on developing new capsules to be used in the visualization of the colon, improvements to our existing products and new technologies for future expansion of our product offering. We view our innovation as an important competitive advantage and intend to continue our focus on research and development activities.

D. Trend Information

See discussion in Parts A and B of Item 5 "Operating Results and Financial Review and Prospects."

E. Off-Balance Sheet Arrangements

None.

F. Contractual Obligations

The following table of our material contractual obligations as of December 31, 2012, summarizes the aggregate effect that these obligations are expected to have on our cash flows in the periods indicated:

Contractual Obligations (4) (5)	Payments Due by Period						
	Total	2013	2014	2015	2016	2017	Later Years
				(In Thousands)			
Capital Leases (1)	$ 38	$ 38	$ —	$ —	$ —	$ —	$ —
Operating Leases (2)	23,230	5,279	4,364	3,565	2,915	2,839	4,268
Purchasing Obligations (3)	21,369	10,306	1,342	2,546	3,363	3,700	112
Total	$ 44,637	$ 15,623	$ 5,706	$ 6,111	$ 6,278	$ 6,539	$ 4,380

(1) Consists of capital leases for motor vehicles.

(2) Consists of operating leases for office and manufacturing space and motor vehicles.

(3) Consists of contractual obligations to third-party vendors and suppliers.

(4) The Company provides for uncertain tax positions based on applicable accounting guidance. The total amount of gross unrecognized tax benefits for uncertain tax positions was $3.8 million at December 31, 2012. Payment of these obligations would result from settlements with taxing authorities. Due to the difficulty in determining the timing of settlements, these uncertain tax position obligations are not included in the table above.

(5) The table above does not include a contingent royalty payment related to a non-exclusive patent license agreement with a third party (see, Note 8d to our consolidated financial statements) and does not include the estimated fair value of the contingent consideration related to the acquisition of the SmartPill assets (see, Note 16d to our consolidated financial statements).

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

Our executive officers and directors and their ages and positions as of the date of this annual report are as follows:

Name	Age	Position
Executive Officers:		
Nachum (Homi) Shamir	59	President, Chief Executive Officer and Director
Kevin Rubey*	55	Chief Operating Officer
Yuval Yanai	60	Chief Financial Officer
Skip Baldino	52	President, Americas
Kazem Samandari	62	President, Asia-Pacific/Japan
Thomas Pracht	55	President, EMEA
Ori Braun	56	Senior Vice President, Business Development
Keith Chrzanowski	52	Senior Vice President, Global Human Resources
Thomas Looby	41	Senior Vice President, Chief Marketing Officer
David Mason	66	Senior Vice President, Chief Medical Officer
Ido Warshavski	44	Senior Vice President, General Counsel & Corporate Secretary
Raphael Nave	63	Senior Vice President, Research & Development
Timothy Thomas	58	Senior Vice President, Regulatory, Clinical & Quality
Steve Murray	51	Senior Vice President, Global Manufacturing & Operations
Directors:		
Nachum (Homi) Shamir	59	President, Chief Executive Officer and Director
Israel Makov	73	Chairman of the Board of Directors
Doron Birger (2)	61	Director
James M. Cornelius (1)(2)(3)	69	Director
Michael Grobstein (1)(2)(3)	70	Director
Stanley Stern (1)	56	Director
Arie Mientkavich	70	Director
Prof. Anat Loewenstein	53	Director
Ari Bronshtein	43	Director

* Mr. Rubey left the position of Chief Operating Officer as of February 15, 2013.

(1) Member of our audit committee.

(2) Member of our compensation and nominating committee.

(3) Outside director under the Israeli Companies Law.

Nachum (Homi) Shamir has served as our President and Chief Executive Officer and a director since April 9, 2006. Prior to joining us, Mr. Shamir served as Corporate Vice President of Eastman Kodak Company and as the President of Eastman Kodak's Transaction and Industrial Solutions Group, which includes several business units, including Kodak Versamark, Inc. (whose operations were previously those of Scitex Digital Printing Inc.) of which Mr. Shamir was President and Chief Executive Officer. From June 2003 to January 2004, Mr. Shamir served as the President and Chief Executive Officer of Scitex Corporation. From January 2001 to January 2004, he served as the President and Chief Executive Officer of Scitex Digital Printing, having previously served as its Chief Operating Officer since July 2000. Prior thereto, Mr. Shamir was Managing Director and General Manager of Scitex Digital Printing (Asia Pacific) Pte Ltd., a Singapore-based company, from its incorporation in 1994. From 1993 until 1994 he was with the Hong Kong based Scitex Asia Pacific (H.K.) Ltd. Before joining Scitex, Mr. Shamir held senior management positions at various international companies mainly in the Asia Pacific regions. Mr. Shamir holds a B.Sc from the Hebrew University of Jerusalem and an M.P.A. from Harvard University.

Kevin Rubey has served as our Chief Operations Officer from June 2001 until February 2013. Prior to joining us, from 1998 to May 2001, Mr. Rubey worked at Eastman Kodak Company, where he led global manufacturing and operations for the Health Imaging Business Unit. From 1996 to 1998, Mr. Rubey was Manufacturing Director of the Medical Imaging Business Unit of Imation Corporation, a U.S. information technology company specializing in data storage and color image management. Prior to that, from 1977 to 1996, Mr. Rubey worked at the 3M Corporation in a variety of positions in the health, consumer and information technology businesses. Mr. Rubey holds a B.Sc. in Mechanical Engineering and an M.B.A. from the University of Minnesota.

Yuval Yanai has served as our Chief Financial Officer since September 1, 2005. From October 2000 through August 2005, he served as Senior Vice President and Chief Financial Officer of Koor Industries Ltd., one of Israel's largest holding companies. Prior to that, from April 1998 to September 2000, he served as Vice President and Chief Financial Officer of NICE Systems Ltd., an Israeli global provider of Insight from Interactions, and from 1991 to April 1998, he was the Vice President, Finance and Chief Financial Officer of Elscint Ltd., a former Israeli company engaged in the manufacturing of medical imaging devices that was acquired by larger companies in this field. He joined Elscint in 1985 and served as Corporate Controller and Corporate Treasurer through 1991. Previously, Mr. Yanai served as a director of Makteshim-Agan Industries Ltd., Equity One, Inc., BVR Systems Ltd., Tadiran Communication Ltd., The Elisra Group and Telrad Networks Ltd. Mr. Yanai holds a B.Sc. in Accounting and Economics from the Tel-Aviv University.

Skip Baldino has served as President, Americas since June 2010. Prior to joining us, Mr. Baldino spent 26 years at Abbott Laboratories, a worldwide diversified health care company. During his Abbott career, Mr. Baldino held various sales, marketing and operational positions with increased responsibility and seniority in several Abbott divisions, including diabetes care, diagnostics, medical products, hospital products, health systems and specialty products. His most recent role at Abbott was Vice President in the diabetes division from June 2007 until May 2010. Mr. Baldino graduated with a bachelor's degree in Marketing from Philadelphia College of Textiles and Sciences.

Kazem Samandari has served as the President of our Asia-Pacific/Japan Region since July 2007. Prior to joining us, from 2004 to 2007, Mr. Samandari was Executive Vice President Global Sales & Marketing at Eastman Kodak, Inkjet Printing Solutions. From 1994 to 2004, Mr. Samandari held several positions at Scitex Digital Printing, including Vice President, Asia Pacific & Japan between 2001 and 2004, and was in charge of the commercial, technical & legal aspects of the activities in the region. From 1986 to 1994, Mr. Samandari served as Managing Director of GMC Digital Systems, a high-tech start-up company founded in 1984, which was a pioneer in the field of high speed, high performance, digital printing equipment. Mr. Samandari holds an M.S. degree in electrical & electronics engineering and a Ph.D. in technical sciences and industrial economy from the Swiss Federal Institute of Technology.

Thomas Pracht has served as President, Europe Middle East and Africa (EMEA), since May 2011. Prior to joining us, from April 2009 until April 2011, Mr. Pracht was a partner at Schaaf Peemoller and Partner, an international executive consulting firm. Prior to that, from 1992 until 2009, Mr. Pracht was with Olympus Medical in various management roles, including Managing Director of the EMEA region for Olympus Life Science Europe in the In-Vitro-Diagnostics unit from July 2006 until March 2009, Managing Director of the Medical Systems unit from January 2005 to June 2006, General Manager of the Endoscope division from 2001 to 2005 and other various sales and marketing roles. Mr. Pracht holds a master's degree in Biomedical Engineering from Hamburg University of Applied Sciences.

Ori Braun has served as Senior Vice President — Business Development since October 2006. Prior to joining us, Mr. Braun served as President of Valor Computerized Systems Inc., a leader in productivity increasing engineering software solutions to the PCB design, fabrication and assembly industry. From 2004 to 2005, he served as President of LifeWatch Inc., a leading cardiac monitoring services company. From 1985 to 2004, he founded and held various executive positions, including as chief executive officer, at 3DV Systems Inc., a company developing and selling 3D camera technology that was acquired by Microsoft, at Helios Software Engineering Ltd., a company in the business of simulation technology that was acquired by Cadence Design Systems Inc., and at Lansoft Computing Ltd. Between 1994 and 1996, Mr. Braun held the position of Vice President Business Development at RDC Rafael Development Corporation Ltd., or RDC, a large shareholder of Given Imaging. Mr. Braun holds a B.Sc. in Mechanical Engineering from the Ben Gurion University in Beer Sheva, Israel.

Keith A. Chrzanowski has served as our Senior Vice President of Human Resources since January 1, 2008. Prior to that, from January 2005 until December 2007, he was Director of Human Resources of our Americas region. Prior to joining us, from July 2002 until January 2005, Mr. Chrzanowski was Senior Director/Vice President of Human Resources for McKesson Provider Technologies, a division of McKesson specializing in delivering software to include automation and robotics, business process re-engineering, analytics, and other services that connect healthcare providers, physicians, third-party payors and patients across all care settings. From July 2000 until July 2002, Mr. Chrzanowski was Vice President of Human Resources for Spherion's Outsourcing Group, which provided services to Fortune 500 customers. From 1991 to 2000, Mr. Chrzanowski worked as a Human Resource Manager and Director of Human Resources for diagnostic and medical supply divisions which initially were a part of Baxter Healthcare and were later acquired by Cardinal Health in 1999. Prior to joining Baxter, Mr. Chrzanowski worked for Schlumberger Industries in the United States and Canada as a Human Resources Manager from 1987 until 1991. From 1983 until 1987 Mr. Chrzanowski held a variety of Human Resources positions in support of Beecham's Consumer Products businesses. Mr. Chrzanowski has a B.A. in Communications from Western Illinois University and an M.A. in Organizational Theory from Norwich University.

Thomas Looby has served as Senior Vice President and Chief Marketing Officer since July 2010. Prior to that, from September 2006 until July 2010, he has served us in various roles including the Vice President of Corporate Strategy and Planning and Director of Upper GI Products. Before joining us, from January 2001 until September 2006, Mr. Looby worked for Eastman Kodak and Scitex Digital Printing as Director of Global Product Marketing and Business Strategy. Additionally, Mr. Looby has worked for Bayer, Chemineer and Giddings & Lewis in a variety of marketing and business management roles. Mr. Looby currently serves on the Board of the Southeast Medical Device Association. Mr. Looby graduated with a B.S. in Chemical Engineering from the University of Notre Dame and holds an MBA from the University of Dayton.

David Mason has served as our Senior Vice President and Chief Medical Officer since November 2008. Prior to joining Given Imaging, Dr. Mason was the founding partner and Chief Medical Officer at Percept BioSciences. Prior to that, from 2003 until 2007, he was Vice President and Global Head of Inflammation at UCB Pharma. From 2000 until the end of 2003, he was Senior Vice President of Clinical Research and Regulatory Affairs at AVI BioPharma and from 1994 until 2000 he was Vice President and Head of Medical Affairs at Elan Pharmaceuticals. From 1985 until 1993, he held several senior roles at Somatogen, Lederle Laboratories and Ciba-Geigy. Prior to becoming a business executive, Dr. Mason was in private practice of Internal Medicine in North Carolina and also was an Assistant Professor of Internal Medicine and Infectious Diseases at the University of Michigan Medical Center, where he completed his postgraduate training. Dr. Mason's postgraduate training also included internship and fellowship at Duke University School of Medicine and fellowship at the US National Institutes of Health, NIAID, Laboratory of Viral Diseases. Dr. Mason holds a BA in Chemistry from Williams College and an MD from Duke University School of Medicine. Dr. Mason is Board Certified in Internal Medicine.

Ido Warshavski has served as our Senior Vice President, General Counsel & Corporate Secretary since February 2013. Prior to that, from September 2004, he served as our General Counsel & Corporate Secretary. Prior to joining us, from September 1999 to August 2004, Mr. Warshavski was a corporate attorney at Proskauer LLP in New York, where he practiced general corporate and securities law, representing clients in public and private offerings, mergers and acquisitions and general corporate matters. Prior to that, from March 1996 to July 1998, Mr. Warshavski was an intern and an attorney practicing commercial litigation, medical malpractice and employment law in leading law firms in Israel and served as a teaching assistant in Civil Procedure at the College of Management Law School in Tel Aviv, Israel. Mr. Warshavski holds an LL.B., cum laude, from the College of Management Law School, and an LL.M. from Duke University School of Law in Durham, North Carolina.

Raphael Nave has served as our Senior Vice President of Research and Development since August 2008. From 2003 until 2008, Mr. Nave served as Vice President of Customers Services and Chief Technology Officer at Tower Semiconductor. From 1995 until 2003 Mr. Nave served as Vice President of R&D of NDS Corp. Prior to that, from 1974 until 1994, Mr. Nave worked at Intel Corp, in a variety of Engineering Management positions, including five years as the General Manager of Intel-Israel (74) Ltd. Mr. Nave graduated from the Electrical Engineering faculty at the Technion, Haifa, Israel in 1974 and was awarded MsEE degree in 1979.

Tim Thomas has served as our Senior Vice President of Regulatory, Clinical, and Quality since February 2013. Prior to that, he has served as our Vice President Regulatory and Quality since February 2009 and prior to that as the Director of Regulatory of our Americas region from June 2007 until February 2009. Prior to joining us, from May 2001 to May 2007, Mr. Thomas was Vice President, Regulatory/Quality/Clinical, for Dornier MedTech America, a company providing medical devices to the urology market. From 1999 until 2001, Mr. Thomas served as Vice President, Regulatory/Quality/Clinical for Neotonus, Inc., a start-up company in the field of pulsed magnetic therapy devices. From 1993 until 1998, Mr. Thomas served as Vice President Regulatory/Quality for Deknatel (Genzyme). From 1978 until 1993, Mr. Thomas held a variety of Quality Assurance positions with Johnson & Johnson. He received a BS in Chemistry and Math from the University of Central Arkansas and an Engineering Management MBA from the University of Dallas. Mr. Thomas also holds a Regulatory Affairs Certificate (RAC), Certified Quality Engineer (CQE), and Certified Quality Auditor (CQA).

Steve Murray has served as our Senior Vice President of Global Manufacturing and Operations since February 2013. From June 2009 until December 2012, Mr. Murray served as our Corporate Vice President of Operations based in Israel. Prior to that, from early 2005 until June 2009, he was based in Atlanta as the Vice President of Operations, helping to establish the U.S operational presence for our company. Prior to joining us, from 1998 to 2005, Mr. Murray was Director of Operations and a Plant Manager for Edwards Lifesciences global manufacturing, managing operations in Utah, Dominican Republic and California producing Class II & Class III devices. He has held manufacturing positions with CR Bard, Abbott Laboratories and Texas Instruments. Mr. Murray holds a BS in Mechanical Engineering from the University of Alabama and an MBA from the University of Dallas. Mr. Murray is a registered Professional Engineer.

Israel Makov has served as the Chairman of our board of directors since July 2007. Mr. Makov also serves as Chairman of SUN Pharmaceutical Industries Limited., a publicly-traded pharmaceutical company, Chairman of Biolight Life Sciences Investments Ltd., a life sciences investment company, Chairman of Micromedic Technologies Ltd., a cluster of companies engaged in cancer diagnostics and Chairman of Eltav Wireless Monitoring Ltd., the pioneer and world leader in wireless monitoring of industrial valves. Prior to joining us, he served as President and Chief Executive Officer of Teva Pharmaceutical Industries Ltd. from April 2002 until March 2007. Previously, he served as Teva's Chief Operating Officer from January 2001, Executive Vice President from 1999 and Vice President for Business Development from 1995 until 1999. Prior to joining Teva, Mr. Makov was Chief Executive Officer of Gottex from 1993 until 1995, Chief Executive Officer of Yachin Hakal Ltd. from 1991 until 1993 and Chairman of Axiom Ltd. from 1987 until 1991. Mr. Makov was also a director of Bank Hapoalim Ltd. from October 2002 until February 2006, a director of Ramot at Tel-Aviv University from 2001 until January 2006, and one of the founders and a director of the INNI-Israel National Nanotechnology Initiative since 2003. Mr. Makov has also served on the Board of Governors of the Technion — Israel Institute of Technology since 2006 and is a member of the Executive Board and Management Committee of the Weizmann Institute of Science since 2007. He has also served as the President of the Friends of Schneider Children's Medical Center of Israel, Chairman of the Friends of Gesher Theatre and as the Chairman of the Board of the Institute for Policy and Strategy at the Interdisciplinary Center, or IDC, in Herzliya. Mr. Makov holds a B.Sc. in Agriculture and M.Sc. in Economics from the Hebrew University of Jerusalem.

Doron Birger has served as a director since June 2000. From August 2002 until July 2007, Mr. Birger was the Chairman of our board of directors. He currently serves as a special advisor to Landmark Ventures, as a director of Hadasit Bio-Holdings Ltd. and Icecure, two publicly traded life sciences companies in Israel, and as chairman of several private companies in Israel in the high-technology sector. Mr. Birger served as Chief Executive Officer of Elron Electronic Industries, Ltd., or Elron, from August 2002 until 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. Until April 2009, Mr. Birger was a director of RDC and a director or chairman of the board of directors of many privately held companies in the Elron group in the fields of medical devices, semiconductors and communication. From 1991 to 1994, Mr. Birger was Chief Financial Officer at North Hills Electronics Ltd., an advanced electronics company. From 1990 to 1991, Mr. Birger served as Chief Financial Officer of Middle-East Pipes Ltd., a manufacturer in the metal industry. From 1988 to 1990, Mr. Birger served as Chief Financial Officer of Maquette Ltd., a manufacturer and exporter of fashion items. From 1981 to 1988, Mr. Birger was Chief Financial Officer and director at Bateman Engineering Ltd. and I.D.C. Industrial Development Company Ltd. Mr. Birger is a director of the National Science & Technology Museum in Haifa, Israel, the chairman of Carmel Ltd., Haifa University Economic Corporation, a participant in the board of the Israeli Association of Electronics & Software Industries, a board member of Young Entrepreneurs, a non-profit organization, and a board member of DVI – Dental Volunteers for Israel. Mr. Birger holds a B.A. and an M.A. in economics from the Hebrew University, Jerusalem.

James M. Cornelius has served as a director since October 2001 and was elected as an outside director in December 2001. Mr. Cornelius was elected Chief Executive Officer of Bristol-Myers Squibb Company, or BMS, on April 30, 2007 and also became Chairman of BMS in February 2008. He retired as Chief Executive Officer of BMS effective May 5, 2010 and became BMS's non-executive Chairman of the Board. In addition, he serves as non-executive Chairman of the Board of Mead Johnson Nutrition, or MJN, since its split off from BMS on December 18, 2009. MJN is also listed on the New York Stock Exchange. Prior to that, he served as interim Chief Executive Officer of BMS from September 12, 2006. He has been a member of the BMS Board since January 2005. From November 15, 2005 to April 21, 2006, Mr. Cornelius was Chairman of the Board and Chief Executive Officer of Guidant Corporation (a leading cardiac and vascular medical device company listed on the New York Stock Exchange), until the sale of Guidant to Boston Scientific Corporation. From 2000 until 2006, Mr. Cornelius served as the non-executive Chairman of the board of directors of Guidant Corporation. From 1994 until 2000, Mr. Cornelius served as the Senior Executive and Chairman of Guidant Corporation. From 1983 to 1994, Mr. Cornelius was a director, member of the Executive Committee, and Chief Financial Officer of Eli Lilly and Company. From 1980 to 1982, Mr. Cornelius served as President and Chief Executive Officer of IVAC Corporation, formerly part of Eli Lilly's Medical Device and Diagnostics Division. Mr. Cornelius holds a B.A. in accounting and an M.B.A. from Michigan State University.

Michael Grobstein has served as a director since October 2001 and was elected as an outside director in December 2001. Mr. Grobstein serves as a director of BMS, as a member of its audit committee (previously, as its chairman) and a member of its compensation and management development committee. Mr. Grobstein served as a director of Guidant Corporation from 1999 to 2006, at which time Guidant was acquired by Boston Scientific Corporation. During that period, he was chairman of Guidant's audit committee and a member of its corporate governance committee. Mr. Grobstein worked with Ernst & Young LLP from 1964 to 1998, and was admitted as a partner in 1975. At Ernst & Young, Mr. Grobstein served as a Vice Chairman-International Operations from 1993 to 1998, as Vice Chairman-Planning, Marketing and Industry Services from 1987 to 1993, and Vice Chairman-Accounting and Auditing Services from 1984 to 1987. In these positions, Mr. Grobstein, among other things, oversaw the global strategic planning of the firm, was responsible for developing and implementing the firm's worldwide audit service delivery process and consulted with multinational corporations on a wide variety of financial reporting matters. Mr. Grobstein is a certified public accountant in the United States and holds a B.Sc. in accounting from the University of Illinois.

Arie Mientkavich has served as a director since July 2007. In addition, he has served as Chairman of the Board of Directors of Elron and RDC since January 2007 and as Deputy Chairman of IDB Holding Corporation Ltd. since May 2006. Mr. Mientkavich has also served as a director of NuLens Ltd. since January 2010, Chairman of the Board of Directors of Gazit Globe (Development) Ltd. since July 2006, and Deputy Chairman of Gazit Globe Ltd. since May 2005, Chairman of the Board of Directors of A. Drori Ltd since March 2012 and director of Ronson Europe since June 2011. Prior to this, from 1997 through January 2006, Mr. Mientkavich served as Chairman of the Board of Directors of Israel Discount Bank Ltd. and its major subsidiaries, Israel Discount Bank of New York, Mercantile Discount Bank Ltd. and Discount Management Provident Funds. Between 1987 and 1997, Mr. Mientkavich served as Active Chairman of the Board of the Israel Securities Authority — the Israeli equivalent of the United States Securities and Exchange Commission. Prior to that, from 1979 through 1987, he was the General Counsel of the Israeli Ministry of Finance. Mr. Mientkavich holds degrees in Political Science and Law from the Hebrew University, Jerusalem and is a member of the Israeli Bar Association.

Stanley Stern has served as a director since May 2012. Mr. Stern Serves as the managing partner of Alnital Capital, a strategic advisory firm. From January 2008 until February 2013 Mr. Stern served as Managing Director and Head of Technology, Defense Electronics, Israeli Banking and FIG at Oppenheimer & Co. Prior to this, from March 2004 until December 2007, he served as a Managing Director and Head of Investment Banking at Oppenheimer. Prior to Oppenheimer, he was a Managing Director and the Head of Investment Banking with C.E. Unterberg, Towbin where he focused on technology and defense related sectors. From January 2000 until January 2002, Mr. Stern ran STI Ventures Advisory USA Inc., a venture capital firm focusing on technology investments. Before running STI Ventures, he spent over 20 years at CIBC Oppenheimer in the investment banking department and started the technology banking group in 1990. Mr. Stern serves as the chairman of the board of directors of AudioCodes, a provider of VoIP infrastructure, and as a director of Tucows, Inc., an internet service provider. From 2004 until 2009 he served as a director of Diamond.com, an online jewelry vendor. From 2005 until its sale in 2011, he served as a director and Chairman of the audit committee of Fundtech Ltd. Mr. Stern received his MBA from Harvard Business School and a BS from Queens College.

Prof. Anat Loewenstein has served as a director since August 2005. Prof. Loewenstein completed her training in Johns Hopkins University Hospital in Baltimore in 1996. She has been the Director of the Department of Ophthalmology, Tel-Aviv Medical Center since January 2000, Vice Dean of the Sackler School of Medicine, Tel-Aviv University since September 2006, and a Professor at the Sackler School of Medicine since April 1999. She is the principal investigator in multiple multicenter drug and device studies for Novartis, Allergan, Bayer and Lumenis, and serves as a consultant to several companies in the healthcare industry, including Novartis, Allergan, Lumenis, Notal Vision Ltd. and ForSight Labs. She is the chairperson of the Institutional Review Board committee of the Israeli Ministry of Health. Prof. Loewenstein holds an M.D. from the Hebrew University of Jerusalem and Masters Degree in Health Administration from Tel-Aviv University.

Mr. Ari Bronshtein has served as our director since December 2010. Mr. Bronstein has served as Chief Executive Officer of Elron, since May 2009. From January 2006, Mr. Bronshtein has also served as vice president at Discount Investment Corporation, or DIC, a holding company in Israel. From 2004 to 2005, Mr. Bronshtein served as vice president and head of the Economics and Business Development division of Bezeq, a leading Israeli telecommunication company. From 2000 to 2003, Mr. Bronshtein served as Director of Finance and Investments at Bezeq. From 1999 to 2000, Mr. Bronshtein served as Manager of Business Analysis at Comverse Technologies, a telecommunication company. From 1996 to 1999, Mr. Bronshtein held various positions at Tadiran, his last position being Director of the Finance and Investments division. Mr. Bronshtein currently serves as a director of CellCom Israel Ltd., a publicly traded cellular telephone company, and other companies within the IDB group. Mr. Bronshtein holds a Bachelors degree in Finance and Management and a Masters degree in Finance and Accounting, both from Tel-Aviv University.

B. Compensation

The aggregate compensation paid by us and our subsidiaries to our directors and executive officers for the year ended December 31, 2012 was $9.1 million. This amount includes the fees we paid our directors and $3.6 million of stock based-compensation and also includes approximately $0.3 million set aside or accrued to provide pension, severance, retirement or similar benefits or expenses. This amount does not include business travel, relocation, professional and business association dues and expenses reimbursed to office holders, and other benefits commonly reimbursed or paid by companies in the jurisdictions in which we operate.

The regular fees for each non-employee director include a quarterly fee of $6,250 for their service on our board of directors, and a $1,500 fee for attending and participating in each meeting of the board of directors or any committee of the board of directors. The total amount of these payments in 2012 was $0.3 million. In addition, all of our directors were reimbursed for their expenses for each board of directors and committee meeting attended. The directors' fees for service by our directors Arie Mientkavich and Ari Bronshtein are paid to Elron, where they serve as Chairman of the board of directors and as the Chief Executive Officer, respectively.

In 2012, we granted our directors and executive officers a total of 204,015 restricted share units, or RSUs. The total number of RSUs granted includes a total of 60,015 RSUs granted to our non-employee directors as part of their directors' fee. RSUs granted to executive officers typically vest 50% on the second anniversary of the grant date and 25% on each of the third and fourth anniversaries of the grant date. RSUs granted to non-employee directors typically vest after one year of continued service on the board of directors or a committee thereof. Fiscal 2010 was the first year in which we granted RSUs. Prior to 2010 we granted our directors and executive officers options to purchase our ordinary shares with an exercise price equal to the fair market value of our ordinary shares on the date of grant. We decided to transition from stock options to RSUs to reduce the potential dilutive effect on shareholders as the total number of RSUs we grant is significantly lower than the number of stock options.

As part of their board service fee, our non-employee directors receive recurring annual grants of equity units relating to our ordinary shares. Any non-employee chairperson of our board of directors and any committee thereof receives an annual grant of 5,000 RSUs, any non-employee director receives an annual grant of 4,545 RSUs for board service and any non-employee director serving on a committee of the board of directors receives an annual grant of 2,275 RSUs for each committee on which such director is serving. These grants are cumulative.

Please see Item 7 — "Major Shareholders and Related Party Transactions — Agreements with Directors and Officers — Employment Agreements" for information regarding the employment agreements and compensation of Nachum Shamir, our President and Chief Executive Officer and Mr. Israel Makov, the Chairman of our board of directors.

C. Board Practice

Board of Directors and Officers

Our articles of association provide that we may have up to 12 directors. Except for "outside directors" whose election is governed by the Israeli Companies Law as further described below, each of our directors is elected at an annual general meeting of our shareholders by a vote of the holders of a majority of the voting power present and voting at that meeting. Our board of directors currently consists of nine directors. Each director listed above will hold office until the next annual general meeting of our shareholders, except for our outside directors who were initially elected in December 2001 for a three-year term and are now serving their fourth three-year term, which will expire December 31, 2013. Other than Nachum Shamir, our President and Chief Executive Officer, and Mr. Israel Makov, our Chairman, none of our directors are our employees or are party to a service contract with us. Mr. Arie Mientkavich, a director, is the Chairman of the Board of Elron and Mr. Ari Bronshtein, also a director, is the Chief Executive Officer of Elron. See, Item 7 – "Major Shareholders and Related Party Transactions – Major Shareholders," for information regarding ownership of our ordinary shares by Elron.

A simple majority of our shareholders at a general meeting may remove any of our directors from office, except the outside directors nominated under the Israeli Companies Law, and elect directors in their stead or fill any vacancy, however created. In addition, vacancies on the board of directors, other than vacancies created by an outside director, may be filled by a vote of a majority of the directors then in office. Our board of directors may also appoint additional directors up to the maximum number permitted under our articles of association. A director so chosen or appointed will hold office until the next annual meeting of our shareholders. There are no family relationships among any of our directors and executive officers.

Each of our executive officers serves at the discretion of the board of directors and holds office until his or her successor is elected or until his or her earlier resignation or removal. All of our executive officers have signed employment agreements.

Outside and Independent Directors

Under the Israeli Companies Law, companies incorporated under the laws of the State of Israel whose shares are listed on an exchange, including the Nasdaq Global Select Market, are required to appoint at least two outside directors. Outside directors are required to meet standards of independence and qualifications set forth in the Israeli Companies Law and related regulations. Outside directors are elected by a majority vote at a shareholders' meeting, provided that either (1) the majority of shares voted at the meeting, including at least a majority of the shares of non-controlling shareholders and shareholders having no personal interest in approving such election voted at the meeting and excluding abstaining votes, vote in favor of the election of the outside director, or (2) the total number of shares of the disinterested shareholders voted against the election of the outside director does not exceed two percent of the aggregate voting rights in the company. The initial term of an outside director is three years. An outside director of a company whose shares are dually listed on an Israeli exchange and on a foreign exchange, including the Nasdaq Global Select Market, may be re-elected to one or more additional three-year terms, subject to the conditions described above for election of outside directors, if the audit committee and the board of directors have determined that these additional terms benefit the company in light of the outside director's expertise and contribution to the company and the reasons for this determination have been presented to the shareholders prior to their approval of the re-election. Outside directors may only be removed by the same percentage of shareholders as is required for their election, or by a court, and then only if the outside directors cease to meet the statutory requirements for their appointment or if they violate their duty of loyalty to the company. If an outside directorship becomes vacant and there are no other two serving outside directors, a company's board of directors is required under the Israeli Companies Law to immediately call a shareholders' meeting to appoint a new outside director. Our two outside directors are James Cornelius and Michael Grobstein. At our annual shareholders meeting in June 2010, after our audit committee and board of directors determined that their re-election will benefit the company in light of their expertise and contribution to the company and the reasons for such determination were presented to the shareholders, Messrs. Cornelius and Grobstein were re-elected to a fourth term as outside directors, which will expire in December 2013.

In addition, the Israeli Companies Law provides that every outside director appointed to the board of directors of an Israeli company must qualify as a "financial and accounting expert" or as "professionally competent," as such terms are defined in the applicable regulations under the Israeli Companies Law, and that at least one outside director must qualify as a "financial and accounting expert." We comply with these requirements. In addition, the Israeli Companies Law requires Israeli companies to determine how many directors, in addition to the outside directors, qualify as "financial and accounting experts" taking into account the nature of the company's business, the complexity of the activities carried out by the company and the size of its board of directors. In February 2012, our board of directors determined that at least one of our directors will be a "financial and accounting expert," in addition to the outside directors. Currently, Doron Birger qualifies as a "financial and accounting expert," as defined in the applicable regulations.

Each committee of a company's board of directors is required to include at least one outside director and our audit committee and compensation committee are required to include both of our outside directors. An outside director is entitled to compensation as provided in regulations adopted under the Israeli Companies Law and is otherwise prohibited from receiving any other compensation, directly or indirectly, in connection with his or her service as a director.

In addition to the requirements of the Israeli Companies Law, we comply with the Nasdaq Global Select Market listing requirements, under which a majority of the members of our board of directors (including all members of our audit committee) are required to be independent, as that term is defined in the rules of the Nasdaq Global Select Market. Our board of directors has determined that a majority of our directors qualify as independent directors in accordance with the applicable rules.

Internal Auditor

Under the Israeli Companies Law, the board of directors must appoint an internal auditor nominated by the audit committee. The role of the internal auditor is to examine whether a company's actions comply with the law and orderly business procedure. Under the Israeli Companies Law, the internal auditor may be an employee of the company but not an "interested party" or an office holder, or affiliate, or a relative of an interested party or an office holder, nor may the internal auditor be the company's independent accountant or its representative. An "interested party" is defined in the Israeli Companies Law as any person or entity holding 5% or more of the outstanding shares or the voting rights in the company, any person or entity who has the right to designate one director or more or the chief executive officer of the company or any person who serves as a director or as a chief executive officer. Our internal auditor is an employee of the Israeli member firm of Deloitte Touche Tohmatsu.

Audit Committee

Under the Israeli Companies Law, the board of directors of any company whose shares are listed on any exchange must also appoint an audit committee comprised of at least three directors including all of the outside directors. The audit committee may not include the chairman of the board of directors, a controlling shareholder or a relative of a controlling shareholder, a director employed by the company or its controlling shareholder or by an entity controlled by a controlling shareholder, a director who provides services to the company or its controlling shareholder or by an entity controlled by a controlling shareholder on a regular basis, or a director who derives most of its income from a controlling shareholder. Under the Nasdaq Global Select Market listing requirements, we are required to have an audit committee consisting of at least three members, each of whom must be "independent," as defined under the rules of the Nasdaq Global Select Market and the Securities Exchange Act of 1934 (the "Exchange Act"), and each must be able to read and understand fundamental financial statements. In addition, one member of the audit committee must have past employment experience in finance or accounting or other comparable experience which results in the individual's financial sophistication. We believe that each of the current members of our audit committee, Michael Grobstein, James Cornelius and Stanley Stern, meets these independence and financial literacy requirements. In addition, the board of directors has determined that Mr. Grobstein has the requisite experience and is the financial expert serving on our audit committee.

Under the Israeli Companies Law, the role of the audit committee is to identify irregularities in the business management of the company, including in consultation with the internal auditor or the company's independent public accountants, and, if irregularities are found, suggest an appropriate course of action to the board of directors. In addition, it is the role of the audit committee to approve certain transactions with related parties and other corporate actions specified in the Israeli Companies Law, to assess the scope of work and compensation of our independent auditors, to assess our internal controls and the performance of our internal auditor and to determine arrangements for handling complaints regarding business irregularities. Under the Nasdaq Global Select Market listing requirements, our audit committee has adopted a charter setting forth its responsibilities. The audit committee's charter states that in fulfilling this role the committee is entitled to rely on interviews and consultations with our management, our internal auditor and our independent public accountants, and is not obligated to conduct any independent investigation or verification. The charter also states that the audit committee is required to nominate the company's independent public accountants, which the shareholders subsequently are required to approve.

Compensation and Nominating Committee

Under Israeli law, the compensation committee must comprise at least three directors, including all outside directors. Our compensation and nominating committee consists of our directors James Cornelius, Doron Birger and Michael Grobstein. The composition of the committee satisfies the requirements of the Israeli Companies Law and of the Nasdaq Global Select Market. The main responsibilities of our compensation and nominating committee include adoption and periodic review of our executive compensation policies, review and approval of employment terms and conditions of individual executive officers, administration of our equity plans, review of nominees for service as executive officers and director, determination of the appropriate approval process related to executive compensation matters and making recommendations to the board of directors on all of these matters. In accordance with the rules of the Nasdaq Global Select Market, our compensation and nominating committee adopted a charter, which sets forth its responsibilities.

D. Employees

The table below shows the number of employees in our primary markets as of December 31 of each of the years indicated:

	2012	2011	2010
Israel	294	299	293
Americas	276	261	255
EMEA	72	68	65
AP/J	162	136	129
	804	764	742

Headcount grew by approximately 5% in 2012 compared to 2011 and 3% in 2011 compared to 2010. The growth in headcount 2012 was primarily due to establishing a subsidiary in Brazil, increasing our sales force in Japan and the growth in production in Vietnam. Growing our headcount in 2011 was primarily due to production requirements in Israel, further integration of the GILA business in the Americas and additional selling resources in Asia.

We employ most of our employees under individual terms and conditions. Except in Vietnam, our employees are not represented by a labor union. We have written employment agreements with most of our Israeli employees, with all of our senior non-Israeli employees and with many employees outside Israel. In our manufacturing facility in Vietnam all of our employees are represented by a labor union with which we have a collective labor agreement in effect until June 2015. We provide our employees with benefits and working conditions above the required minimum and which we believe are competitive with benefits and working conditions provided by similar companies in the jurisdictions we operate. Competition for qualified personnel in our industry is intense and we dedicate significant resources to employee retention.

In each jurisdiction we operate, the employment relationship is subject to laws and regulations that may impact the contractual employment relationship. For example, such laws may include protective labor provisions, including restrictions on working hours, minimum wages, minimum vacation, minimum termination notice, sick pay, severance pay and social security as well as equal opportunity and anti-discrimination laws. In Israel, orders issued by the Israeli Ministry of Labor and Welfare make certain industry-wide collective bargaining agreements applicable to us. These agreements affect matters such as cost of living adjustments to salaries, number of daily and weekly working hours, recuperation, travel expenses, and pension rights. We have never experienced labor-related work stoppages and believe that our relations with our employees are good.

E. Share Ownership

Share Ownership by Directors and Executive Officers

For information regarding ownership of our ordinary shares by our directors and executive officers, and regarding equity awards granted to Nachum Shamir, our President and Chief Executive Officer and to Israel Makov, the Chairman of our board of directors, see Item 7 — "Major Shareholders and Related Party Transactions."

Stock Option Plans

2009 Equity Incentive Plan

Our 2009 Equity Incentive Plan provides for the grant of equity awards, such as options to purchase our ordinary shares or awards of restricted stock or restricted stock units to our (and our subsidiaries') eligible employees, directors and consultants. The 2009 equity plan is administered by our board of directors and compensation and nominating committee. The 2009 equity plan contains provisions relating to the vesting, price, exercise and other terms of awards; however, our compensation and nominating committee has authority to grant awards under different terms at its discretion. A total of 1,000,000 authorized but unissued ordinary shares are reserved for issuance under the 2009 equity plan. Shares underlying equity awards that have been cancelled or forfeited return to the pool of equity units available for grant under the plan. As of December 31, 2012, we had outstanding under this plan 495,117 restricted share units, or RSUs.

The 2009 equity plan permits us to grant a number of equity instruments, such as options, restricted stock, restricted stock units and stock appreciation rights. Option awards under this plan must be granted at no less than the fair market value of our ordinary shares on the date of the grant and the term of the awards may not exceed ten years.

Generally, where a grant of an award under the 2009 equity plan is the first grant of equity to a particular person, 50% of the award is exercisable on the second anniversary of the date of grant, and 25% becomes exercisable on each of the third and fourth anniversaries of the date of the grant. In cases of subsequent grants to a recipient, awards vest in four equal installments beginning with the first anniversary of the grant. Our Compensation and Nominating Committee has the authority to grant awards with different vesting terms and to accelerate the time periods for the vesting of awards. To the extent the awards have vested, they may be exercised in whole or in part from time to time until their expiration.

Upon the termination of employment or service of participating employees and consultants, all unvested awards are cancelled. All vested awards may be exercised within 180 days following termination, except if termination of employment is due to specified circumstances such as death or disability of a plan participant, in which case vested awards may be exercised within one year following termination. All vested awards not exercised within this period are automatically forfeited and cancelled. Unvested awards to non-employee directors whose service is terminated or discontinued for any reason other than for cause and who have been members of our board of directors for more than five years, will automatically vest and become exercisable immediately prior to termination or discontinuation of service. These vested awards may be exercised within 180 days following termination of service, except in cases of where termination or discontinuation of service is a result of statutory requirements, death, disability or other circumstances of forced cessation of service, in which case awards may be exercised at any time until their expiration date. In a case of termination for cause of a plan participant, all awards, whether vested or unvested, are automatically forfeited and cancelled.

Under the 2009 equity plan, in the event of an acquisition, merger or other share exchange in which we are not the surviving entity and the acquiring entity does not agree to assume the awards, all outstanding, but unvested, awards of each plan participant having been employed by us at least one year, will be accelerated and exercisable, ten days prior to the completion of the acquisition, merger or share exchange. In addition, if the employment of a particular holder of outstanding awards is terminated by us as of or during the 12-month period following a change in control (as defined in the 2009 equity plan), all unvested awards of such holder will be automatically accelerated and exercisable, subject to certain adjustments and exceptions. In 2012, we amended the change in control definition in the 2009 equity plan to include the acquisition by any person of beneficial ownership of more than 30% (previously 50%) of our then outstanding shares.

Awards granted under the 2009 equity plan to Israeli residents may be granted under Section 102 of the Israeli Income Tax Ordinance pursuant to which the awards or the ordinary shares issued upon their exercise must be deposited with a trustee for at least two years following the date of the grant. Under Section 102, any tax payable by an employee from the grant or exercise of the awards is deferred until the transfer of the awards or ordinary shares by the trustee to the employee or upon the sale of the awards or ordinary shares. Awards granted under Section 102 may qualify for certain tax benefits under the Israeli Tax Ordinance.

Options granted under the plan to U.S. residents may also qualify as incentive stock options within the meaning of Section 422 of the U.S. Internal Revenue Code of 1986, as amended. The exercise price for incentive stock options must not be less than the fair market value on the date the option is granted, or 110% of the fair market value if the option holder holds more than 10% of our share capital.

2006 Equity Incentive Plan

Our 2006 Equity Incentive Plan provides for the grant of options to purchase our ordinary shares or the grant of restricted stock or restricted stock units to our (and our subsidiaries') eligible employees, directors and consultants. The 2006 equity plan is administered by our board of directors and compensation and nominating committee. The plan contains provisions relating to the vesting, price, exercise and other terms of awards; however, in many cases our Compensation and Nominating Committee has authority to grant awards under different terms at its discretion. We have reserved for issuance a total of 4,000,000 authorized but unissued ordinary shares under the 2006 equity plan. Shares underlying equity awards that have been cancelled or forfeited return to the pool of equity units available for grant under the plan. As of December 31, 2012, we had outstanding under this plan options to purchase 3,344,814 ordinary shares.

The 2006 equity plan permits us to grant a number of equity instruments, such as options, restricted stock, restricted stock units and stock appreciation rights. Our previous plans only permitted the grant of options. Option awards under this plan must be granted at no less than the fair market value of our ordinary shares on the date of the grant and the term of the awards may not exceed ten years. Generally, stock options granted under the 2006 equity plan expire five years following the date of the grant.

Generally, where a grant of an award under the plan is the first grant of equity to a particular person, 50% of the award is exercisable on the second anniversary of the date of grant, and 25% becomes exercisable on each of the third and fourth anniversaries of the date of the grant. In cases of subsequent grants, awards vest in four equal installments beginning with the first anniversary of the grant. Our Compensation and Nominating Committee has the authority to grant awards with different vesting terms and to accelerate the time periods for the vesting of awards. To the extent the awards have vested, they may be exercised in whole or in part from time to time until their expiration.

Upon the termination of employment or service of participating employees and consultants, all unvested awards are cancelled. All vested awards may be exercised within 180 days following termination, except if termination of employment is due to specified circumstances such as death or disability of a plan participant, in which case vested awards may be exercised within one year following termination. All vested awards not exercised within this period are automatically forfeited and cancelled. Unvested awards to non-employee directors whose service is terminated or discontinued for any reason other than for cause and who have been members of our board of directors for more than five years, will automatically vest and become exercisable immediately prior to termination or discontinuation of service. These vested awards may be exercised within 180 days following termination of service, except in cases of where termination or discontinuation of service is a result of statutory requirements, death, disability or other circumstances of forced cessation of service, in which case awards may be exercised at any time until their expiration date. In a case of termination for cause of a plan participant, all awards, whether vested or unvested, are automatically forfeited and cancelled.

Under the 2006 equity plan, in the event of an acquisition, merger or other share exchange in which we are not the surviving entity and the acquiring entity does not agree to assume the awards, all outstanding, but unvested, awards of each plan participant having been employed by us at least one year will be accelerated and exercisable, ten days prior to the completion of the acquisition, merger or share exchange. In addition, if the employment of a particular holder of outstanding awards is terminated by us as of or during the 12 month period following a change in control (as defined in the 2006 equity plan), all unvested awards of such holder will be automatically accelerated and exercisable, subject to certain adjustments and exceptions. In 2012, we amended the change in control definition in the 2006 equity plan to include the acquisition by any person of beneficial ownership of more than 30% (previously 50%) of our then outstanding shares.

Awards granted under the 2006 equity plan to Israeli residents may be granted under Section 102 of the Israeli Income Tax Ordinance pursuant to which the awards or the ordinary shares issued upon their exercise must be deposited with a trustee for at least two years following the date of the grant. Under Section 102, any tax payable by an employee from the grant or exercise of the awards is deferred until the transfer of the awards or ordinary shares by the trustee to the employee or upon the sale of the awards or ordinary shares. Awards granted under Section 102 may qualify for certain tax benefits under the Israeli Tax Ordinance.

Options granted under the plan to U.S. residents may also qualify as incentive stock options within the meaning of Section 422 of the U.S. Internal Revenue Code of 1986, as amended. The exercise price for incentive stock options must not be less than the fair market value on the date the option is granted, or 110% of the fair market value if the option holder holds more than 10% of our share capital.

2003 Stock Option Plan

Our 2003 stock option plan provides for a grant of options to our directors, employees and consultants, including members of our medical advisory committee, and to the directors, employees or consultants of our subsidiaries. We have reserved a total of 2,500,000 ordinary shares for issuance under the plan. Shares underlying equity awards that have been cancelled or forfeited return to the pool of equity units available for grant under the plan. In addition, we have reserved for issuance under the plan any ordinary shares underlying unvested options granted under our 1998 and 2000 stock option plans that expired without exercise.

The 2003 stock option plan was materially amended in February 2012 and renamed the Amended and Restated 2003 Equity Incentive Plan, or the 2003 equity plan. The 2003 equity plan permits us to grant a number of equity instruments, such as options, restricted stock, restricted stock units and stock appreciation rights. Our previous 2003 stock option plan only permitted the grant of options. As of December 31, 2012, we had outstanding options to purchase 1,396,665 ordinary shares and 315,924 RSUs under the 2003 stock option plan. The 2003 stock option plan has expired in February 2013 and no equity grants will be made under this plan after this date.

Generally, where a grant of an award under the 2003 equity plan is the first grant of equity to a particular person, 50% of the award is exercisable on the second anniversary of the date of grant, and 25% becomes exercisable on each of the third and fourth anniversaries of the date of the grant. In cases of subsequent grants, awards vest in four equal installments beginning with the first anniversary of the grant. Our Compensation and Nominating Committee has the authority to grant awards with different vesting terms or accelerate the time periods for the vesting of awards. To the extent the awards have vested, they may be exercised in whole or in part from time to time until their expiration. Upon the termination of employment or service of participating employees and consultants, all unvested awards are cancelled. For awards made beginning in 2006, vested awards may be exercised within 180 days following termination, except if termination of employment is due to specified circumstances such as death or disability of a plan participant, in which case vested awards may be exercised within one year following termination. All vested awards not exercised within this period are automatically forfeited and cancelled. Unvested awards to non-employee directors whose service is terminated or discontinued for any reason other than for cause and who have been members of our board of directors for more than five years, will automatically vest and become exercisable immediately prior to termination or discontinuation of service. These vested awards may be exercised within 180 days following termination of service, except in cases of where termination or discontinuation of service is a result of statutory requirements, death, disability or other circumstances of forced cessation of service, in which case awards may be exercised at any time until their expiration date. In a case of termination for cause of a plan participant, all awards, whether vested or unvested, are automatically forfeited and cancelled.

Under the 2003 equity plan, in the event of an acquisition, merger or other share exchange in which we are not the surviving entity and the acquiring entity does not agree to assume the awards, all outstanding, but unvested, awards of each plan participant having been employed by us at least one year, will be accelerated and exercisable, ten days prior to the completion of the acquisition, merger or share exchange. In addition, if the employment of a particular holder of outstanding awards is terminated by us as of or during the 12-month period following a change in control (as defined in the 2003 equity plan), all unvested awards of such holder will be automatically accelerated and exercisable, subject to certain adjustments and exceptions. In 2012, we amended the change in control definition in the 2003 equity plan to include the acquisition by any person of beneficial ownership of more than 30% (previously 50%) of our then outstanding shares.

Option awards under this plan must be granted at no less than the fair market value of our ordinary shares on the date of the grant and the term of the awards may not exceed ten years.

Options granted under the 2003 equity plan to Israeli residents may be granted under Section 102 of the Israeli Income Tax Ordinance pursuant to which the options or the ordinary shares issued upon their exercise must be deposited with a trustee for a minimum period equal to the shorter of 30 months commencing on the date of grant or 24 months commencing on the end of the year in which the grant was made. Under Section 102, any tax payable by an employee from the grant or exercise of the options is deferred until the transfer of the options or ordinary shares by the trustee to the employee or upon the sale of the options or ordinary shares. Awards granted under Section 102 may qualify for certain tax benefits under the Israeli Tax Ordinance.

Options granted under the plan to U.S. residents may also qualify as incentive stock options within the meaning of Section 422 of the U.S. Internal Revenue Code of 1986. The exercise price for incentive stock options must not be less than the fair market value on the date the option is granted, or 110% of the fair market value if the option holder holds more than 10% of our share capital.

2000 Stock Option Plan

Our 2000 stock option plan provides for the grant of options to our directors, employees or consultants, including members of our medical advisory committee, and to the directors, employees or consultants of our subsidiaries. As of December 31, 2012, we had no outstanding options to purchase ordinary shares under the 2000 stock option plan. Ordinary shares underlying options which expire without exercise under the 2000 stock option plan become available for issuance under the 2003 stock option plan.

The plan is administered by our Compensation and Nominating Committee which makes recommendations to our board of directors regarding grantees of options and the terms of the grant, including exercise prices, vesting schedules, acceleration of vesting and other matters necessary in the administration of the plan. Upon the recommendation of our Compensation and Nominating Committee, options granted under the plan to Israeli residents may be granted under Section 102 of the Israeli Income Tax Ordinance pursuant to which the options or the ordinary shares issued upon their exercise must be deposited with a trustee for at least two years. Any tax payable by an employee from the grant or exercise of the options is deferred until the transfer of the options or ordinary shares by the trustee to the employee or upon the sale of the options or ordinary shares. Options granted under the plan to U.S. residents may also qualify as incentive stock options within the meaning of Section 422 of the U.S. Internal Revenue Code of 1986. The exercise price for incentive stock options must not be less than the fair market value on the date the option is granted, or 110% of the fair market value if the option holder holds more than 10% of our share capital.

Under the 2000 stock option plan, options issued under the plan are not exercisable before the second anniversary of the date of grant at which time 50% of the options become exercisable with 25% becoming exercisable on each of the third and fourth anniversaries of the date of grant. Unexercised options expire ten years after the date of grant. If the employment of an employee is terminated for cause, all of his or her vested and unvested options will automatically be forfeited and cancelled.

In the event of an acquisition or merger, we will endeavor to ensure that the rights of the holders of outstanding options are maintained. If we are unable to do so or if our board of directors resolves otherwise, all outstanding, but unvested, stock options will be accelerated and exercisable, ten days prior to the completion of the acquisition or merger.

Shareholder Approval of Stock Option Plans

In connection with Nasdaq Listing Rule 5615(a)(3) and IM 5615-3, which allow foreign private issuers such as us to follow such issuer's home country practices in lieu of certain listing requirements of Nasdaq, we have elected to follow Israel's practices in lieu of the requirement of Nasdaq Listing Rule 5635(c) that companies receive shareholder approval when certain stock option or purchase plans are to be established or materially amended. We seek shareholder approval in specified situations, including upon issuance of options to directors in their capacity as directors or to controlling shareholders, as required by Israeli law.

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table sets forth certain information regarding the beneficial ownership of our outstanding ordinary shares as of February 16, 2013 for: (1) each person who we believe beneficially owns 5% or more of the outstanding ordinary shares, (2) each of our directors individually, (3) each of the listed executive officers individually, and (4) all of our directors and listed executive officers as a group. Beneficial ownership of shares is determined under rules of the Securities and Exchange Commission and generally includes any shares over which a person exercises sole or shared voting or investment power. The table also includes the number of shares underlying options and restricted share units that will become vested and exercisable within 60 days of February 15, 2013. We had 31,127,376 issued and outstanding shares as of February 15, 2013. Ordinary shares subject to these options are deemed to be outstanding for the purpose of computing the ownership percentage of the person holding these options, but are not deemed to be outstanding for the purpose of computing the ownership percentage of any other person.

The shareholders listed below do not have any different voting rights from our other shareholders. Unless otherwise noted below, each shareholder's address is c/o Given Imaging Ltd., P.O. Box 258, Yoqneam 20692, Israel.

Name and Address	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Principal Shareholders:		
IDB Holding Corporation Ltd. (1)	14,184,348	45.6%
Leon Cooperman (2)	2,105,061	6.8
Directors and Listed Executive Officers:		
Nachum Shamir (3)	666,125	2.1
Yuval Yanai (4)	276,000	*
Kevin Rubey (5)	367,594	1.1
Israel Makov (6)	590,742	1.9
Doron Birger (7)	100,518	*
James M. Cornelius (8)	371,465	1.2
Michael Grobstein (9)	402,015	1.3
Arie Mientkavich (10)	14,248,438	45.7
Stanley Stern	--	*
Anat Loewenstein (11)	79,365	*
All directors and listed executive officers as a group (12)	17,102,262	54.9%

* Less than 1%

(1) Based on a Schedule 13D/A filed on May 11, 2011 and on information provided to us supplementally:

This number consists of 2,662,110 ordinary shares held by RDC Rafael Development Corporation Ltd., or RDC, a private Israeli company, 6,802,710 ordinary shares held by Elron Electronic Industries Ltd., or Elron, a public Israeli company, and 4,719,528 ordinary shares held by Discount Investment Corporation Ltd., or DIC, a public Israeli company.

Elron owns all of the outstanding shares of DEP Technology Holdings Ltd. which, in turn, holds 50.1% of the voting power of RDC. As a result, Elron may be deemed to be a beneficial owner of, and to share with RDC the power to vote and dispose of, the 2,662,110 ordinary shares held by RDC. In addition, Elron and DIC are parties to a voting agreement with respect to our ordinary share held by them, as a result of which Elron shares the power to vote 4,719,528 Ordinary Shares held by DIC and, therefore, may be deemed to be a beneficial owner of a total of 14,184,348, or approximately 45.6% of our ordinary shares. This voting agreement was entered into on September 29, 2003 with a term of one year which renews automatically annually unless terminated by notice of either party to the other party no later than August 30 in each year, or unless earlier terminated by agreement of both parties thereto, and currently it is in effect.

As of February 15, 2013, DIC held approximately 50.3% of the outstanding shares of Elron and, as a result and also due to the voting agreement described above, DIC may be deemed to be a beneficial owner of, and to share with Elron and RDC the power to vote and dispose of, the foregoing 14,184,348 ordinary shares held by RDC Elron and DIC.

As of such date, IDB Development Corporation Ltd., or IDBD, a private Israeli company, held approximately 73.9% of the outstanding shares of DIC. IDBD is a wholly-owned subsidiary of IDB Holding Corporation Ltd., or IDBH, a public Israeli company which is controlled as follows: (i) Ganden Holdings Ltd., or Ganden, a private Israeli company controlled by Nochi Dankner and his sister Shelly Bergman, held, directly and through a wholly-owned subsidiary, approximately 47.2% of the outstanding shares of IDBH; (ii) Nochi Dankner held, directly and through a company controlled by him, approximately 7.65% of the outstanding shares of IDB; (iii) Shelly Bergman, through a wholly-owned company, held approximately 3.8% of the outstanding shares of IDBH; (iv) Avraham Livnat Ltd., or Livnat, a private Israeli company controlled by Avraham Livnat, held, directly and through a wholly-owned subsidiary, approximately 11.8% of the outstanding shares of IDBH; and (v) Manor Holdings B.A. Ltd., or Manor, a private company controlled by Ruth Manor, held, directly and through a majority-owned subsidiary, approximately 9.9% of the outstanding shares of IDBH. A portion of the foregoing shareholdings in IDBH have been pledged to financial institutions as collateral for loans taken to finance the purchase of these shareholdings in IDBH. Upon certain events of default, these financial institutions may foreclose on the loans and assume ownership of or sell such shareholdings.

Subsidiaries of Ganden, Livnat and Manor are parties to a shareholders' agreement with respect to most of the shares of IDBH held by them for the purpose of maintaining and exercising control of IDBH as a group. Their additional shareholdings in IDBH are not subject to the shareholders agreement. The term of the shareholders agreement expires in May 2023.

Based on the foregoing, each of IDBD and IDBH (by reason of their control DIC), Ganden, Manor and Livnat (by reason of their control of IDBH) and Nochi Dankner, Shelly Bergman, Ruth Manor and Avraham Livnat (by reason of their control of Ganden, Manor and Livnat, respectively) may be deemed to be a beneficial owner of, and to share with DIC, Elron and RDC the power to vote and dispose of our ordinary shares held by DIC, Elron and RDC. Each of IDBD, IDBH, Ganden, Manor, Livnat, Nochi Dankner, Shelly Bergman, Ruth Manor and Avraham Livnat disclaims beneficial ownership of our ordinary shares held by DIC, Elron and RDC.

Nochi Dankner is Chairman of IDBH, IDBD and DIC. Rona Dankner, the daughter of Nochi Dankner, is a director of Elron. Isaac Manor (the husband of Ruth Manor) is a director of IDBH, IDBD and DIC and Dori Manor (a son of Isaac and Ruth Manor) is a director of IDBH, IDBD, DIC and Elron.

According to an investment agreement between Ganden and an entity controlled by Mr. Eduardo Elzstain (which, as of December 31, 2012, held 10% of Ganden's outstanding share capital), such entity received an option to increase its holding in Ganden to up to approximately 30.8% of Ganden's outstanding share capital. The option is exercisable until April 10, 2013 subject to certain conditions. In case of full exercise of the option, and subject to obtaining of regulatory approvals and other conditions, certain shareholders arrangements will become effective, including that material decisions in Ganden would require the consent of both Nochi Dankner and Eduardo Elzstain. With entry into force of these shareholders arrangements, Mr. Elzstain may be considered as one of IDB's controlling shareholders and one of our indirect controlling shareholders.

Securities of each of IDBH, IDBD, DIC and Elron are traded on the Tel-Aviv Stock Exchange. The address of each of DIC, IDBD, IDBH and Nochi Dankner is The Triangular Tower, 44th Floor, 3 Azrieli Center, Tel-Aviv 67023, Israel. The address of each of Elron and RDC is The Triangular Tower, 42nd Floor, 3 Azrieli Center, Tel-Aviv 67023, Israel. The address of Shelly Bergman is 9 Mishmar Ezrehi Street, Afeka, Tel-Aviv 69697, Israel. The address of Ruth Manor is 26 Hagderot Street, Savyon 56526, Israel. The address of Avraham Livnat is Taavura Junction, Ramle 72102, Israel.

(2) Based on a Schedule 13G/A filed on February 8, 2013, Mr. Cooperman is the managing member of Omega Associates, L.L.C., or Associates, a limited liability company organized under the laws of the State of Delaware. Associates is a private investment firm formed to invest in and act as general partner of investment partnerships or similar investment vehicles. Associates is the general partner of limited partnerships organized under the laws of Delaware known as Omega Capital Partners, L.P., or Capital LP, Omega Capital Investors, L.P., or Investors LP, and Omega Equity Investors, L.P., or Equity LP. These entities are private investment firms engaged in the purchase and sale of securities for investment for their own accounts. Mr. Cooperman is the President, CEO and majority stockholder of Omega Advisors, Inc., or Advisors, a Delaware corporation engaged in investing for its own account and providing investment management services, and Mr. Cooperman is deemed to control said entity. Advisors serves as the investment manager to Omega Overseas Partners, Ltd., or Overseas, a Cayman Island exempted company. Mr. Cooperman has investment discretion over portfolio investments of Overseas and is deemed to control such investments. Advisors serves as a discretionary investment advisor to a limited number of institutional clients referred to as the Managed Accounts.

Mr. Cooperman is the ultimate controlling person of Associates, Capital LP, Investors LP, Equity LP, and Advisors. Therefore, Mr. Cooperman may be deemed the beneficial owner of 2,105,061 of our ordinary shares, consisting of 511,277 ordinary shares owned by Capital LP, 206,598 ordinary shares owned by Equity LP, 130,346 ordinary shares owned by Investors LP, 455,249 ordinary shares owned by Overseas and 801,591 ordinary shares owned by the Managed Accounts.

The address of the principal business office of Mr. Cooperman is 2700 No. Military Trail, Suite 230, Boca Raton FL 33431 and the principal business office of each Capital LP, Equity LP, Investors LP, Overseas, and Advisors is 88 Pine Street, Wall Street Plaza - 31st Floor, New York, NY 10005.

(3) Consists of 56,000 ordinary shares, including 51,000 shares issued upon vesting of restricted share units and shares of restricted stock, and options to purchase 593,750 ordinary shares.

(4) Consists of 41,000 ordinary shares, including 36,000 shares issued upon vesting of restricted share units, and options to purchase 240,000 ordinary shares.

(5) Consists of options to purchase 340,000 ordinary shares and 27,594 shares issued upon vesting of restricted share units.

(6) Consists of 10,000 ordinary shares and options to purchase 580,742 ordinary shares.

(7) Consists of 16,518 ordinary shares, including 13,640 ordinary shares issued upon vesting of restricted share units, and options to purchase 84,000 ordinary shares.

(8) Consists of 221,465 ordinary shares, including 30,465 ordinary shares issued upon vesting of stock options and restricted share units, and options to purchase 150,000 ordinary shares.

(9) Consists of 125,015 ordinary shares, including 40,015 ordinary shares issued upon vesting of restricted share units, and options to purchase 277,000 ordinary shares.

(10) Consists of 9,090 ordinary shares issued upon vesting of restricted share units, 55,000 options to purchase ordinary shares, and 14,184,348 ordinary shares beneficially owned by DIC, Elron and RDC. Mr. Mientkavich may be deemed an affiliate of these entities. Mr. Mientkavich disclaims beneficial ownership of the shares owned by these entities.

(11) Consists of 16,365 ordinary shares issued upon vesting of restricted share units and options to purchase 63,000 ordinary shares.

(12) Includes 14,184,348 ordinary shares beneficially owned by DIC, Elron and RDC, as well as ordinary shares and options to purchase ordinary shares beneficially held by directors and listed executive officers in their personal capacities or by their nominees. Our directors and listed executive officers disclaim beneficial ownership of the shares owned by the foregoing entities except to the extent of their pecuniary interest therein.

B. Related Party Transactions

Registration Rights Agreement

In November 2011, an Amended and Restated Registration Rights Agreement among us, Elron, DIC and RDC was approved at a special meeting of our shareholders. Elron, DIC and RDC collectively owned an aggregate of 45.6% of our ordinary shares as of February 15, 2013 and are collectively referred to as the "affiliated shareholders." The Amended and Restated Registration Rights Agreement was signed as of February 29, 2012 and amended and restated a similar agreement among us and the affiliated shareholders that had been entered into in 2007. The 2007 agreement replaced earlier registration rights granted by us to Elron, DIC, RDC, entities affiliated with OrbiMed Capital LLC and other shareholders in connection with a private placement of our ordinary shares completed in September 2000, before our initial public offering. These earlier registration rights expired in October 2006.

The main terms of the registration rights agreement are as follows:

Demand Registration Rights

At the request of one or more of the affiliated shareholders holding at least 5% of our then outstanding ordinary shares, we must use our commercially reasonable efforts to register any or all of the requesting shareholders' ordinary shares on the condition that the minimum aggregate offering price of the shares to be registered is at least $15 million. We must also give notice of the registration to other affiliated shareholders and include in the registration any ordinary shares that they request to include. This registration also may include ordinary shares offered by us for our own account and by our directors and officers. We may only be requested to carry out two of these demand registrations.

In connection with any such demand registration, the managing underwriter may limit the number of shares offered for marketing reasons. In such case, the managing underwriter must exclude first any shares to be registered by us for the company's own account and, second, any shares to be registered by our directors and officers. Thereafter, the shares to be registered by the affiliated shareholders would be reduced pro rata among the affiliated shareholders requesting inclusion of their shares according to the number of shares held by each of them.

Incidental Registration Rights

The affiliated shareholders also have the right to request that we include their ordinary shares in any registration statements filed by us in the future for the purposes of a public offering, subject to specified limitations. The managing underwriter may limit the number of shares offered for marketing reasons. In this case, the managing underwriter must exclude first any shares to be registered by us, unless we initiated the registration, second the shares that the affiliated shareholders have requested to include in the registration, and third the shares of the party initiating the registration.

Form F-3 Registration Rights

At the request of an affiliated shareholder, we must make our best efforts to register such shareholder's ordinary shares on Form F-3. We must also give notice of the registration to other affiliated shareholders to whom we have granted registration rights and include in the registration any ordinary shares they request to include. These demand rights may only be exercised if nine months have passed since the last registration that we filed in which the affiliated shareholder requesting registration was entitled to include its shares. The minimum aggregate offering price of the shares to be registered is $15 million, in case of an underwritten offering, or $5.0 million, in case of a non-underwritten offering. The managing underwriter may limit the number of shares offered for marketing reasons. In such case, the rights of each shareholder to include its ordinary shares in the registration are allocated in the same manner as in a demand registration described above.

Termination

All registration rights will expire on the fifth anniversary of the agreement. With respect to any shareholder, registration rights will expire if that shareholder can sell all of its ordinary shares within a 90 day period under Rule 144 under the United States Securities Act of 1933, as amended.

Expenses

Generally, we will pay all expenses incurred in carrying out the above registrations, as well as the fees and expenses of one legal counsel for the selling shareholders in each registration.

February 2012 Amendment

The main changes incorporated into the Amended and Restated Registration Rights Agreement are as follows:

- The extension of the affiliated shareholders' registration rights until July 18, 2017;
- In the event that any of the affiliated shareholders pledge its respective shares in the company in favor of a lending institution in connection with any credit line or loan and an event of default occurs that would allow the lending institution to institute foreclosure proceedings regarding the pledged shares, then in connection with any transfer of such shares to one or more purchasers pursuant to such foreclosure, we agreed:
    - to waive the requirement for a legal opinion or "no action" letter prior to the transfer of such shares;
    - to lower the financial thresholds necessary for a lending institution to require registration of shares;
    - to waive the requirement that a shareholder not transfer shares during a specified period following the effective date of any registration statement filed by us; and
    - to waive certain restrictions on the right of a shareholder to assign registration rights.
- Each of the affiliated shareholders could require that any registration be a shelf registration under Rule 415 under the United States Securities Act of 1933.
- We agreed to maintain such a shelf registration for the maximum possible time, which, as of the date hereof, is three (3) years from the effective date of registration.

Directors' Fees

We pay directors fees in respect of service by our directors (other than our President and Chief Executive Officer, Nachum Shamir, and Chairman, Israel Makov). See Item 6 "Directors, Senior Management and Employees — Compensation."

Agreements With Directors and Officers

We maintain written employment agreements with all of our officers. All of these agreements contain typical provisions for a company in our industry regarding noncompetition, confidentiality of information and assignment of inventions. The enforceability of covenants not to compete in Israel is limited.

Employment Agreement With the Chairman of the Board of Directors

In June 2007, we entered into an employment agreement with Mr. Israel Makov, who serves as the Chairman of our board of directors. This agreement was approved by our shareholders in the annual shareholders meeting held in July 2007. In consideration for his service as a director and Chairman of the Board of Directors, Mr. Makov receives NIS70,500 per month, or NIS 843,000 annually (approximately $18,900 per month, or $219,000 annually, as of the date of this annual report), subject to adjustment based on the Israeli Consumer Price Index, in lieu of any statutory or other typical adjustments. In addition, Mr. Makov is entitled to pension, disability, study fund, health insurance and other benefits in accordance with standard terms of employment in Israel, including a monthly deduction to severance fund in lieu of statutory severance. The total monthly contributions required to be made by us under all of these items is 23.3% of base salary and the total contribution by Mr. Makov is 7.5% of base salary. Mr. Makov is entitled to vacation and sick leave in accordance with standard practices in Israel. We reimburse Mr. Makov for all business-related expenses and provide him with directors' and officers' insurance coverage and indemnification, in accordance with the terms approved by our shareholders.

In addition, in 2007 we granted Mr. Makov options to purchase 580,742 of our ordinary shares. The exercise price of these options is $29.42, equal to the closing price of the ordinary shares on the Nasdaq Global Select Market on July 18, 2007, the date of the annual meeting of our shareholders approving this grant. These options have vested over four years and became fully vested in July 2011. These options may be exercised by Mr. Makov at any time during a period beginning with the vesting date of each installment and ending four years thereafter. Any options not exercised within the exercise period will be forfeited and cancelled.

Mr. Makov's employment agreement contains provisions that we believe are customary for a firm in our industry regarding non-competition and confidentiality of information.

Either we or Mr. Makov may terminate his employment for any reason upon three months' prior written notice, in which case Mr. Makov is entitled to receive his base salary and benefits payable during the notice period and continued vesting of options during a period of six months following termination. Vested options will terminate if not exercised within 12 months after the latest vesting date. Mr. Makov's employment may be terminated by us for cause immediately and without any termination-related payments.

The compensation of Mr. Makov as described above represents the entire compensation that Mr. Makov is entitled to receive from us. All terms described above are in lieu of the fees (in cash and equity) ordinarily paid to our non-employee directors and any payments, including bonus payments, typically paid to our officers and employees.

Employment Agreement With Our President and Chief Executive Officer

We have an employment agreement with Mr. Shamir, which we signed in April 2006 and amended in 2007. The employment agreement contains provisions standard for a firm in our industry regarding non-competition, confidentiality of information and assignment of inventions.

Mr. Shamir's annual salary has been $432,640 since June 2010. In May 2012, following approval of our shareholders at the annual shareholders meeting Mr. Shamir received (1) a cash bonus of $649,000 relating to our results in 2011, and (2) a grant of 35,000 RSUs under the Company's 2003 Plan, vesting 50% at the second anniversary of the grant date and 25% on each of the third and fourth anniversaries of the grant date.

In February 2013, our compensation committee, audit committee and board of directors approved for Mr. Shamir (1) a cash bonus of $515,923 relating to our results in 2012, (2) a grant of 30,000 RSUs under our 2009 Plan vesting 50% at the second anniversary of the grant date and 25% on each of the third and fourth anniversaries of the grant date, and (3) a bonus plan for 2013 under which Mr. Shamir may be entitled to a bonus of up to 200% of his annual base salary, similar to percentage cap in prior years, subject to meeting certain personal and company performance targets determined by the board of directors. The payment of the amounts and the grant of RSUs approved by our board of directors in February 2013 as described above are subject to approval by our shareholders at our next annual shareholders' meeting expected in May 2013. Based on a December 2012 amendment to the Israeli Companies Law, Mr. Shamir's bonus and RSU grant must be approved by a majority vote at a shareholders' meeting, provided that either (1) the majority of shares voted at the meeting in favor of such bonus or RSU grant, includes at least a majority of the shares of non-controlling shareholders and shareholders having no personal interest in such approval, excluding abstaining votes, or (2) the total number of shares voted against the approval of such bonus and RSU grant does not exceed two percent of the aggregate voting rights in the company.

Under his employment agreement, Mr. Shamir is entitled to pension, disability, health insurance and other benefits in accordance with standard terms of employment in the United States, including a monthly car allowance, vacation and sick leave. We reimburse Mr. Shamir for all business-related expenses and provide him with directors' and officers' insurance coverage and indemnification, in accordance with the terms approved by our shareholders.

Mr. Shamir's employment may be terminated by either side without cause upon three months' prior written notice. The employment agreement provides for certain severance payments and benefits depending on the reason for the termination. If Mr. Shamir's employment were to be terminated other than in connection with a "change in control", Mr. Shamir would receive, contingent upon executing a release of claims, cash severance benefits equal to two times the sum of his base salary and target bonus, accelerated vesting of equity awards otherwise scheduled to vest in the next 24 months and continuation of certain benefits for 24 months. If such a termination were to occur in connection with a "change in control", Mr. Shamir would additionally vest in all outstanding equity awards. In addition, Mr. Shamir is entitled to a gross up for any "golden parachute" taxes imposed under Section 4999 of the US tax code.

Since Mr. Shamir is also a director, under Israeli law his employment agreement and terms, as well as any changes to the agreement, are subject to approval by our shareholders by a special majority as described above.

Exculpation, Insurance and Indemnification

Under the Israeli Companies Law, an Israeli company may not exculpate an office holder from liability for a breach of the duty of loyalty of the office holder. However, a company may approve an act performed in breach of the duty of loyalty of an office holder provided that the office holder acted in good faith, the act or its approval does not harm the company, and the office holder discloses the nature of his or her personal interest in the act and all material facts and documents a reasonable time before discussion of the approval. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for a breach of duty of care, subject to specified exceptions, but only if a provision authorizing such exculpation is inserted in its articles of association. Our articles of association include such a provision.

An Israeli company may indemnify an office holder in respect of certain liabilities either in advance of an event or following an event provided a provision authorizing such indemnification is inserted in its articles of association. Our articles of association contain such an authorization. An undertaking by an Israeli company to indemnify an office holder must be limited to foreseeable liabilities and reasonable amounts determined by the board of directors. A company may indemnify an office holder against the following liabilities incurred for acts performed as an office holder:

- a financial liability imposed on him or her in favor of another person pursuant to a judgment, settlement or arbitrator's award approved by a court, to extent such liability is related to events, which in the opinion of the Board, are anticipated in light of our actual activities at the time of granting the obligation to indemnify and is limited to sum or measurements determined by the Board as reasonable under the circumstances;

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf or by a third party, or in connection with criminal proceedings in which the office holder was acquitted or as a result of a conviction for a crime that does not require proof of criminal intent; and

- reasonable expenses, including attorneys' fee, incurred by the office holder in connection with an investigation or other proceeding by a governmental authority, if such proceeding did not result in an indictment of the office holder, or if such proceeding did not result in an indictment of the office holder and the office holder was requested to pay a fine for a crime that does not require proof of criminal intent.

An Israeli company may insure an office holder against the following liabilities incurred for acts performed as an office holder:

- a breach of duty of loyalty 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 to the company or to a third party; and

- a financial liability imposed on the office holder in favor of a third party.

An Israeli company may not indemnify, insure or exculpate an office holder against any of the following:

- a breach of duty of loyalty, except for insurance and indemnification where 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;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine levied against the office holder.

Under the Israeli Companies Law, exculpation, indemnification and insurance of office holders must be approved by our audit committee and our board of directors and, in respect of our directors, by our shareholders as well.

Our articles of association allow us to exculpate, indemnify and insure our office holders to the fullest extent permitted by the Israeli Companies Law. Our office holders are currently covered by a directors' and officers' liability insurance policy.

We have entered into agreements with each of our office holders undertaking to exculpate, indemnify and insure them to the fullest extent permitted by law. We may enter into additional agreements to indemnify or insure our directors and officers when circumstances change or when new directors and officers join us. This indemnification is limited to events and amounts determined as foreseeable by the board of directors, and the insurance is subject to our discretion depending on its availability, effectiveness and cost. In the opinion of the U.S. Securities and Exchange Commission, however, indemnification of directors and office holders for liabilities arising under the Securities Act is against public policy and therefore unenforceable.

C. Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

A. Consolidated Financial Statements and Other Information

Financial Statements

See Item 17 — "Financial Statements" for audited consolidated financial statements.

Export Sales

We maintain our primary manufacturing facilities in Israel and Vietnam. We also have a small manufacturing facility in Los Angeles. Substantially all of our products are exported out of Israel and Vietnam. For information regarding our revenues by geographic market, see Item 5 — "Operating and Financial Review and Prospects."

Legal Proceedings

From time to time we may be involved in legal proceedings.

In October 2011, we became aware of a claim filed against us in Portugal by a former distributor seeking equitable compensation and damages in an amount of approximately €1.7 million due to alleged wrongful termination of a distribution agreement. We filed our defense statement in this case in January 2012. In June 2012, this claim was dismissed by a Portuguese court on the basis of lack of jurisdiction to try the case. In December 2012, an appeal by the former distributor was rejected on the basis of its failure to file the appeal on time. The former distributor has appealed the court ruling that it failed to file its appeal on time. This appeal was rejected in February 2013.

Other than as described above, we are not currently party to any legal proceedings whose outcome we expect will be material to our financial condition or results of operations.

Dividend Policy

On March 11, 2009, we paid a cash dividend of $0.54 per share, or a total of approximately $16 million. This was the only dividend we have distributed to date. This was a special dividend paid out of income not related to our "approved enterprise" status under Israeli law and we currently intend to retain future earnings to finance our operations and to expand our business. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, potential loss of tax benefits, legal restrictions, financial condition and future prospects and other factors the board of directors may deem relevant.

We have an approved enterprise status under Israel's Investment Law and are therefore eligible for tax benefits that may we lost if we pay a dividend out of income derived from the approved enterprise during the tax exemption period. Substantially all of our income is derived from our approved enterprise. If we pay dividends out of this income, we will be subject to corporation tax on the gross amount of dividends distributed and may lose our tax benefits for future periods. The tax rate on dividend distributions is subject to corporate taxes at rates varying from 10% - 25%, depending on the percentage of foreign investment. This tax rate is at 25% as of the date of this annual report.

This potential loss of tax benefits would impact any future determination on the payment of dividends or any other payment to shareholders treated as a dividend under Israeli law, such as a stock repurchase. An amendment to the Investment Law enacted in December 2010 provides an elective alternative tax benefit track in future years that may reduce the tax benefit associated with the approved enterprise status and at the same time reduce the potential adverse tax consequences of dividend distributions out of income derived from the approved enterprise. For more details, see Item 10 – "Taxation - Taxation of Companies in Israel - Tax Benefits Under the Law for the Encouragement of Capital Investments, 1959."

In addition, our ability to distribute a dividend or make any other payments that are treated as dividends under Israeli law, such as a stock repurchase, is limited by the Israeli Companies Law. Under the Israeli Companies Law, a company may only distribute "distributable profits" as dividends, and such distribution can only occur when no reasonable concern exists that the distribution will prevent the company from meeting its current and foreseeable liabilities. "Distributable profits" are defined for these purposes as the balance of a company's accumulated surplus, or the portion of such accumulated surplus accumulated over the last two years, whichever is greater, in accordance with the financial statements of the company. We must get court approval if we wish to distribute a dividend in an amount that exceeds the amount of our "distributable profits."

Significant Changes

Except as otherwise disclosed in this Form 20-F, there has been no significant change in our financial position since December 31, 2012.

Item 9. The Offer and Listing

A. Offer and Listing Details

Nasdaq Global Select Market

The following table lists the high and low closing sale prices of our ordinary shares for the periods indicated as reported by the Nasdaq Global Select Market:

Annual Highs and Lows	**High**	**Low**
2012	$ 19.79	$ 12.69
2011	22.26	14.25
2010	23.61	13.61
2009	18.00	7.06
2008	23.59	6.51

Quarterly Highs and Lows	**High**	**Low**
4th quarter 2012	$ 19.19	$ 14.84
3rd quarter 2012	17.00	12.69
2nd quarter 2012	19.79	15.61
1st quarter 2012	19.75	17.27
4th quarter 2011	17.78	14.29
3rd quarter 2011	22.19	14.25
2nd quarter 2011	22.26	19.27
1st quarter 2011	20.02	14.52

Most Recent Six Months	**High**	**Low**
February 2013	$ 16.48	$ 15.69
January 2013	18.39	15.90
December 2012	18.31	17.18
November 2012	19.19	17.99
October 2012	18.55	14.94
September 2012	14.75	13.12

On February 28, 2013, the closing price of our ordinary shares on the Nasdaq Global Select Market was $15.84 per share. We estimate that there are approximately 7,000 holders of record of our ordinary shares.

Tel-Aviv Stock Exchange

The following table lists the high and low closing sale prices of our ordinary shares for the periods indicated as reported by the Tel-Aviv Stock Exchange:

Annual Highs and Lows	High	Low
2012	NIS 75.23	NIS 50.33
2011	77.88	51.71
2010	87.80	51.33
2009	68.23	29.50
2008	89.95	24.32

Quarterly Highs and Lows	High	Low
4th quarter 2012	NIS 75.23	NIS 57.14
3rd quarter 2012	67.72	50.33
2nd quarter 2012	74.98	60.54
1st quarter 2012	74.18	64.63
4th quarter 2011	67.90	54.13
3rd quarter 2011	75.53	51.71
2nd quarter 2011	77.88	64.86
1st quarter 2011	72.64	52.00

Most Recent Six Months	High	Low
February 2013	NIS 60.96	NIS 58.92
January 2013	69.44	59.11
December 2012	70.47	64.64
November 2012	74.35	69.23
October 2012	75.23	57.14
September 2012	57.22	51.95

On February 28, 2013, the closing price of our ordinary shares on the Tel-Aviv Stock Exchange was NIS 58.92 per share.

B. Plan of Distribution

Not applicable.

C. Markets

Our ordinary shares have traded publicly on the Nasdaq Global Select Market under the symbol “GIVN” since October 2001 and on the Tel-Aviv Stock Exchange under the symbol “GIVN” since March 2004. Our ordinary shares trade publicly only on the Nasdaq Global Select Market and the Tel-Aviv Stock Exchange.

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

Objects

We are registered with the Israeli registrar of companies in Jerusalem. Our registration number is 51-257802-2. Our objects under our memorandum of association are to engage in any type of manufacturing, trade, production, labor, agriculture, and professional and business services in all branches and areas of economic activity, to advance trade, importing and exporting, and any other object determined by our board of directors from time to time. Our objects under our articles of association are to engage in any lawful business. Our ordinary shares are the only class of shares we have issued and outstanding.

Share Capital

Our registered share capital is NIS 4,500,000, divided into 90,000,000 authorized shares, par value NIS0.05 per share. Changes in registered capital and the number of authorized shares must be approved by the shareholders.

Transfer of Shares and Notices

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, Israeli law or the rules of a stock exchange on which the shares are traded. Our articles of association provide that each shareholder of record is entitled to receive prior notice of any shareholders' meeting in accordance with any applicable rule or regulation, including the rules of the stock exchange on which our shares are traded.

Non-residents of Israel may freely hold and trade our securities. Neither our memorandum of association nor our articles of association nor the laws of the State of Israel restrict in any way the ownership or voting of ordinary shares by non-residents, except that such restrictions may exist with respect to citizens of countries which are in a state of war with Israel.

Directors

Our ordinary shares do not have cumulative voting rights for the election of directors. Rather, under our articles of association our directors are appointed by the holders of a simple majority of our ordinary shares at a general shareholder meeting. As a result, the holders of our ordinary shares that represent more than 50% of the voting power represented at a shareholder meeting have the power to elect or remove any or all of our directors, subject to the special approval requirements for outside directors described under "Management-Outside Directors." Under the Israeli Companies Law, the procedures for the appointment and removal and the term of office of directors, other than outside directors, may be contained in the articles of association of a company. Our articles of association currently do not contain provisions for staggered terms for directors. However, our articles of association may be amended in the future by a majority of our shareholders at a general shareholder meeting to provide for a staggered board or other method of electing our directors, other than with respect to our outside directors.

Under the Israeli Companies Law and our articles of association, a director must disclose to us any personal interest he or she has, directly or indirectly, in any existing or proposed transaction to which we are a party (a "Related Party Transaction") and specify the nature of such interest. Generally, a director is not permitted to participate in a discussion and vote on any transaction in which he or she has a personal interest, unless and to the extent permitted under the Israeli Companies Law. If a majority of the directors have an interest in a "Related Party Transaction," all of the directors may attend the meeting and vote and the transaction will require the approval of the shareholders. Under the Israeli Companies Law, Related Party Transactions with our directors, including compensation to directors, must be approved by the audit committee, the board of directors and the shareholders.

Dividend and Liquidation Rights

Our board of directors may declare a dividend to be paid to the holders of ordinary shares in proportion to the paid up capital attributable to the shares that they hold. Dividends may only be paid out of our profits, as defined in the Israeli Companies Law, namely surplus funds or profits accrued over a period of eight quarters, whichever is higher, provided that there is no reasonable concern that a payment of a dividend will prevent us from satisfying out 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 ordinary shares in proportion to the paid up capital attributable to the shares that they hold. This right 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.

Shareholder Meetings

We are required under the Israeli Companies Law to convene an annual general meeting of our shareholders once every calendar year within a period of not more than 15 months following the preceding annual general meeting. Our board of directors is required to convene a special general meeting of our shareholders at the request of (i) two directors, (ii) one-quarter of the members of our board of directors, (iii) one or more holders of 5% or more of our share capital and 1% of our voting power, or (iv) the holder or holders of 5% or more of our voting power. The chairperson of our board of directors or any other person appointed by the board presides over our general meetings. Under the Israeli Companies Law, 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.

Quorum

The quorum required for an ordinary meeting of shareholders consists of at least two shareholders present, in person or by proxy, who hold or represent between them at least one-third of the total voting rights attached to the shares then outstanding. A meeting adjourned for lack of a quorum generally is adjourned to the same day in the following week at the same time and place or any time and place as the directors designate in a notice to the shareholders. At the reconvened meeting, the required quorum consists of one or more shareholders present in person or by proxy, unless the meeting was called pursuant to a request by our shareholders in which case the quorum required is the number of shareholders holding the minimum number of voting shares necessary to make such requisition as described under "— Shareholder Meetings."

Voting

Holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote of shareholders at a shareholder meeting. Shareholders may vote at shareholder meetings either in person or by proxy. Israeli law does not provide for public companies such as us to have shareholder resolutions adopted by means of a written consent in lieu of a shareholder meeting. Shareholder voting rights may be affected by the grant of any special voting rights to the holders of a class of shares with preferential rights that may be authorized in the future. The Israeli Companies Law provides that a shareholder, in exercising his or her rights and performing his or her obligations toward the company and its other shareholders, must act in good faith and in an acceptable manner, and avoid abusing his or her powers. This is required when voting at general meetings on matters such as changes to the articles of association, increasing the company's registered capital, mergers and approval of related party transactions. A shareholder must also avoid oppression of other shareholders. In addition, any controlling shareholder, any shareholder who knows that its vote can determine the outcome of a shareholder vote and any shareholder who, under the company's articles of association, can appoint or prevent the appointment of an office holder, is required to act with fairness towards the company. The Israeli Companies Law does not describe the substance of this duty and there is no binding case law that addresses this subject directly.

Alteration of Rights

Under our Articles of Association, the rights attached to our ordinary shares may be modified with the approval by the holders of a majority of our ordinary shares. Accordingly, modifications to our Articles of Association must be approved by our shareholders.

Resolutions

An ordinary resolution requires approval by the holders of a simple majority of the voting rights represented at the meeting, in person, by proxy or by voting instrument, and voting on the resolution.

Under the Israeli Companies Law, unless otherwise provided in the articles of association or applicable law, approval of all resolutions of the shareholders requires a simple majority. A resolution for the voluntary winding up of the company requires approval by holders of 75% of the voting rights represented at the meeting, in person, by proxy or by voting instrument and voting on the resolution.

Access to Corporate Records

Under the Israeli Companies Law, all shareholders generally have the right to review minutes of our general meetings, our shareholder register, our articles of association and any document we are required by law to file publicly with the Israeli Companies Registrar or the Israeli Securities Authority. Any shareholder who specifies the purpose of its request may request to review any document in our possession that relates to any action or transaction with a related party which requires shareholder approval under the Israeli Companies Law. We may deny a request to review a document if we determine that the request was not made in good faith, that the document contains a commercial secret or a patent or that the document's disclosure may otherwise harm our interests.

Acquisitions Under Israeli Law

Tender Offer. A person wishing to acquire shares or any class of shares of a publicly traded Israeli company and who would as a result hold over 90% of the company's issued and outstanding share capital or of a class of shares is required by the Israeli Companies Law to make a full tender offer to all of the company's shareholders or all shareholders of such class of shares, as applicable, for the purchase of all of the issued and outstanding shares of the company or of that class of shares, as applicable. A full tender offer can only be accepted if either (i) the shareholders who do not accept the offer hold less than 5% of the issued share capital of the company or of that class of shares, as applicable, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, or (ii) 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. In such case, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, the shareholders may petition the court to alter the consideration for the acquisition. If the full tender offer is not accepted, the acquirer may not acquire additional shares of the company or of such class of shares, as applicable, from shareholders who accepted the tender offer if following such acquisition the acquirer would then own over 90% of the company's issued and outstanding share capital or of the shares comprising such class, as applicable.

The Israeli Companies Law provides that, except in specified circumstances, an acquisition of shares of a public company must be made by means of a tender offer if as a result of the acquisition a person becomes the owner of 25% or more of the voting rights. This rule does not apply if there is already another 25% shareholder of the company. To our knowledge, IDBH beneficially owns more than 25% of our outstanding ordinary shares as determined in accordance with the Israeli Companies Law. Similarly, the Israeli Companies Law provides that, except in specified circumstances, an acquisition of shares in a public company must be made by means of a tender offer if as a result of the acquisition the purchaser becomes the owner of more than 45% of the voting rights, if at such time there is no other shareholder that owns more than 45% of the voting rights of the company. To our knowledge, IDBH beneficially owns more than 45% of our outstanding ordinary shares as determined in accordance with the Israeli Companies Law.

Merger. The Israeli Companies Law permits merger transactions if approved by each party's board of directors and by the shareholders of each party to the proposed merger. Shareholder approval is not required in certain specified circumstances, such as a merger between a company and its wholly-owned subsidiary. Under the Israeli Companies Law, merger transactions must be approved by our shareholders by a majority that is dependent on the circumstances of the transaction. In determining whether the required majority has approved the merger, if our shares are held by the other party to the merger, or by any person holding at least 25% of the outstanding voting shares or 25% of the means of appointing directors of the other party to the merger, then a vote against the merger by holders of the majority of the voting shares present and voting, excluding shares abstaining and shares held by the other party or by such person, or anyone acting on behalf of either of them, is sufficient to reject the merger transaction. In certain circumstances, 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 of the parties to the merger and the consideration offered to the shareholders. 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 company. In addition, a merger may not be executed unless at least 50 days have passed from the time that a proposal for approval of the merger has been filed with the Israeli Registrar of Companies and at least 30 days have passed from the approval of the shareholders of each of the parties.

Anti-Takeover Measures

The Israeli Companies Law allows us to create and issue shares having rights different to those attached to our ordinary shares, including shares providing certain preferred or additional rights to voting, distributions or other matters and shares having preemptive rights. However, the Israeli Securities Law will prevent our ordinary shares from trading on the Tel-Aviv Stock Exchange if we create shares having different voting rights than those attached to our ordinary shares. In the future, if we do create and issue a class of shares other than ordinary shares, such class of shares, depending on the specific rights that may be attached to them, may delay or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization of a new class of shares will require an amendment to our articles of association which requires the prior approval of a majority of our shareholders at a general meeting. Shareholders voting at such a meeting will be subject to the restrictions under the Israeli Companies Law described in "Voting."

Transfer Agent and Registrar

The transfer agent and registrar for our ordinary shares is American Stock Transfer & Trust Company. Its address is 59 Maiden Lane, New York, New York 10038 and its telephone number at this location is (212) 936-5100.

C. Material Contracts

Summaries of certain material contracts and amendments to these contracts are included in this Form 20-F under Item 4 — "Information on the Company — Part B: Business Overview" and under Item 7 — "Major Shareholders and Related Party Transaction — Related Party Transactions."

D. Exchange Controls

Israeli residents generally may freely deal in foreign currency and foreign assets, and non-residents may freely deal in Israeli currency and Israeli assets. There are currently no Israeli currency control restrictions on remittances of dividends on the ordinary shares or the proceeds from the sale of the shares provided that all taxes were paid or withheld; however, legislation remains in effect pursuant to which currency controls can be imposed by administrative action at any time.

E. Taxation

Certain Material Israeli Tax Considerations and Government Programs

The following is a description of the material Israeli income tax consequences of the ownership of our ordinary shares. The following also contains a description of material relevant provisions of the current Israeli income tax structure applicable to companies in Israel, with special reference to its effect on us. To the extent that the discussion is based on new tax legislation which has not been subject to judicial or administrative interpretation, there can be no assurance that the tax authorities will accept the views expressed in the discussion in question. The discussion is not intended, and should not be taken, as legal or professional tax advice and is not exhaustive of all possible tax considerations.

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

Taxation of Companies in Israel

General Corporate Tax Structure. In 2012, Israeli companies were subject to corporate tax at the rate of 25% of taxable income. However, the effective tax rate payable by a company that derives income from an approved enterprise, as discussed further below, may be considerably less.

Tax Benefits Under the Law for the Encouragement of Capital Investments, 1959. The Law for the Encouragement of Capital Investments, 1959, commonly referred to as the Investment Law, provides that a proposed capital investment by a company in eligible facilities maybe designated as an approved enterprise. Prior to March 2005, companies were required to submit an application to the Investment Center of the Ministry of Industry, Trade and Labor of the State of Israel to get an approval for each specific capital investment program in its facilities.

Each certificate of approval for an approved enterprise relates to a specific investment program delineated both by its financial scope, including its capital sources, and by its physical characteristics, for example, the equipment purchased and utilized under the program. The tax benefits derived from any certificate of approval relate only to taxable income attributable to the specific approved enterprise. If a company has more than one approval or only a portion of its capital investments is approved, its effective tax rate is the result of a weighted average of the applicable rates.

In March 2005, the Investment Law was reformed and its provisions were significantly changed. Under this reform, the term "approved enterprise" was replaced by "beneficiary enterprise." Beneficiary enterprise status is generally limited to companies that derive at least 25% of their income from export activities, such as our company. In addition, instead of filing an application in advance for approval of tax benefits with the Investment Center, companies are now allowed to claim the tax benefits on their corporate tax returns subject to fulfilling certain conditions, without prior approval and without submitting any reports to the Investment Center. Audit of any claim for tax benefits will take place by the Israeli income tax authority as part of general tax assessments it may perform from time to time. If a company does not meet the conditions specified by the Investment Law for an approved or beneficiary enterprise, it would be required to refund the amount of tax benefits, with the addition of a consumer price index linkage adjustment and interest.

Generally, taxable income of a company derived from an approved or beneficiary enterprise is subject to company tax at a reduced tax rate, rather than the regular corporate tax rate, for a period of seven years, or ten years if the company qualifies as a foreign investors' company as described below, commencing with the year in which the approved enterprise first generates taxable income. However, the ten-year period may not extend beyond the later of 14 years from the year in which approval was granted or 12 years from the year in which operations or production by the enterprise began. A company's undistributed income derived from an approved enterprise in top priority locations (commonly known as "Zone A") will be exempt from corporate tax for a period of ten years.

A company that has an approved or beneficiary enterprise program is eligible for further tax benefits if it qualifies as a foreign investors' company. A foreign investors' company is a company where more than 25% of its share capital and combined share and loan capital is owned by non-Israeli residents. A company that qualifies as a foreign investors' company and has an approved enterprise program is eligible for tax benefits for a ten-year benefit period. As specified above, depending on the geographic location of the approved enterprise within Israel, income derived from the approved enterprise program, if undistributed, may be exempt from tax for a period of between two to 10 years, and will be subject to a reduced tax rate for the remainder of the benefit period. The tax rate for the remainder of the benefit period will be (i) 25% for levels of foreign investment that do not exceed 49%, (ii) 20% for levels of foreign investment of 49% or more and less than 74%, (iii) 15% for levels of foreign investment of 74% or more and less than 90%, and (iv) 10% for levels of foreign investment of 90% or more.

The Investment Law also provides that an approved or beneficiary enterprise is entitled to accelerated depreciation for property and equipment that is included in an approved investment program. Generally, such accelerated depreciation ranges from 200% of ordinary depreciation rates for equipment to 400% for buildings, and is applied during the first five tax years of the operation of these assets, with a ceiling of 20% per year for depreciation on buildings.

A company having an approved or beneficiary enterprise status may elect to receive an alternative package of benefits. Under the alternative package of benefits, a company's undistributed income derived from an approved enterprise will be exempt from company tax for a period of between two and ten years from the first year of taxable income, depending on the geographic location of the approved enterprise within Israel, and the company will be eligible for a reduced tax rate for the remainder of the benefits period.

A company that has an approved or beneficiary enterprise in Zone A or that has elected the alternative package of benefits and that subsequently pays a dividend out of income derived from the approved enterprise during the tax exemption period is subject to corporation tax on the gross amount of dividends distributed. The rate of the tax will be the rate which would have been applicable had the company not been tax exempt. This corporation tax rate ranges from 10% to 25%, depending on the percentage of the company's shares held by foreign shareholders. The recipient of dividends distributed from such income is taxed at the rate applicable to dividends from approved enterprises which is 15%, or less under certain anti double-taxation treaties, if the dividend is distributed during the tax benefit period or within 12 years after the period and there is no time limit with respect to dividend distributed from an exempt income of foreign investors' company. The company must withhold this tax at source.

Subject to applicable provisions concerning income under the alternative package of benefits, all dividends are considered to be attributable to the entire enterprise and their effective tax rate is the result of a weighted average of the various applicable tax rates. Under the Investment Law, a company that has elected the alternative package of benefits is not obliged to distribute exempt retained profits, and may generally decide from which year's profits to declare dividends.

The Investment Center of the Ministry of Industry and Trade granted our manufacturing facility approved enterprise status under the Investment Law for several investments between 1999 and March 2005 and we have claimed an approved enterprise status on our tax returns for several capital investments programs in our facility in Israel since 2005. We have elected the alternative package of benefits under these approved enterprise programs. Since our manufacturing facility is located in a "Zone A," the portion of our income derived from these approved enterprise programs will be exempt from tax for a period of ten years, commencing when we begin to realize net income from these programs, but such period may not extend beyond the later of 14 years from the year in which approval was granted or 12 years from the year in which operations or production by the enterprise began. The first year in which we generated taxable income was 2005. Accordingly, the ten-year period applicable to our initial approved enterprise program will end in 2014 and our income will be subject to corporate tax after such date; however, we have additional investments that we believe qualify for approved or beneficiary enterprise status that are expected to result in tax benefits on a portion of our income generated under these additional investments until approximately 2021. We expect to derive a substantial portion of our income from our approved enterprise programs. The benefits available to an approved enterprise program are dependent upon the fulfillment of conditions stipulated in the Investment Law and in the certificate of approval.

The Investment Law and the criteria for receiving an "approved enterprise" or "beneficiary enterprise" status may be amended from time to time and there is no assurance that we will be able to obtain additional benefits under the Investment Law.

On December 29, 2010, the Investment Law was amended to significantly revise the tax incentive regime in Israel commencing on January 1, 2011. The December 2010 amendment introduced a new status of "preferred enterprise," replacing the existing status of "beneficiary enterprise." Similarly to "beneficiary enterprise," a preferred enterprise is an industrial company meeting certain conditions, including deriving a minimum of 25% of its income from export activities. However, under the December 2010 amendment, the requirement for a minimum investment in production assets in order to be eligible for the benefits granted under the Investments Law was cancelled. A preferred enterprise is entitled to a reduced flat tax rate with respect to preferred enterprise income at the following rates:

Tax Year	Development "Zone A"	Other Areas within Israel	Regular Corporate Tax Rate
2011-2012	10%	15%	24%-25%
2013-2014	7%	12.5%	25%
2015 onwards	6%	12%	25%

In addition, the December 2010 amendment introduced a new status of "special preferred enterprise" which is an industrial company fulfilling certain additional conditions, including having a total preferred enterprise income of at least NIS 1.5 billion in a given tax year. The tax rate applicable for a period of 10 years to income generated by such an enterprise will be reduced to 5% if located in development "Zone A," or to 8% if located in other area within the State of Israel.

Dividend distributed from income which is attributed to "preferred enterprise" or "special preferred enterprise" will be subject to withholding tax at source at the following rates: (i) Israeli resident corporation – 0%, (ii) Israeli resident individual – 15% (iii) non-Israeli resident - 15%, subject to a reduced tax rate under the provisions of an applicable double tax treaty.

The December 2010 amendment was also revised to allow financial assistance to companies located in development Zone A to be granted not only as a cash grant but also as a loan. The rates for grants and loans could be up to 20% of the amount of the approved investment.

The provisions of the December 2010 amendment do not apply to companies currently having an "approved enterprise" or "beneficiary enterprise "status, which will continue to be entitled to the tax benefits according to the provisions of the Investment Law prior to the December 2010 amendment, unless the company having the benefits of such status has elected by filing 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, to adopt the provisions of the December 2010 amendment. Such election cannot be later rescinded. A company having the status of "beneficiary enterprise" or "approved enterprise" making such election by July 30, 2015 will be entitled to distribute income generated by the "approved enterprise," subject to withholding tax at source at the following rates: (i) Israeli resident corporations – 0%, (ii) Israeli resident individuals – 15% (iii) non-Israeli residents - 15%, subject to a reduced tax rate under the provisions of an applicable double tax treaty.

Currently, we believe that the tax benefits we have as an “approved” or “beneficiary” enterprise under the Investment Law as existed prior to the December 2010 amendment are greater than the benefits we can derive from a “preferred” enterprise status that we can elect under the December 2010 amendment and, therefore, we plan to maintain our status as a beneficiary enterprise under the Investment Law as existed prior to the December 2010 amendment.

An amendment to the Investments Law, which was enacted on November 12, 2012 (the "Trapped Profits Law"), offers reduced corporate income tax rates intended to encourage the distribution of profits derived from tax-exempt income accumulated up to December 31, 2011. The Trapped Profits Law provides a formula pursuant to which the higher the amount of income a company would be willing to release, the lower would be the applicable corporate income tax rate for that company with respect to such income (the tax rate may be reduced to a minimum of 6%). A company opting to utilize the Trapped Profits Law would be required to meet certain conditions, including, among others, an obligation of the company to invest in an Industrial Enterprise.

Grants Under the Law for the Encouragement of Industrial Research and Development, 1984. Under the Law for the Encouragement of Industrial Research and Development, 1984, commonly referred to as the R&D Law, research and development programs which meet specified criteria and are approved by a governmental committee of the Office of the Chief Scientist, or OCS, are eligible for grants of up to 50% of the project’s expenditure, as determined by the research committee, in exchange for the payment of royalties from the revenues generated from the sale of products and related services developed, in whole or in part pursuant to, or as a result of, a research and development program funded by the OCS. The royalties are generally at a range of 3.0% to 5.0% of revenues until the entire OCS grant is repaid, together with an annual interest generally equal to the 12 month London Interbank Offered Rate applicable to dollar deposits that is published on the first business day of each calendar year. To date, we have repaid in full all the grants we had received from the OCS and currently have no financial obligation to the OCS. However, other restrictions under the R&D Law such as restrictions regarding location of manufacturing activities and transfer of know-how continue to apply, irrespective of the grant repayment, as described in more details below.

The terms of the R&D Law also require that the manufacture of products developed with government grants be performed in Israel. The transfer of manufacturing activity outside Israel may be subject to the prior approval of the OCS. Under the regulations of the R&D Law, assuming we receive approval from the Chief Scientist to manufacture our OCS-funded products outside Israel, we may be required to pay increased royalties. The increase in royalties depends upon the manufacturing volume that is performed outside of Israel as follows:

Manufacturing Volume Outside of Israel	**Royalties to the Chief Scientist as a Percentage of Grant**
Up to 50%	120%
between 50% and 90%	150%
90% and more	300%

If the manufacturing is performed outside of Israel by us, the rate of royalties payable by us on revenues from the sale of products manufactured outside of Israel will increase by 1% over the regular rates. If the manufacturing is performed outside of Israel by a third party, the rate of royalties payable by us on those revenues will be equal to the ratio obtained by dividing the amount of the grants received from the Office of the Chief Scientist and our total investment in the project that was funded by these grants. The transfer of no more than 10% of the manufacturing capacity in the aggregate outside of Israel is exempt under the R&D Law from obtaining the prior approval of the OCS. A company requesting funds from the OCS also has the option of declaring in its OCS grant application an intention to perform part of its manufacturing outside Israel, thus avoiding the need to obtain additional approval. On January 6, 2011, the R&D Law was amended to clarify that the potential increased royalties specified in the table above will apply even in those cases where the OCS approval for transfer of manufacturing outside of Israel is not required, namely when the volume of the transferred manufacturing capacity is less than 10% of total capacity or when the company received an advance approval to manufacture abroad in the framework of its OCS grant application.

In addition, in recent years the government of Israel has accelerated the repayment of Chief Scientist grants, and may further accelerate them in the future. Following our request, the Office of the Chief Scientist has approved the manufacture of limited quantities of the PillCam capsule using the back-up production line that we have established in Ireland without increasing royalty rates.

The know-how developed within the framework of the Chief Scientist plan may not be transferred to third parties outside Israel without the prior approval of a governmental committee charted under the R&D Law. The approval, however, is not required for the export of any products developed using grants received from the Chief Scientist. The OCS approval to transfer know-how created, in whole or in part, in connection with an OCS-funded project to third party outside Israel where the transferring company remains an operating Israeli entity is subject to payment of a redemption fee to the OCS calculated according to a formula provided under the R&D Law that is based, in general, on the ratio between the aggregate OCS grants to the company's aggregate investments in the project that was funded by these OCS grants, multiplied by the transaction consideration. The transfer of such know-how to a party outside Israel where the transferring company ceases to exist as an Israeli entity is subject to a redemption fee formula that is based, in general, on the ratio between the aggregate OCS grants received by the company and the company's aggregate R&D expenses, multiplied by the transaction consideration.

New regulations adopted in November 2012 establish a maximum payment of the redemption fee paid to the OCS under the above mentioned formulas. In the event that a company sells its OCS funded know-how, in whole or in part, as an asset or as part of a sale of the company and subsequently ceases to conduct business in Israel, the maximum redemption fee under the above mentioned formulas shall be no more than six times the consideration received for the applicable know-how being transferred, or the for the sale of the company, as applicable, plus annual interest. In the event that following such transaction the company continues to conduct its R&D activity in Israel for at least three years following such transfer and keeps on staff at least 75% of the number of R&D employees it had for the six months before the know-how transfer, then the foregoing cap is reduced to three times the consideration received.

Transfer of know-how within Israel is subject to an undertaking of the recipient Israeli entity to comply with the provisions of the R&D Law and related regulations, including the restrictions on the transfer of know-how and the obligation to pay royalties, as further described in the R&D Law and related regulations.

The funds available for grants from the Chief Scientist depend on several criteria and prevailing government policy and budget, and may be reduced or eliminated in the future. Even if the ability to apply for these grants is maintained, there is no assurance that we will receive Chief Scientist grants in the future. In addition, each application to the Chief Scientist is reviewed separately, and grants are based on the program approved by the research committee. Expenditures supported under other incentive programs of the State of Israel are not eligible for grants from the Chief Scientist. We cannot provide any assurance that applications to the Chief Scientist will be approved and, until approved, the amounts of any grants are not determinable.

While to date we have paid all of our royalty obligations resulting from grants we received from the Office of the Chief Scientist, the restrictions described above associated with receiving such grants under the R&D Law continue to apply. These restrictions may impair our ability to outsource manufacturing, engage in change of control transactions or otherwise transfer our know-how outside Israel and may require us to obtain the approval or the OCS for certain actions and transactions and pay additional royalties to the OCS. In particular, any change of control and any change of ownership of our ordinary shares that would make a non-Israeli citizen or resident an "interested party," as defined in the R&D Law, requires a prior written notice to the OCS in addition to any payment that may be required of us for transfer of manufacturing or know-how outside Israel. If we fail to comply with the R&D Law, we may be subject to criminal charges.

Tax Benefits and Grants for Research and Development. Israeli tax law allows, under specific conditions, a tax deduction in the year incurred for expenditures that were paid in cash, including capital expenditures, relating 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 is for the promotion of the company; and
- The research and development is carried out by or on behalf of the company seeking the deduction.

Expenditures not so approved are deductible over a three-year period. However, the amounts of any government grant made available to us are subtracted from the amount of the deductible expenses according to Israeli law.

Tax Benefits Under the Law for the Encouragement of Industry (Taxes), 1969. According to the Law for the Encouragement of Industry (Taxes), 1969, generally referred to as the Industry Encouragement Law, an industrial company is a company resident in Israel, at least 90% of the income of which, in a given tax year, determined in Israeli currency exclusive of income from specified government loans, capital gains, interest and dividends which are not classified for such company as business income, is derived from an industrial enterprise owned by it. An industrial enterprise is defined as an enterprise whose major activity in a given tax year is industrial production activity.

Under the Industry Encouragement Law, industrial companies are entitled to certain preferred corporate tax benefits, including the following:

- deduction of 12.5% per year on purchases of know-how and patents over an eight-year period for tax purposes; and
- claiming expenses in connection with the issuance and listing of shares on the Tel-Aviv Stock Exchange or, on or after January 1, 2003, on a recognized stock market outside of Israel, over a period of three years.

Eligibility for benefits under the Industry Encouragement Law is not subject to receipt of prior approval from any governmental authority.

If we qualify as an industrial company within the definition of the Industry Encouragement Law, we are entitled to the benefits described above. We believe that in 2012 we qualified as an Industrial Company under the Industry Encouragement Law. We cannot provide any assurance that the Israeli tax authorities will agree with the determination that we qualified as an industrial company in the past or that we will maintain this qualification or our status as an industrial company.

Taxation of Our Shareholders

Capital Gains on Sales of Our Ordinary Shares. Israeli law imposes a capital gains tax on the sale of capital assets. The law distinguishes between real gain and inflationary surplus. The inflationary surplus is the portion of the total capital gain that is equivalent to the increase of the relevant asset's purchase price which is attributable to the increase in the Israeli consumer price index between the date of purchase and the date of sale. Foreign residents who purchased an asset in foreign currency may request that the inflationary surplus be computed on the basis of the devaluation of the Shekel against such foreign currency. The real gain is the excess of the total capital gain over the inflationary surplus. The inflationary surplus accumulated from and after December 31, 1993 is exempt from any capital gains tax in Israel while the real gain is taxed at the applicable rate discussed below. Under an amendment to the Inflationary Adjustments Law, non-Israeli corporations might be subject to Israeli taxes on the sale of shares in an Israeli company which are traded on certain stock markets, including the Nasdaq Global Select Market, subject to the provisions of any applicable double taxation treaty.

The capital gain recognized by individuals on the sale of our shares that were purchased on or after January 1, 2003, will be taxed at the rate of 25%. However, if the shareholder is a "Controlling Shareholder," namely a person holding, directly or indirectly, 10% or more of one of our 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%. In addition, an individual claiming deduction of financing expenses in respect of capital gain recognized from the sale of our shares will be taxed at the rate of 30%. Generally, the capital gain recognized by a corporation was subject to tax at the rate of 25% in 2012. The capital gain recognized from the sale of our shares that were purchased prior to January 1, 2003 will be subject to different tax rates depending on the date of acquisition of such shares. The marginal tax rate for individuals (up to 48% in 2012 or up to 50% in 2013 for individuals whose taxable income from Israeli sources exceeds NIS 811,560) and the regular corporate tax rate for corporations (25% in 2012) will be applied to the amount obtained by multiplying the entire recognized gain on the sale by a fraction the numerator of which is the number of days from the date of the purchase of such shares until January 1, 2003 and the denominator of which is the number of days from the date of purchase of such shares and the date of sale. The remainder of the gain realized on the sale will be subject to capital gains tax at the rates applicable to an asset purchased after January 1, 2003, as described above.

Individual and corporate shareholders dealing in securities in Israel are taxed at the tax rates applicable to business income. In 2012, the corporate tax rate was 25% and tax rate for individuals was up to 48%. In 2013, the maximum tax rate for individuals whose taxable income from Israeli sources exceeds NIS 811,560 will be 50%.

Non-Israeli Residents. Under Israeli law, the capital gain from the sale of shares by non-Israeli residents is tax exempt in Israel as long as our shares are listed on the Nasdaq Global Select Market or any other stock exchange recognized by the Israeli Ministry of Finance, and provided certain other conditions are met, the most relevant of which are: (A) the capital gain is not attributed to the foreign resident's permanent establishment in Israel, (B) the shares were acquired by the foreign resident after the company's shares had been listed for trading on the foreign exchange, and (C) if the seller is a corporation, less than 25% of its means of control are held by Israeli residents.

In addition, under the Convention between the Government of the United States of America and the Government of Israel with Respect to Taxes on Income, as amended, or the U.S.-Israel Tax Treaty, Israeli capital gains tax will not apply to the sale, exchange or disposition of ordinary shares by a person:

- who holds such shares as a capital asset;
- who qualifies as a resident of the United States within the meaning of the U.S.-Israel tax treaty; and
- who is entitled to claim the benefits available to the person by the U.S.-Israel Tax Treaty.

However, this exemption does not apply, among other cases, if the gain is attributable to a permanent establishment of such person in Israel, or if the holder is a resident of the United States within the meaning of the U.S.-Israeli Tax Treaty who holds, directly or indirectly, shares representing 10% or more of our voting power during any part of the 12-month period preceding the sale, exchange or disposition, subject to certain conditions. Under these circumstances, the sale, exchange or disposition would be subject to Israeli tax, to the extent applicable. However, under the U.S.-Israel Tax Treaty, such U.S. resident generally will be permitted to claim a credit for the Israeli taxes paid against the U.S. federal income tax imposed on the sale, exchange or disposition, subject to the limitations under U.S. law applicable to foreign tax credits. The U.S.-Israel Tax Treaty does not relate to U.S. state or local taxes.

If our securities are sold in Israel, the purchaser of such shares, any Israeli stockbroker used in the transaction and any financial institution through which the sold securities are held, are obliged, subject to some exemptions, to withhold tax on the amount of consideration paid with respect to such sale (or on the capital gain realized on the sale, if known) at the rate of 25% for corporations and individuals.

Dividends. A distribution of dividends from income attributed to an "approved enterprise" is subject to tax in Israel at the rate of 15%, subject to a reduced rate under any applicable double tax treaty. A distribution of dividends from income attributed to a "preferred enterprise" status under the December 2010 amendment to the Investment Law will be subject to tax in Israel at the following rates: Israeli resident individuals - 15%, Israeli resident companies – 0% and non-Israeli residents – 15%, subject to a reduced rate under the provisions of any applicable double tax treaty.

In 2013, a distribution of dividends from income, which is not attributed to an "approved 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." 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.

In 2013, a distribution of dividends which is not attributed to an "approved enterprise" to a non-Israeli resident is generally subject to an Israeli income tax on the receipt of dividends at the rate of 25%, or 30% if the dividend recipient is a "Controlling Shareholder," as defined above. Those rates may be subject to a reduced tax rate under an applicable double tax treaty.

Under the U.S.-Israel Tax Treaty, the tax rate in respect of dividends distributed by an Israeli resident company to a U.S. resident corporation may be 12.5%, 15% or 25%, depending on the percentage of holding in the resident company and the resident company's type of income distributed. Dividends distributed to a U.S. individual resident are taxed at a rate of 25%, or 30% if this individual is considered to be a "Controlling Shareholder."

Israeli Withholding Tax on Dividends. We are required to withhold income tax upon the distribution of a dividend attributed to an approved enterprise's income at the following rates: (i) Israeli resident corporations – 15%, (ii) Israeli resident individuals – 15%, and (iii) non-Israeli residents – 15%, subject to a reduced tax rate under the provisions of an applicable double tax treaty. If a dividend is distributed from an income attributed to a "preferred enterprise," the following withholding tax rates will apply: (i) Israeli resident corporations – 0%, (ii) Israeli resident individuals – 15% (iii) non-Israeli residents - 15%, subject to a reduced tax rate under the provisions of an applicable double tax treaty. If the dividend is distributed from an income not attributed to the "approved enterprise" the following withholding tax rates will apply in 2012: (i) Israeli resident corporations – 0%, (ii) Israeli resident individuals– 25% (iii) non-Israeli residents - 25%, or 30% if this individual is considered to be a "Controlling Shareholder," subject to a reduced tax rate under the provisions of an applicable double tax treaty.

The foregoing discussion is intended only as a summary and does not purport to be a complete analysis or listing of all potential Israeli tax effects of holding our shares. We recommend that shareholders consult their tax advisors concerning the Israeli and non-Israeli tax consequences to them of holding our shares.

Certain Material U.S. Federal Income Tax Considerations

U.S. Shareholders. The following is a description of certain material U.S. federal income tax consequences of the ownership of our ordinary shares. This description does not purport to address all of the tax considerations that may be relevant to a decision to purchase, own or dispose of our ordinary shares. This description assumes that holders of our ordinary shares will hold the ordinary shares as capital assets within the meaning of Section 1221 of the U.S. Internal Revenue Code of 1986, as amended, referred to as the Code. This discussion does not address all of the tax considerations that may be relevant to shareholders in light of their particular circumstances or certain types of shareholders subject to special tax treatment, including, without limitation:

- broker-dealers (including in securities or foreign currency) or insurance companies;
- persons who have elected to apply a mark-to-market method of accounting;
- tax-exempt organizations, qualified retirement plans, individual retirement accounts or other tax-deferred accounts;
- certain former citizens or former long-term residents of the United States;
- persons subject to the alternative minimum tax;
- banks, real estate investment trusts, regulated investment companies or other financial institutions;
- persons who hold their shares as part of a position in a "straddle" or as part of a "hedging," "conversion," "constructive sale," synthetic security, or other integrated investment;
- holders who received their shares through the exercise of compensatory stock options or otherwise as compensation;
- holders who own directly, indirectly or by attribution at least 10.0% of the voting power of our shares or holders who within the past five-year period owned at least 10.0% of the voting power of our shares; and
- persons whose functional currency is not the U.S. dollar.

Further, this description does not address any U.S. federal estate and gift or alternative minimum tax consequences, nor any state, local, or non-U.S. tax consequences relating to the acquisition, ownership and disposition of our ordinary shares.

This discussion is based on current provisions of the Code, current and proposed Treasury regulations promulgated under the Code, administrative pronouncements and judicial decisions and interpretations as of the date hereof, all of which are subject to differing interpretations or change, which change may apply retroactively and could materially affect the continued validity of this summary and the tax considerations described herein.

The following description applies only to owners of our ordinary shares that are U.S. Holders, as defined below, for U.S. federal income tax purposes.

For purposes of this description, a "U.S. Holder" is a beneficial owner of our ordinary shares that, for U.S. federal income tax purposes, is:

- An individual citizen or resident of the United States;
- a corporation or other entity taxable as a corporation for U.S. federal income tax purposes created or organized in or under the laws of the United States or any state thereof, or the District of Columbia;

- an estate if its income is subject to U.S. federal income taxation regardless of its source; or

- a trust (A) if a court within the United States is able to exercise primary jurisdiction over its administration and one or more U.S. persons have authority to control all of its substantial decisions, or (B) if it has made a valid election to continue to be treated as a U.S. person under the Code.

If a partnership (or any other entity treated as a partnership for U.S. federal income tax purposes) holds our ordinary shares, the tax treatment of the partnership and a partner in such partnership generally will depend on the status of the partner and the activities of the partnership. Such a partner or partnership should consult its own tax advisor.

Shareholders should consult their tax advisors with respect to the U.S. federal, state, local and foreign tax consequences of acquiring, owning or disposing of our ordinary shares.

Distributions

Subject to the discussion below under "Passive Foreign Investment Company Considerations", the entire amount of any distribution made to you with respect to our ordinary shares, other than any distributions of our ordinary shares made to all of our shareholders, will constitute a dividend to the extent of our current or accumulated earnings and profits as determined under U.S. federal income tax principles. For these purposes, the amount of the distribution will not be reduced by the amount of any Israeli tax withheld from the distribution. Subject to the discussion below under "Passive Foreign Investment Company Considerations," non-corporate U.S. Holders may be taxed on the dividend distributions at the lower rates applicable to long-term capital gains (i.e., gains with respect to 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. In addition, the dividends generally will not be eligible for the dividends received deduction applicable to corporate U.S. holders. Subject to the discussion below under "Passive Foreign Investment Company Considerations", if distributions with respect to our ordinary shares exceed our current and accumulated earnings and profits as determined under U.S. federal income tax principles, the excess distributed with respect to any ordinary share would be treated first as a tax-free return of capital to the extent of your adjusted basis in that ordinary share and thereafter as capital gain. We do not maintain calculations of our earnings and profits under U.S. federal income tax principles, and U.S. Holders should therefore assume that any distribution made by us with respect to our ordinary shares will constitute a dividend.

If we pay a dividend or distribution in Shekels, any such dividend or distribution will be included in your gross income in an amount equal to the U.S. dollar value of the Shekels on the date of receipt, regardless of whether the Shekels are converted into U.S. dollars at that time. You will have a tax basis for U.S. federal income tax purposes in the Shekels received equal to that dollar value, and any subsequent gain or loss in respect of the Shekels arising from exchange rate fluctuations will generally be taxable as U.S.-source ordinary income or loss.

Dividends received by you with respect to your ordinary shares generally will be treated as foreign source income, which may be relevant in calculating your foreign tax credit limitation. You may generally elect to claim the Israeli income tax withheld from dividends and distributions you receive with respect to your ordinary shares as a foreign tax credit against your U.S. federal income tax liability, subject to a number of limitations. Among the limitations, the foreign tax credits allowable with respect to specific classes of income cannot exceed the U.S. federal income tax payable with respect to each such class. Dividends we pay generally will be included in the "passive income" class for these purposes, or, in the case of certain financial services entity holders, "general category income."

Sale or Exchange of Our Ordinary Shares

Subject to the discussion below under "Passive Foreign Investment Company Considerations," if you are a U.S. Holder, you generally will recognize capital gain or loss for U.S. federal income tax purposes when you sell, exchange or otherwise dispose of our ordinary shares equal to the difference between your adjusted tax basis in the ordinary shares and the amount realized on their disposition. If you are a non-corporate U.S. Holder, the maximum marginal U.S. federal income tax rate applicable to such gain will be lower than the maximum marginal U.S. federal income tax rate applicable to ordinary income (other than certain dividends) if your holding period for our ordinary shares exceeds one year (*i.e.* , such gain is long-term capital gain). Any gain or loss recognized by you generally will be treated as U.S. source income or loss for U.S. foreign tax credit purposes. The deductibility of capital losses is subject to limitations.

Passive Foreign Investment Company Considerations

A non-U.S. corporation will be classified as a "passive foreign investment company" or a PFIC, for U.S. federal income tax purposes in any taxable year in which, after applying applicable look-through rules, either (1) at least 75% of its gross income is "passive income," or (2) at least 50% of the value of its gross assets is attributable to assets that produce passive income or are held for the production of passive income. Passive income for this purpose includes items such as dividends, interest, royalties, rents and gains from commodities and securities transactions.

Based on our estimated gross income, the average value of our gross assets (determined by reference to the market value of our shares and valuing our intangible assets using the methods prescribed for publicly traded corporations) and the nature of our business, we believe that we were not classified as a PFIC for the taxable year ended December 31, 2012. Our status in future years will depend on our assets and activities in those years, although you will be treated as continuing to own an interest in a PFIC if we are a PFIC in any year while you own your shares unless you make certain elections. We have no reason to believe that our assets or activities will change in a manner that would cause us to be classified as a PFIC, but because the market price of our ordinary shares is likely to fluctuate, there can be no assurance that we will not be considered a PFIC for any taxable year. In general, if we were characterized as a PFIC for any taxable year, any gain recognized by a U.S. Holder who sells our ordinary shares, absent the making and ongoing maintenance of certain elections described below, would be treated as ordinary income and would be subject to tax as if the gain had been realized ratably over the holding period of such ordinary shares. The amount allocated to the current taxable year and any taxable year before we became a PFIC would be taxed as ordinary income (rather than capital gain) earned in the current taxable year. The amount allocated to other taxable years would be taxed at the highest marginal rates applicable to ordinary income for such taxable years, and the U.S. Holder also would be liable for an additional tax equal to the interest on such tax liability for such years.

If we were a PFIC, you could make a variety of elections that may alleviate the tax consequences referred to above. However, it is expected that the conditions necessary for making certain of such elections will not apply in the case of our ordinary shares. You should consult your own tax advisor regarding our potential status as a PFIC and the tax consequences that would arise if we were treated as a PFIC.

Medicare Surtax on Unearned Income

For tax years beginning after December 31, 2012, certain U.S. Holders who are individuals, estates or trusts will be required to pay an additional 3.8% tax on the lesser of (1) the U.S. Holder's "net investment income" for the relevant taxable year and (2) the excess of the U.S. Holder's modified adjusted gross income for the taxable year over a certain threshold (which in the case of individuals will be between $125,000 and $250,000, depending on the individual's circumstances). A U.S. Holder's net investment income generally will include interest, dividends, royalties, rents, gross income from a trade or business involving certain passive or trading activities, and net gain from disposition of property (other than property held in a trade or business that does not consist of certain passive or trading activities), less certain deductions. Each U.S. Holder that is an individual, estate or trust is urged to consult its own tax advisor regarding the applicability of this tax to its income and gains in respect of its investment in our ordinary shares.

Backup Withholding and Information Reporting

United States backup withholding taxes and information reporting requirements generally apply to certain payments to certain non-corporate holders of stock. Information reporting requirements will, and a backup withholding tax may, apply to payments of dividends on, and to proceeds from the sale, exchange or redemption of, our ordinary shares made within the United States, or by a U.S. payor or U.S. middleman, to a holder of our ordinary shares, other than an exempt recipient (including a corporation, a payee that is not a U.S. person that provides an appropriate certification and certain other persons). Backup withholding is not an additional tax and may be claimed as a credit against your U.S. federal income tax liability, and you may obtain a refund of any excess amounts withheld under the backup withholding rules by filing an appropriate claim for refund with the IRS and furnishing any required information. The backup withholding tax rate currently is 28%.

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

F. Dividends and Paying Agents

Not applicable.

G. Statements by Experts

Not applicable.

H. Documents on Display

We are currently subject to the information and periodic reporting requirements of the Exchange Act, and file periodic reports and other information with the Securities and Exchange Commission through its electronic data gathering, analysis and retrieval (EDGAR) system. Our securities filings, including this Annual Report and the exhibits thereto, are available for inspection and copying at the public reference facilities of the Securities and Exchange Commission 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 Securities and Exchange Commission at 100 F Street, N.E., Washington, DC 20549. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the public reference room. The Commission also maintains a website at *http://www.sec.gov* from which certain filings may be accessed.

As a foreign private issuer, we are exempt from the rules under the Exchange Act relating 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 periodic reports and financial statements with the Securities and Exchange Commission as frequently or as promptly as United States companies whose securities are registered under the Exchange Act.

I. Subsidiary Information

Not applicable.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

In 2012, we derived 66% of our revenues in U.S. dollars, 23% in Euro, 5% in Japanese Yen and 4% in Australian dollars, with the remainder denominated in other currencies, depending on the location of the customer or the distributor used to fulfill our customers' orders. As most of our sales are made in U.S. dollars, a strengthening of the U.S. dollar could make our products less competitive in foreign markets and could cause our non-U.S. customers to cancel or decrease orders or default on payment.

We develop and manufacture products primarily in Israel and Vietnam and sell the majority of the products in the United States, and to a lesser extent in other countries. If the value of a currency in which our revenues are denominated weakens against the value of a currency in which our expenses are denominated, there will be a negative impact on the profit margins for sales of our products. In 2012, 55% of our expenses were denominated in U.S. dollars and 25% of our expenses were denominated in Shekels, principally consisting of salaries and related personnel expenses. We expect this level of Shekel expenses to continue for the foreseeable future. During 2012, the U.S. dollar [weakened] against the Shekel by approximately 2.4%. We estimate that a change of 10% in the exchange rate between the Shekel and the U.S. dollar has an impact of approximately $4 million on our operating expenses. In addition, 11% of our expenses were denominated in Euros and 6% were denominated in Yen, 2% denominated in Australian dollar and 1% in other currencies. However, since we also generate revenues in these currencies the net effect on our business of exchange rate fluctuations of these currencies against the U.S. dollars is not material.

As of December 31, 2012, 33% of our cash and cash equivalents were denominated in currencies other than the U.S. dollar and we are therefore subject to the risk of exchange rate fluctuations among the U.S. dollar, Yen, Shekel, Australian dollar and Euro. In 2012, we have used a variety of hedging tools to seek to minimize the effect of currency fluctuations on our income.

Interest Rate Fluctuations. We invest some of our cash in bank accounts and deposits with maturities of three months or less located with a number of highly-rated banks inside and outside of Israel. We invest the majority of our cash in longer-term financial instruments in order to seek to achieve a higher yield. As of December 31, 2012, all of our investments were subject to the risk of changes in interest rates. Due to the current low interest rates in the United States and other countries, we estimate that a change of 10% in interest rates would not have a material impact on our finance income.

General Market Risks. Our cash balances are held in bank deposits, commercial papers and corporate bonds that were highly-rated by rating agencies at the time of investment. We believe this represents a conservative investment policy primarily intended to preserve our cash resources. Nonetheless, these investments are subject to general credit, counterparty, liquidity and market risks, which were exacerbated by the recent turmoil that has affected the financial markets and the global economy and caused credit and liquidity issues for a number of reputable financial institutions.

Market acceptance of our products in the United States and other countries is dependent upon the medical equipment purchasing and procurement practices of our customers, patient demand for our products and procedures and the reimbursement of patient's medical expenses by third-party payors, including government healthcare programs. The current uncertainty surrounding world financial markets may result in the purchasers of medical equipment decreasing their medical equipment purchasing and procurement activities. In addition, tightening in world credit markets may result in our customers having increased difficulty securing the financing necessary to purchase our products which may result in decreased sales. The financial condition of our customers may deteriorate and our ability to collect payments due to us may be adversely affected. Widespread economic uncertainty may also result in cost-conscious patients making fewer trips to their physicians and specialists, which could result in reduced demand for our products and procedures. Furthermore, third-party payors, including governments, around the world facing tightening budgets could move to further reduce their offered reimbursement rates or countries may adopt healthcare reforms to reduce healthcare spending. If the current economic condition results in the occurrence of any of these events, our liquidity and financial results may be materially and adversely affected.

Item 12. Description of Securities Other Than Equity Securities

Not applicable.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

None.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

Not applicable.

Item 15. Controls and Procedures

Disclosure Controls and Procedures. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our periodic filings with the Securities and Exchange Commission is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Furthermore, management necessarily was required to use its judgment in evaluating the cost to benefit relationship of possible disclosure controls and procedures.

As of the end of the period covered by this report, we performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures. The evaluation was performed with the participation of senior management of each business unit and key corporate functions, and under the participation and supervision of our Chief Executive Officer and Chief Financial Officer. Based on the evaluation, our management, including the CEO and CFO, concluded that our disclosure controls and procedures were effective at the reasonable assurance level, as of December 31, 2012.

Management's Annual Report on Internal Control Over Financial Reporting. Management of the company is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act, as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management, with the participation and under the supervision of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of the company's internal control over financial reporting as of December 31, 2012. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO in *Internal Control — Integrated Framework.* Based on its assessment, management believes that, as of December 31, 2011, the company's internal control over financial reporting is effective.

Auditors' Attestation Report. Our independent auditor, Somekh Chaikin, a member firm of KPMG International, has issued a report on the company's consolidated financial statements and a report on management's assessment of the company's internal control over financial reporting. This report is contained in Item 17 — "Financial Statements," on page F-2.

Changes in Internal Controls Over Financial Reporting. There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [Reserved]

Item 16A. Audit Committee Financial Expert.

The board of directors has determined that Michael Grobstein is the financial expert serving on its audit committee and that Mr. Grobstein is independent as that term is defined under the Nasdaq Global Select Market listing requirements.

Item 16B. Code of Ethics.

We have adopted a code of ethics applicable to our chief executive officer, chief financial officer, controller and persons performing similar functions. The code of ethics was filed with the Securities and Exchange Commission as Exhibit 11.1 to our Annual Report on Form 20-F for the fiscal year ended December 31, 2003 and is also available on our website, *www.givenimaging.com* . A hard copy of our code of ethics may be obtained by sending an e-mail request to *info@givenimaging.com* or by a written request to the corporate secretary at 2 Hacarmel Street, 20692, Yoqneam, Israel.

Item 16C. Principal Accountant Fees and Services

The following table sets forth fees for professional audit services rendered by Somekh Chaikin, a member firm of KPMG International, for the audit of our financial statements for the years ended December 31, 2012 and 2011, and fees billed for other services rendered by Somekh Chaikin, including through other offices of KPMG worldwide:

	2012	2011
	(In Thousands)	
Audit fees	$ 804	$ 760
Audit-related fees	16	30
Tax fees (1)	468	205
All other fees (2)	185	—
Total	$ 1,473	$ 995

(1) "Tax fees" includes fees for professional services rendered by our auditors for tax compliance, tax advice on actual or contemplated transactions and work regarding transfer prices.

(2) "All other fees" includes fees for due diligence performed by KPMG in connection with business development activities.

In accordance with our pre-approval policy, our audit committee pre-approved all audit and non-audit services provided to us and to our subsidiaries during the periods listed above. Audit services must be pre-approved by the full audit committee. The authority to pre-approve non-audit services has been delegated to the Chairman of the audit committee. Any services pre-approved by the Chairman are reported to the full committee at its next scheduled meeting.

Item 16D. Exemptions from the Listing Standards for Audit Committees.

None.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 16F. Change in Registrant's Certifying Accountants

Not applicable.

Item 16G. Corporate Governance

In connection with Nasdaq Listing Rule 5615(a)(3) and IM 5615-3, which allow foreign private issuers such as us to follow such issuer's home country practices in lieu of certain listing requirements of Nasdaq, we have elected to follow Israel's practices in lieu of the requirement of Nasdaq Listing Rule 5635(c) that companies receive shareholder approval when certain stock option or purchase plans are to be established or materially amended. We seek shareholder approval in specified situations, including upon issuance of options to directors in their capacity as directors or to controlling shareholders, as required by Israeli law.

Item 16H. Mine Safety Disclosure

Not applicable.

PART III

Item 17. Financial Statements

See pages F-1 to F-45.

Item 18. Financial Statements

Not applicable.

Item 19. Exhibits

Exhibit	Description
1.1	Amended and Restated Articles of Association as of June 17, 2008, incorporated by reference to Exhibit 1.1 of the Annual Report on Form 20-F for the fiscal year ended December 31, 2008, filed with the Commission on March 31, 2009.
4.1	Production Development, Manufacturing and Sales Agreement, dated as of November 26, 2002, by and between Micron Technology, Inc. and the Registrant, incorporated by reference to Exhibit 4.3 of the Annual Report on Form 20-F for the fiscal year ended December 31, 2003, filed with the Commission on March 17, 2004.†
4.2	Addendum, dated as of June 10, 2005, to Production Development, Manufacturing and Sales Agreement, dated as of November 26, 2002, by and between Micron Technology, Inc. and the Registrant, incorporated by reference to Exhibit 4.2 of the Annual Report on Form 20-F for the fiscal year ended December 31, 2007, filed with the Commission on March 31, 2008.†
4.3	Amended Form of Indemnification Agreement between directors and officers of the Registrant and the Registrant, as of June 17, 2008, incorporated by reference to Exhibit 4.3 of the Annual Report on Form 20-F for the fiscal year ended December 31, 2008, filed with the Commission on March 31, 2009.
4.4	Lease Agreement, dated as of November 26, 2001, by and between Sha'ar Yoqneam L.P. and the Registrant, incorporated by reference to Exhibit 10.20 of the Registration Statement on Form F-1 (File No. 333-81514) filed with the Commission on February 1, 2002.
4.5	Summary of Material Terms of Addendum, dated December 2002, to Lease Agreement, dated as of November 26, 2001, by and between Sha'ar Yoqneam and the Registrant, incorporated by reference to Exhibit 4.11 of the Annual Report on Form 20-F for the fiscal year ended December 31, 2002, filed with the Commission on April 10, 2003.
4.6	Second Addendum, dated July 5, 2004, to the Lease Agreement, dated as of November 26, 2001, by and between Sha'ar Yoqneam L.P. and the Registrant, incorporated by reference to Exhibit 4.15 of the Annual Report on Form 20-F for the fiscal year ended December 31, 2004, filed with the Commission on March 25, 2005.
4.7	Development and Supply Agreement, dated April 8, 2002, by and between Zarlink Semiconductor AB and the Registrant, incorporated by reference to Exhibit 4.11 of the Annual Report on Form 20-F for the fiscal year ended December 31, 2004, filed with the Commission on March 25, 2005.†
4.8	Addendum to Development and Supply Agreement, dated July 2005, by and between Zarlink Semiconductor AB and the Registrant, incorporated by reference to Exhibit 4.12 of the Annual Report on Form 20-F for the fiscal year ended December 31, 2005, filed with the Commission on April 7, 2006.†

Exhibit	Description
4.9	Amended and Restated Registration Rights Agreement, dated as of February 29, 2012, by and among the Registrant and Discount Investment Corporation Ltd., Elron Electronic Industries Ltd. and RDC Rafael Development Corporation Ltd., incoparated by reference to Exhibit 4.9 of the Annual Report on Form 20-F for the fiscal year ended December 31, 2011, filed with the Commission on March 7, 2012.
4.10	Amended and Restated 2003 Equity Incentive Plan, incoparated by reference to Exhibit 4.11 of the Annual Report on Form 20-F for the fiscal year ended December 31, 2011, filed with the Commission on March 7, 2012.
4.11	Amended and Restated 2006 Equity Incentive Plan , incoparated by reference to Exhibit 4.12 of the Annual Report on Form 20-F for the fiscal year ended December 31, 2011, filed with the Commission on March 7, 2012.
4.12	Amended and Restated 2009 Equity Incentive Plan , incoparated by reference to Exhibit 4.13 of the Annual Report on Form 20-F for the fiscal year ended December 31, 2011, filed with the Commission on March 7, 2012.
4.13	Amendment No. 1 to the Company's Amended and Restated 2003 Equity Incentive Plan.
4.14	Amendment No. 1 to the Company's Amended and Restated 2006 Equity Incentive Plan.
4.15	Amendment No. 1 to the Company's Amended and Restated 2009 Equity Incentive Plan.
8.1	List of subsidiaries of the Registrant, incorporated by reference to Exhibit 8.1 of the Annual Report for the fiscal year ended December 31, 2011, filed with the Commision on March 7, 2012.
11.1	Code of Ethics adopted on December 9, 2003, incorporated by reference to Exhibit 11.1 of the Annual Report on Form 20-F for the fiscal year ended December 31, 2003, filed with the Commission on March 17, 2004.
12.1	Certification of Chief Executive Officer of the Registrant pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
12.2	Certification of Chief Financial Officer of the Registrant pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
13.1	Certification of Chief Executive Officer of the Registrant pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
13.2	Certification of Chief Financial Officer of the Registrant pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
15.1	Consent of Somekh Chaikin, a member firm of KPMG International, independent registered public accountants.

† Portions of this exhibit were omitted and have been filed separately with the Secretary of the Securities and Exchange Commission pursuant to an application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.

* This document is being furnished in accordance with SEC Release Nos. 33-8212 and 34-47551.

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, 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 annual report on its behalf.

GIVEN IMAGING LTD.

By: /s/ Nachum Shamir
Name: Nachum Shamir
Title: President and Chief Executive Officer

By: /s/ Yuval Yanai
Name: Yuval Yanai
Title: Chief Financial Officer

Date: March 7, 2013

Given Imaging Ltd.
and its Subsidiaries

Consolidated Financial Statements

As of and for the
Year Ended December 31, 2012

Given Imaging Ltd. and its subsidiaries

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
Given Imaging Ltd.

We have audited the accompanying consolidated balance sheets of Given Imaging Ltd. (the "Company") and subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of income and comprehensive income, changes in equity and cash flows for each of the years in the three-year period ended December 31, 2012. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits 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. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company and subsidiaries as of December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 7, 2013 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Somekh Chaikin
Certified Public Accountants (Israel)
Member Firm of KPMG International

Haifa, Israel
March 7, 2013

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
Given Imaging Ltd.

We have audited Given Imaging Ltd.'s (the "Company") internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying *Management's Annual Report on Internal Control Over Financial Reporting* appearing under Item 15 of Part II of this Form 20-F. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of the Company and its subsidiaries as of December 31, 2012 and 2011, and the related consolidated statements of income and comprehensive income, changes in equity, and cash flows for each of the years in the three-year period ended December 31, 2012, and our report dated March 7, 2013 expressed an unqualified opinion on those consolidated financial statements.

Somekh Chaikin
Certified Public Accountants (Israel)
Member Firm of KPMG International

Haifa, Israel
March 7, 2013

Given Imaging Ltd. and its Subsidiaries
Consolidated Balance Sheets
(In thousands except share data)

	Note	December 31, 2012	December 31, 2011
Assets			
Current assets			
Cash and cash equivalents	1D; 2	$ 35,442	$ 24,285
Short-term investments	1H; 5	58,446	64,762
Accounts receivable:			
Trade	1E	31,279	32,406
Other	3	4,654	5,259
Inventories	1F; 4	22,591	22,921
Advances to suppliers		1,349	1,207
Deferred tax assets	1Q; 14D	2,646	1,538
Other current assets		2,689	1,373
Total current assets		159,096	153,751
Other long term assets		924	1,266
Assets held for employees' severance payments	1G; 10	7,974	6,854
Long-term investments	1H; 5	30,188	16,003
Non-current inventory	1F; 4	6,150	4,926
Fixed assets, less accumulated depreciation	1I; 6	12,335	12,301
Intangible assets, less accumulated amortization	1J; 7; 16	30,705	29,075
Goodwill	1K; 16; 17	26,942	24,089
Total Assets		$ 274,314	$ 248,265

President and CEO

CFO

March 7, 2013

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

Given Imaging Ltd. and its Subsidiaries
Consolidated Balance Sheets
(In thousands except share data)

	Note	December 31, 2012	December 31, 2011
Liabilities and equity			
Current liabilities			
Current installments of obligation under capital lease	8A	$ 38	$ 139
Accounts payable:			
Trade		8,756	8,081
Other	9	27,091	28,397
Deferred income		929	521
Total current liabilities		36,814	37,138
Long-term liabilities			
Obligation under capital lease, net	8A	78	120
Liability in respect of employees' severance payments	10	8,761	7,720
Contingent consideration in respect of business combination	1W, 16D	1,038	-
Deferred tax liabilities	14D	4,675	5,362
Total long-term liabilities		14,552	13,202
Total liabilities		51,366	50,340
Commitments and contingencies	8		
Equity			
Shareholders` equity:	11		
Ordinary Shares, NIS 0.05 par value each (90,000,000 shares authorized as of December 31, 2012 and 2011, 31,080,876 and 30,448,838 shares issued and fully paid as of December 31, 2012 and 2011, respectively)		367	359
Additional paid-in capital		219,103	208,838
Capital reserve		1,591	2,051
Accumulated other comprehensive income (loss)		266	(885)
Retained earnings (accumulated deficit)		1,621	(12,729)
Total shareholders` equity		222,948	197,634
Non-controlling interests		-	291
Total equity		222,948	197,925
Total liabilities and equity		$ 274,314	$ 248,265

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

Given Imaging Ltd. and its Subsidiaries
Consolidated Statements of Income and Comprehensive Income
(In thousands except share and per share data)

	Note	Year ended December 31, 2012	2011	2010
Revenues	1O; 12	$ 180,501	$ 177,955	$ 157,809
Cost of revenues		(42,971)	(41,466)	(37,629)
Gross profit		137,530	136,489	120,180
Operating expenses				
Research and development, gross	1R	(25,627)	(26,129)	(21,695)
Government grants	1P	1,439	1,113	1,477
Research and development, net		(24,188)	(25,016)	(20,218)
Sales and marketing		(76,272)	(75,014)	(67,114)
General and administrative		(22,746)	(23,078)	(25,138)
Other, net	6; 7; 17	(455)	(397)	(759)
Total operating expenses		(123,661)	(123,505)	(113,229)
Operating profit		13,869	12,984	6,951
Financial income, net	13	847	1,343	2,599
Profit before taxes on income		14,716	14,327	9,550
Income tax expense	1Q; 14	(459)	(2,158)	(1,362)
Net Profit		14,257	12,169	8,188
Net loss (profit) attributable to non-controlling interest		93	(191)	290
Net profit attributable to shareholders		$ 14,350	$ 11,978	$ 8,478
Net change in respect of available for sale securities		1,151	(980)	(304)
Total comprehensive profit attributable to Shareholders		$ 15,501	$ 10,998	$ 8,174
Total comprehensive profit (loss) attributable to non-controlling interest		(93)	191	(290)
Total comprehensive profit		$ 15,408	$ 11,189	$ 7,884
Earnings per share:				
Basic Earnings attributed to shareholders per Ordinary Share	1M	$ 0.47	$ 0.40	$ 0.29
Diluted Earnings attributed to shareholders per Ordinary Share	1M	$ 0.45	$ 0.39	$ 0.28
Weighted average number of Ordinary Shares used to compute basic Earnings per Ordinary Share	1M	30,853,581	30,212,787	29,670,842
Weighted average number of Ordinary Shares used to compute diluted Earnings per Ordinary Share	1M	31,563,208	31,089,499	30,525,654

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

Given Imaging Ltd. and its Subsidiaries
Consolidated Statements of Changes in Equity
(In thousands except share data)

	Shareholders of the Company							
	Ordinary shares		Additional Paid-In Capital	Capital Reserve	Accumulated Other Comprehensive Income (loss)	Retained Earnings (Accumulated Deficit)	Non-controlling interests	Total
	Shares	Amount						
Balance as of January 1, 2010	29,370,972	$ 345	$ 182,203	$ 2,166	$ 399	$ (33,185)	$ 678	$ 152,606
Change during the year 2010:								
Net profit (loss)	-	-	-	-	-	8,478	(290)	8,188
Net change in respect of available for sale securities	-	-	-	-	(304)	-	-	(304)
Exercise of stock options	458,305	5	4,214	-	-	-	-	4,219
Stock based compensation	-	-	8,482	-	-	-	-	8,482
Change in non-controlling interest	-	-	-	(115)	-	-	(288)	(403)
Balance as of December 31, 2010	29,829,277	350	194,899	2,051	95	(24,707)	100	172,788
Change during the year 2011:								
Net profit	-	-	-	-	-	11,978	191	12,169
Net change in respect of available for sale securities	-	-	-	-	(980)	-	-	(980)
Exercise of equity awards	619,561	9	6,576	-	-	-	-	6,585
Stock based compensation	-	-	7,363	-	-	-	-	7,363
Balance as of December 31, 2011	30,448,838	359	208,838	2,051	(885)	(12,729)	291	197,925
Change during the year 2012:								
Net profit (loss)	-	-	-	-	-	14,350	(93)	14,257
Net change in respect of available for sale securities	-	-	-	-	1,151	-	-	1,151
Exercise of equity awards	632,038	8	4,107	-	-	-	-	4,115
Stock based compensation	-	-	6,158		-	-	-	6,158
Change in non-controlling interest	-	-	-	(460)	-	-	(198)	(658)
Balance as of December 31, 2012	31,080,876	$ 367	$ 219,103	$ 1,591	$ 266	$ 1,621	$ -	$ 222,948

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

Given Imaging Ltd. and its Subsidiaries
Consolidated Statements of Cash Flows
(In thousands)

	Year ended December 31,		
	2012	**2011**	**2010**
Cash flows from operating activities:			
Net profit	$ 14,257	$ 12,169	$ 8,188
Adjustments required to reconcile net profit to net cash provided by operating activities:			
Depreciation and amortization	8,597	8,296	7,662
Goodwill impairment	-	-	20
Change in deferred taxes	(1,795)	(409)	(127)
Stock based compensation	6,158	7,363	8,482
Loss from disposal of fixed assets and intangible assets	484	397	739
Decrease (increase) in accounts receivable – trade	977	(4,544)	560
Decrease (increase) in other accounts receivable – other	1,252	(968)	(488)
Decrease (increase) in other current assets	(1,316)	212	(23)
Decrease (increase) in advances to suppliers	(142)	(766)	93
Decrease (increase) in inventories	(299)	(3,145)	2,331
Increase (decrease) in accounts payable	(691)	1,433	3,389
Increase (decrease) in deferred revenue	408	(267)	554
Other	(62)	158	304
Net cash provided by operating activities	27,828	19,929	31,684
Cash flows from investing activities:			
Purchase of fixed assets and intangible assets	(7,005)	(10,551)	(5,056)
Other long term assets	(538)	(39)	(6)
Acquisition of businesses, net of cash acquired (1)	(6,000)	-	(34,709)
Change in short term deposits, net	4,968	(20,176)	(26,830)
Proceeds from sales and maturity of marketable securities	13,343	11,141	25,167
Investments in marketable securities	(24,827)	(16,910)	(5,953)
Net cash used in investing activities	(20,059)	(36,535)	(47,387)
Cash flows from financing activities:			
Principal payments on capital lease obligation	(129)	(168)	(143)
Proceeds from the issuance of Ordinary Shares	4,115	6,585	4,219
Purchase of shares from a non-controlling shareholder in a subsidiary	(658)	-	(403)
Net cash provided by financing activities	3,328	6,417	3,673
Effect of exchange rate changes on cash and cash equivalents	60	(145)	191
Increase (decrease) in cash and cash equivalents	11,157	(10,334)	(11,839)
Cash and cash equivalents at beginning of year	24,285	34,619	46,458
Cash and cash equivalents at end of year	$ 35,442	$ 24,285	$ 34,619
Supplementary cash flow information:			
Income taxes paid	$ 2,883	$ 2,179	$ 234

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

Given Imaging Ltd. and its Subsidiaries
Consolidated Statements of Cash Flows
(In thousands)

(1) Acquisition of businesses, net of cash acquired:

	Year ended December 31, 2012	Year ended December 31, 2011	Year ended December 31, 2010
Working capital (excluding cash and cash equivalents)	$ (595)	$ -	$ (3,165)
Deposits	-	-	(65)
Fixed assets, net	(183)	-	(533)
Intangible assets (including Goodwill)	(6,260)	-	(37,714)
Deferred tax liabilities	-	-	6,759
Other long-term liabilities	1,038	-	9
	$ (6,000)	$ -	$ (34,709)

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

Note 1 - Organization and Summary of Significant Accounting Policies

A. General

Given Imaging Ltd. (the "Company") was incorporated in Israel in January 1998.

The Company has developed the Given System, a proprietary wireless imaging system for visual examination of the gastrointestinal ("GI") tract. The system uses a miniaturized video camera contained in a capsule, referred to as the PillCam™ capsule, which is ingested by the patient and delivers high quality color images in a painless and noninvasive manner.

The Given System consists of three principal components:

- a single-use, disposable PillCam color-imaging capsule that is ingested by the patient;
- a portable data recorder and sensors that are worn by the patient; and
- a proprietary software, known as RAPID, for downloading, processing and analyzing recorded data.

In 2001, the Company commenced marketing the Given System with the PillCam SB capsule for visualizing and detecting disorders of the small bowel. PillCam SB is cleared for marketing in the United States, the European Union and Japan, which are the Company's principal markets. In November 2004, the Company began marketing and sale of the PillCam ESO capsule for visualization of the esophagus. This capsule is cleared for marketing in all principal markets, except Japan. In the second half of 2007, the Company began selling the first generation of its PillCam COLON capsule in Europe. The Company received the CE mark for this capsule in late 2009. The European Union is currently the only major market with clearance to market and sell the PillCam COLON capsule.

The Company has direct or indirect wholly-owned subsidiaries in the United States, Brazil, the Netherlands, Germany, France, Australia, Hong Kong, Vietnam, Japan and Singapore.

In December 2008, the Company acquired the Bravo pH monitoring business from Medtronic, Inc. The Bravo pH monitoring system is the only wireless, catheter-free pH test for Gastro Esophageal Reflux Disease, or GERD, and uses a disposable capsule temporarily placed in the esophagus that measures pH levels and transmits the data to an external receiver. pH testing is considered the standard test for diagnosing GERD.

In April 2010, the Company acquired privately-held Sierra Scientific Instruments ("Sierra"), now known as Given Imaging (Los Angeles) ("GILA"), for approximately $35 million in cash. GILA is a leading provider of specialty diagnostic devices for the gastrointestinal tract. GILA's primary business is the development, manufacture and sale of high-resolution pressure systems, also known as high resolution manometry, for the diagnosis of motility disorders within the GI tract. GILA's high resolution manometry systems are sold under the name ManoScan. Since sales began in 2004, GILA has produced and installed ManoScan™ systems world-wide and supported numerous clinical procedures. GILA also markets and sells catheter-based pH and impedance monitoring systems. As part of the acquisition, the Company acquired 100% of the shares of GILA's subsidiary, a Vietnamese company, which manufactures catheters (for more details see Note 16B).

In October 2012, the Company acquired from The SmartPill Corporation ("SmartPill"), a U.S. based-company, assets related to the SmartPill® GI Monitoring System for $6 million plus an earn-out component. The SmartPill® is an ingestible capsule that uses sensor technology to measure pH, pressure and temperature in the gastrointestinal tract. The SmartPill System measures gastric emptying and the transit time of solid and liquid content through the entire gastrointestinal tract and is used to evaluate motility disorders such as gastroparesis and constipation.

Note 1 - Organization and Summary of Significant Accounting Policies (cont'd)

A. General (cont'd)

The Company operates in the medical device industry and its business is subject to numerous risks, including, without limitations, (1) the Company's ability to develop and bring to market new products, (2) the Company's ability to receive regulatory clearance or approval to market its products or changes in regulatory environment, (3) the Company's success in implementing its sales, marketing and manufacturing plans, (4) continuous supply of certain components from third-party suppliers, (5) protection and validity of patents and other intellectual property rights, (6) the impact of currency exchange rates, (7) the effect of competition by other companies, (8) the outcome of significant litigation, and (9) the existence of favorable reimbursement for its product from government and commercial payors, (10) changes and reforms in applicable healthcare laws and regulations, (11) quarterly variations in operating results, (12) the possibility of armed conflicts or civil or military unrest in Israel, (13) risks associated with the acquisition and integration of other businesses, and (14) the impact of macro-economic and market conditions in the Company's main markets.

B. Basis of presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and include the accounts of the Company and its wholly-owned subsidiaries in the United States (including GILA, see note 16B), Germany, France, the Netherlands, Hong-Kong, Singapore, Vietnam, Japan, Brazil and Australia. The accounts of the subsidiaries are consolidated from the date of their inception, except for the accounts of GILA, which are consolidated from April 1, 2010, the closing date of the GILA acquisition. All intercompany balances and transactions have been eliminated in consolidation. As of December 31, 2012, the Company considers itself operating in only one segment.

C. Functional and reporting currency

The functional and reporting currency of the Company and all its subsidiaries is the U.S. dollar.

Transactions denominated in foreign currencies other than the U.S. dollar are translated into the functional currency using the prevailing exchange rates at the date of the transactions. Monetary accounts maintained in currencies other than the U.S. dollar are re-measured using the representative foreign exchange rate at the balance sheet date. Gains and losses from the translation of foreign currency balances are recorded in financial income, net.

D. Cash and cash equivalents

All highly-liquid investments with original maturity of three months or less from the date of deposit are considered to be cash equivalents.

E. Allowance for doubtful accounts receivable - trade

The allowance for doubtful accounts receivable is calculated on the basis of specific identification of balances, the collection of which, in management's opinion, is doubtful. In determining the adequacy of the allowance, management bases its opinion on the estimated risk, in reliance on available information with respect to the debtor's financial position and an evaluation of the collateral received.

(In thousands)

Note 1 - Organization and Summary of Significant Accounting Policies (cont'd)

E. Allowance for doubtful accounts receivable - trade (cont'd)

The activity in the allowance for doubtful accounts for the three years ended December 31, 2012 is as follows:

	Year ended December 31,		
	2012	2011	2010
Opening balance	$ 311	$ 295	$ 252
Additional provision	261	150	362
Write-offs	(229)	(134)	(319)
Closing balance	$ 343	$ 311	$ 295

F. Inventories

Inventories are stated at lower of cost or market. Cost is determined using the average cost method for raw materials, components and finished goods and on the basis of actual manufacturing costs for work in progress.

Inventory that is not expected to be consumed in the next operating cycle, based upon sales forecast, is classified as non-current (for more details see Note 4).

G. Assets held for employees' severance payments

Assets held for employees' severance payments represent contributions to insurance policies that are recorded at their current redemption value.

H. Marketable securities

The Company accounts for marketable securities under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 320-10 "Accounting for Certain Investments in Debt and Equity Securities" ("ASC 320-10").

Available-for-sale securities are recorded at fair value. Changes in fair value based on closing market prices of the securities at balance sheet date are recorded directly to shareholders' equity as accumulated other comprehensive income (loss). A decline in market value of available for sale security below cost deemed "other than temporary" will be charged to the statement of income when it occurs.

As of December 31, 2012, marketable securities consist of corporate bonds, which the Company classified as "available-for-sale".

(In thousands)

Note 1 - Organization and Summary of Significant Accounting Policies (cont'd)

I. Fixed assets

Fixed assets are stated at cost. Depreciation is computed by the straight-line method over the estimated useful lives of the assets at the following annual rates:

	%
Computers and software	33
Instruments and laboratory equipment	15
Leasehold improvements	10
Motor vehicles	15
Machinery and equipment	15
Communication equipment	15
Office furniture and equipment	10-15

Motor vehicles purchased under capital lease arrangements are recorded at the present value of the minimum lease payments at lease inception. Such assets and leasehold improvements are depreciated and amortized, respectively, using the straight-line method over the shorter of the lease term or estimated useful life of the asset.

The Company evaluates fixed assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable, in accordance with the provisions of ASC 360-10, "Accounting for the Impairment of or Disposal of Long-Lived Assets" ("ASC 360-10"). Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to undiscounted future net cash flows expected to be generated by the asset. If the carrying amount of the assets is less than the undiscounted future net cash flows, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets.

J. Definite-life intangible assets

Definite-life intangible assets acquired in business combinations consist mainly of acquired technology (including in-process research and development expenditures), trademarks, patents and customer relationships, and are amortized using the straight-line method over their estimated period of useful life, mainly 8 to 20 years (for more details see Note 16B and Note 16D).

Legal expenses related to patents and trademarks registration have been capitalized and amortized over the expected useful life of the assets, which is mainly 8 years.

Technology and content costs are generally expensed as incurred, except for certain costs relating to the development of the Company's website that are capitalized and amortized over their estimated useful life which is generally 3 years.

Amortization charges are classified according to the expense category that benefits from the related intangible asset.

Definite-life intangible assets are evaluated for recoverability whenever events or changes in circumstances indicate that the carrying amount may not be recoverable, in accordance with ASC 360-10 (see Note 1I above).

Note 1 - Organization and Summary of Significant Accounting Policies (cont'd)

K. Goodwill

Pursuant to ASC 350-20, "Goodwill and Other Intangible Assets," goodwill and indefinite life intangible assets are not amortized but rather tested for impairment at least annually.

Goodwill is an asset representing the future economic benefits arising from other assets acquired in a business combination that are not individually identified and separately recognized. Goodwill is reviewed for impairment at least annually in accordance with the provisions of FASB ASC Topic 350, Intangibles - Goodwill and Other. The goodwill impairment test is a two-step test. Under the first step, the fair value of the reporting unit is compared with its carrying value (including goodwill). If the fair value of the reporting unit exceeds its carrying value, step two does not need to be performed. If the fair value of the reporting unit is less than its carrying value, an indication of goodwill impairment exists for the reporting unit and the enterprise must perform step two of the impairment test (measurement). Under step two, an impairment loss is recognized for any excess of the carrying amount of the reporting unit's goodwill over the implied fair value of that goodwill. The implied fair value of goodwill is determined by allocating the fair value of the reporting unit in a manner similar to a purchase price allocation and the residual fair value after this allocation is the implied fair value of the reporting unit goodwill. Fair value of the reporting unit is determined using a discounted cash flow analysis.

The Company performs its annual impairment review of goodwill at December 31, and when a triggering event occurs between annual impairment tests. (See also Note 17 for details.)

L. Stock compensation plans

Stock-based compensation is accounted for based on the provisions of ASC 718-20, "Share-Based Payment" ("ASC 718-20"). ACS 718-20 requires compensation expense relating to share-based payments to be recognized in income using a fair-value measurement method. Under the fair value method, the estimated fair value of awards at the grant date is charged to income on a straight-line basis over the requisite service period, which is generally the vesting period.

Stock-based compensation recognized in the consolidated statements of income is based on awards ultimately expected to vest. As a result, the expense has been reduced for estimated forfeitures. ASC 718-20 requires forfeitures to be estimated at the time of grant and revised in subsequent periods if actual forfeitures differ from those estimates.

M. Earnings per Ordinary Share

Basic and diluted earnings per Ordinary Share are presented in conformity with ASC 260-10, "Earnings Per Share". Basic earnings per Ordinary Share are calculated by dividing the net profit attributable to Ordinary Shares, by the weighted average number of Ordinary Shares outstanding. Diluted earnings per Ordinary share calculation is similar to basic earnings per share except that the weighted average of Ordinary Shares outstanding is increased to include the number of additional Ordinary Shares that would have been outstanding if the dilutive potential Ordinary Shares from options and restricted share units had been exercised.

(In thousands)

Note 1 - Organization and Summary of Significant Accounting Policies (cont'd)

M. Earnings per Ordinary Share (cont'd)

The following table summarizes information related to the computation of basic and diluted earnings per Ordinary Share for the years indicated.

	Year ended December 31,		
	2012	2011	2010
Net profit attributable to Ordinary Shares	$ 14,350	$ 11,978	$ 8,478
Weighted average number of Ordinary Shares outstanding used in basic earnings per Ordinary Share Calculation	30,853,581	30,212,787	29,670,842
Add assumed exercise of outstanding dilutive potential Ordinary Shares	709,627	876,712	854,812
Weighted average number of Ordinary Shares outstanding used in diluted earnings per Ordinary Share Calculation	31,563,208	31,089,499	30,525,654
Basic earnings per Ordinary Share	$ 0.47	$ 0.40	$ 0.29
Diluted earnings per Ordinary Share	$ 0.45	$ 0.39	$ 0.28
Number of equity awards excluded from the diluted earnings per share calculation due to their anti-dilutive effect	1,508,694	3,904,630	4,763,410

N. Use of estimates

The preparation of the consolidated financial statements, in accordance with generally accepted principles in the United States of America, requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Significant items subject to such estimates and assumptions include the useful lives of fixed assets, allowances for doubtful accounts, the valuation of deferred tax assets, intangible assets, goodwill, inventory, derivatives, share-based compensation, reserves for income tax uncertainties, contingent consideration in respect of business combination and other contingencies. Actual results could differ from those estimates.

O. Revenue recognition

Revenues from sales of products are recognized upon delivery provided that the collection of the resulting receivable is reasonably assured, persuasive evidence of an arrangement exists, no significant obligations in respect of installation remain and the sales price is fixed or determinable.

The Company accrues estimated warranty costs at time of shipment based on contractual rights and historical experience. The Company's policy is not to grant return rights.

Note 1 - Organization and Summary of Significant Accounting Policies (cont'd)

O. Revenue recognition (cont'd)

Taxes collected from customers and remitted to governmental authorities are presented in the financial statements on a net basis.

For sales contracts, which include a Post Contract Customer Support ("PCS") component, revenues allocated to PCS in accordance with ASC Subtopic 605-25, "Revenue Recognition - Multiple Element Arrangements", are deferred and recognized ratably over the term of the support period. For multi-element arrangements that include tangible products that contain software that is essential to the tangible product's functionality and undelivered software elements that relate to the tangible product's essential software, the Company allocates revenue to all deliverables based on their relative selling prices, in accordance with ASU 2009-13, Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements. In such circumstances, the Company uses a hierarchy to determine the selling price to be used for allocating revenue to deliverables: (i) vendor-specific objective evidence of fair value ("VSOE"), (ii) third-party evidence of selling price ("TPE"), and (iii) best estimate of the selling price ("ESP").

The Company accounts for multiple element arrangements that consist only of software or software-related products, including PCS, in accordance with ASC Subtopic 985-605 "Software Revenue Recognition". For such arrangements, revenue that includes multiple elements is allocated to each element based on the relative fair value of each element, and fair value is determined by VSOE. If the Company cannot objectively determine the fair value of any undelivered element included in such multiple-element arrangements, the Company defers revenue until all elements are delivered and services have been performed, or until fair value can objectively be determined for any remaining undelivered elements.

P. Government-Sponsored Research and Development

The Company participates in various programs of the Office of the Chief Scientist of the Israeli Ministry of Industry and Trade (the "OCS"), some of which are royalty bearing. Grants received from the OCS are recorded as a reduction of research and development expenses, at the time the related expense is incurred and subject to grant approval. Royalties payable to OCS are classified as cost of revenues.

Note 1 - Organization and Summary of Significant Accounting Policies (cont'd)

Q. Taxes on income

The Company accounts for income taxes under ASC 740, "Income Taxes" ("ASC 740"). Under ASC 740, deferred tax assets or liabilities are recognized in respect of temporary differences between the tax bases of assets and liabilities and their financial reporting amounts as well as in respect of tax loss and credit carry forwards, based on enacted statutory tax rates applicable to the periods in which such deferred taxes will be realized. The tax effect resulting from a change in tax rates is recognized in the period that includes the enactment date. Valuation allowances are established when necessary to reduce deferred tax assets to the amount that is more likely than not to be realized.

The Company may incur additional tax liability in the event of intercompany dividend distributions by some of its subsidiaries. Those subsidiaries have, at December 31, 2012, accumulated retained earnings of approximately $8 million which may be distributed as dividends. Such additional tax liability in respect of these non-Israeli subsidiaries has not been provided for in these financial statements as the Company does not expect these subsidiaries to distribute dividends in the foreseeable future.

The Company accounts for uncertainty in income taxes, under ASC 740-10 which prescribe a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. ASC 740-10 also provides guidance on de-recognition of tax benefits, classification on the balance sheet, interest and penalties, accounting in interim periods, disclosure and transition. The Company follows a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement.

The Company's accounting policy is to accrue interest and penalties related to unrecognized tax benefits as a component of income tax expenses in the consolidated statements of income.

R. Research and development costs

Research and development costs, net of grants received, are charged to the statement of income as incurred (excluding in-process research and development expenditures acquired in business combinations). ASC 985-20, "Accounting for the Costs of Computer Software to be Sold, Leased or Otherwise Marketed", requires capitalization of certain software development costs subsequent to the establishment of technological feasibility. Technological feasibility is established upon completion of a working model and success in clinical trials. Costs, incurred by the Company between completion of the working models and success in clinical trials and the point at which the products are ready for general release, have been insignificant. Therefore, research and development costs are charged to the statement of income, as incurred.

S. Allowance for product warranty

It is the Company's policy to grant a warranty for certain products. The balance sheet provision for warranties is determined based upon the Company's experience regarding the relationship between sales and warranty costs.

Note 1 - Organization and Summary of Significant Accounting Policies (cont'd)

T. Concentration of credit risk

Financial instruments that may subject the Company to significant concentrations of credit risk consist principally of cash and cash equivalents, trade accounts receivable and marketable securities.

Cash and cash equivalents are deposited with major financial institutions in Europe, the United States, Japan, Australia, Singapore, Hong Kong, Brazil, Vietnam and Israel.

The Company performs ongoing credit evaluations of the financial condition of its customers. The risk of collection associated with trade receivables is reduced by the large number and geographical dispersion of the Company's customer base and the Company's policy of requiring collateral or security with respect to receivables due from distributors.

The marketable securities held by the Company are highly rated corporate bonds, see also Note 5B.

U. Comprehensive Income

In addition to net profit, comprehensive income includes unrealized gains or losses arising from marketable securities classified as available-for-sale.

V. Fair Value Measurements

The Company's financial instruments include mainly cash and cash equivalents, accounts receivable, short term investments, contingent consideration in respect of business combination, marketable securities and accounts payable. The carrying amounts of these financial instruments approximate their fair value.

The Company implements ASC Topic 820 "Fair Value Measurements and Disclosures" ("ASC 820") for fair value measurements of financial assets and financial liabilities and for fair value measurements of nonfinancial items that are recognized or disclosed at fair value in the financial statements. ASC 820 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to measurements involving significant unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are as follows:

Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3 inputs are unobservable inputs for the asset or liability. (For details see Note 15).

Derivative financial instruments

The Company enters into forward exchange contracts to hedge certain anticipated transactions which are expected to be denominated in non-dollar currencies. These derivatives are not designated as hedging instruments for accounting purposes. The derivatives are recognized on the balance sheet at their fair value. Changes in the fair value are recognized in the statement of income as ‘financial income – net’.

(In thousands)

Note 1 - Organization and Summary of Significant Accounting Policies (cont'd)

W. Business Combinations

The Company accounts for business combinations under the revised principles of ASC Topic 805 ("ASC 805"), Business Combinations, related to business combinations and non-controlling interests. ASC 805 requires recognition of assets acquired, liabilities assumed, and non-controlling interest in the acquiree at the acquisition date, measured at their fair values as of that date. ASC 805 also requires the fair value of acquired in-process research and development ("IPR&D") to be recorded as intangibles with indefinite lives, contingent consideration to be recorded on the acquisition date, and restructuring and acquisition-related deal costs to be expensed as incurred. In addition, changes in valuation allowance related to acquired deferred tax assets and in acquired income tax position are to be recognized in earnings.

The Company applied the revised principles to the acquisitions of SmartPill in 2012 and Sierra in 2010 (see Note 16D and 16B, respectively, for details).

X. Recent accounting pronouncements

In December 2011, the FASB issued ASU 2011-11 Balance Sheet (Topic 210)-Disclosures about Offsetting Assets and Liabilities: The amendments in this ASU will enhance disclosures by requiring improved information about financial instruments and derivative instruments that are either (1) offset in accordance with either Section 210-20-45 or Section 815-10-45 or (2) subject to an enforceable master netting arrangement or similar agreement, irrespective of whether they are offset in accordance with either Section 210-20-45 or Section 815-10-45. The Company will be required to apply the amendments for annual reporting periods beginning on January 1, 2013. It is not expected to have a material impact on the Company's consolidated financial statements.

Note 2 - Cash and Cash Equivalents

	December 31,	
	2012	**2011**
Denominated in U.S. dollars	$ 23,846	$ 15,405
Denominated in New Israeli Shekels	3,424	1,686
Denominated in Euros	3,968	4,754
Denominated in Japanese Yen	3,050	1,146
Denominated in other currencies	1,154	1,294
	$ 35,442	$ 24,285

(In thousands)

Note 3 - Accounts Receivable - Other

	December 31,	
	2012	2011
Government institutions	$ 2,662	$ 2,139
Other	1,992	3,120
	$ 4,654	$ 5,259

Note 4 - Inventories

	December 31,	
	2012	2011
Raw materials and components	$ 12,744	$ 13,051
Work-in-progress	5,846	6,169
Finished goods	10,151	8,627
	$ 28,741	$ 27,847

Inventories are presented in:

	December 31,	
	2012	2011
Current assets	$ 22,591	$ 22,921
Non-current assets	6,150	4,926
	$ 28,741	$ 27,847

Long term Inventory:

At December 31, 2012, $6,150 of the Company's components inventory is in excess of requirements for the year 2013 based on management’s estimate of sales. This long term components inventory is mainly comprised of imaging sensor and transmitter of its PillCam capsules and raw material used for the production of new products. Management believes that this amount will be utilized according to its forecasted sales.

(In thousands)

Note 5 - Short-term Investments and Marketable Securities

A. Short-term investments and marketable securities

As of December 31, 2012 and 2011, Short-term investments consist of:

	December 31,	
	2012	2011
Available-for-sale securities	$ 2,446	$ 3,794
Bank deposits	56,000	60,968
Total	$ 58,446	$ 64,762

B. Available for sale marketable securities

As of December 31, 2012 and 2011, marketable securities consist of corporate bonds only.

During 2012, the Company recorded $1,151 of realization and adjustments of unrealized gains from corporate bonds. Proceeds from the sale and maturity of available-for-sale securities were $13,343 in 2012; net realized gains included in finance income in 2012 were $85 (net realized gains included in finance income in 2011 - $281; in 2010 - $43).

The carrying amount, gross unrealized holding gains, gross unrealized holding losses, and fair value marketable securities classified as available-for-sale at December 31, 2012 and 2011 are as follows:

	Carrying amount	Gross unrealized holding gains	Gross unrealized holding (losses)	Fair value
At December 31, 2012	$ 32,368	$ 295	$ (29)	$ 32,634
At December 31, 2011	$ 20,682	$ 3	$ (888)	$ 19,797

Maturities of debt securities classified as available-for-sale at December 31, 2012 were as follows:

	Carrying amount	Fair value
Current maturities	$ 2,434	$ 2,446
Due after one year through five years	29,934	30,188
	$ 32,368	$ 32,634

At December 31, 2012, all marketable securities which were in an unrealized loss position, had been in such a position for less than 12 months.

(In thousands)

Note 6 - Fixed Assets, Less Accumulated Depreciation

	December 31,	
	2012	2011
Computers and software	$ 13,633	$ 12,195
Instruments and laboratory equipment	1,494	1,476
Leasehold improvements	6,338	5,471
Motor vehicles	140	140
Machinery and equipment	20,035	18,926
Communication equipment	558	558
Office furniture and equipment	2,550	2,306
Fixed assets, at cost	44,748	41,072
Accumulated depreciation	(32,413)	(28,771)
Fixed assets at cost, less accumulated depreciation	$ 12,335	$ 12,301

Depreciation expenses for the years ended December 31, 2012, 2011 and 2010 were $4,213, $4,550 and $4,321, respectively. During 2012, the Company wrote off fixed assets which was no longer in use. This resulted in a charge of $239 recorded in operating expenses - other on the consolidated statement of income.

As of December 31, 2012 and 2011, the cost of fixed assets under capital lease was $607 and $607, and the accumulated depreciation for year ended December 31, 2012 and 2011 was $484 and $397, respectively.

(In thousands)

Note 7 - Intangible Assets, Less Accumulated Amortization

	December 31,	
	2012	2011
Patents and trademarks	$ 16,222	$ 14,414
Web site development	1,821	1,518
Software development	647	647
IPR&D acquired in a business combination (note 16B)	5,306	5,306
Patents and technology acquired in business combinations	15,667	12,562
Trademarks and trade names acquired in business combinations	4,020	4,020
Customer relationships acquired in business combinations	3,556	2,891
Intangible assets, at cost	47,239	41,358
Accumulated amortization	(16,534)	(12,283)
Intangible assets, less accumulated amortization	$ 30,705	$ 29,075

Amortization expenses for the years ended December 31, 2012, 2011 and 2010 were $4,384, $3,746 and $2,729, respectively (expenses for 2010 do not include $612 amortization of backlog acquired as part of the GILA acquisition, see Note 16B). Estimated amortization expenses for the next five years are: $4,361 in 2013, $4,286 in 2014, $4,210 in 2015, $4,171 in 2016 and $3,256 in 2017. During 2012, the Company wrote off patents, trademarks and software development which are no longer expected to be used. This resulted in a charge of $245 recorded in Operating expenses - other in the consolidated statements of income.

(In thousands)

Note 8 - Commitments and Contingencies

A. Leases

The Company and its subsidiaries lease office space and manufacturing space for periods of up to 11 years (including options to extend the terms of the leases). The current lease for the Company's headquarters is in Yoqneam, Israel. This facility houses the Company's corporate headquarters, research and development and manufacturing facilities. Under this lease agreement, the Company will pay approximately $1,775 a year in rent and management fees. These payments are subject to adjustments based on changes in the Israeli Consumer Price Index. In addition, to secure its obligations under the lease, the Company provided bank guarantees in the amount of approximately $788 in favor of the lessor. The lease expires on December 31, 2015. The Company has an option to extend the lease until December 31, 2020.

The Company and its subsidiaries signed several motor vehicle lease agreements, which are viewed as capital leases. The companies deposited a total amount of $210 to guarantee their performance under the terms of the lease agreements.

The Company is committed to minimum annual lease payments over the next five years as follows:

	Capital leases	Operating leases
2013	$ 38	$ 5,279
2014	-	4,364
2015	-	3,565
2016	-	2,915
2017 and thereafter	-	7,107
	$ 38	$ 23,230

Depreciation of vehicles and equipment under capital lease for the years ended December 31, 2012, 2011 and 2010 was $87, $93 and $91, respectively (see also note 6).

Rental expenses under the lease agreements for the years ended December 31, 2012, 2011 and 2010 were $4,976, $5,311 and $4,557, respectively.

B. Agreements with key single - source suppliers and commitments to suppliers

(1) The Company has agreements with a number of single source suppliers for some of the components necessary for the production of its products. For example, the Company has sole suppliers for the imaging sensor and transmitter of its PillCam capsules and the data recorder unit of the Bravo system.

The Company relies on other single source suppliers with whom it does not have long term contracts for some other components necessary for the production of its products, such as the electrical circuit boards used in the PillCam and Bravo capsules and for computer workstations.

Purchases under such agreements with the five largest single source suppliers for the years ended December 31, 2012, 2011, 2010 were $15,690, $5,553 and $9,880, respectively.

(In thousands)

Note 8 - Commitments and Contingencies (cont'd)

B. Agreements with key single - source suppliers and commitments to suppliers (cont'd)

(2) The Company's annual commitments under agreements with single source and other suppliers for the next 5 years are as follows:

2013	$	10,306
2014		1,342
2015		2,546
2016		3,363
2017 and beyond		3,812
	$	21,369

C. Office of the Chief Scientist Grants

The Company's research and development efforts have been partially financed through royalty-bearing grants from OCS. In return for the OCS's participation, the Company is committed to pay royalties to the Israeli Government at the rate of 3%-5% of the sales of its product, up to 100% of the amount of the grants received plus LIBOR interest. The Company is entitled to the grants only upon incurring research and development expenditures. There are no future performance obligations related to the grants received from the OCS. However, under certain limited circumstances, the OCS may withdraw its approval of a research program or amend the terms of its approval. Upon withdrawal of approval, the grant recipient may be required to refund the grant, in whole or in part, with or without interest, as the OCS determines. The Company received from the OCS a total cumulative amount of $400 which is the total outstanding obligation for royalty-bearing grants as of December 31, 2012.

D. Non-Exclusive Patent License Agreement

In August 2012, the Company entered into a non-exclusive patent license agreement with a third party. Under this license agreement, the Company licensed on a non-exclusive basis a portfolio of patents related to research and development activity of the Company. In consideration for this license, the Company paid EURO 1 million upon signing the agreement and may be obligated to pay royalties of up to EURO 8 million if the Company commercializes products in the field covered by the licensed patents. The Company does not anticipate royalty payments in the foreseeable future.

E. Litigation

In October 2011, a claim was filed against the Company in Portugal by a former distributor seeking equitable compensation and damages in an amount of approximately EURO 1.7 million due to alleged wrongful termination of a distribution agreement.

On June 19, 2012, the claim was dismissed as a result of a court ruling that determined that Portuguese courts do not have jurisdiction to try this case under Portuguese and European applicable rules.

On September 9, 2012 the former distributor filed an appeal, challenging the dismissal of the claim as described above. This appeal was rejected on the grounds of late filing. The distributor has appealed the ruling that it was late filing the appeal and this appeal was rejected as well. Based on the advice of counsel, management believes that the Company was entitled to terminate the distribution agreement without any compensation. Accordingly, no provision has been made in the Company's financial statements for the claim.

Note 8 - Commitments and Contingencies (cont'd)

E. Litigation (cont'd)

From time to time, as a result of the nature of its business, the Company is subject to actual or threatened patent litigation. Based on consultation with counsel, management believes that the potential exposure to the Company from such actual or threatened patent litigation as of December 31, 2012 is remote. Accordingly, no provision has been made in the Company's financial statements for any of such claims.

F. Registration Rights Agreement

In November 2011, an Amended and Restated Registration Rights Agreement among the Company, Elron Electronic Industries ("Elron"), Discount Investment Corporation ("DIC") and Rafael Development Corporation ("RDC") was approved at a special meeting of our shareholders. As of December 31, 2012, Elron, DIC and RDC collectively owned an aggregate of 45.6% of the Company's ordinary shares and are collectively referred to as the "affiliated shareholders." This Amended and Restated Registration Rights Agreement has amended and restated a similar agreement among us and the affiliated shareholders that had been entered into in 2007. The 2007 agreement replaced earlier registration rights granted by the Company to Elron, DIC, RDC, entities affiliated with OrbiMed Capital LLC and other shareholders in connection with a private placement of our ordinary shares completed in September 2000, before our initial public offering. These earlier registration rights expired in October 2006.

Under this agreement, at the request of one or more of the affiliated shareholders holding at least 5% of the Company's then outstanding ordinary shares, the Company must use its best efforts to register any or all of these shareholders' ordinary shares to the extent that the aggregate offering price of the shares to be registered is at least $15 million. In addition, the affiliated shareholders also have the right to request that the Company include their ordinary shares in any registration statements filed by the Company in the future for the purpose of a public offering, subject to specified limitations. With respect to any shareholder, registration rights will expire if that shareholder can sell all of its ordinary shares within a 90 day period under Rule 144 under the United States Securities Act of 1933, as amended. Generally, the Company is obligated to pay all expenses incurred in carrying out the above registrations, as well as the fees and expenses of one legal counsel for the selling shareholders in each registration.

(In thousands)

Note 8 - Commitments and Contingencies (cont'd)

F. Registration Rights Agreement (cont'd)

The 2011Amended and Restated Registration Rights Agreement extended the affiliated shareholders' registration rights until July 18, 2017 and provides relief from certain requirements and financial thresholds necessary to trigger registration rights to the benefit of lending institution to which any of the affiliated shareholders pledge its respective shares in the Company in connection with any credit line or loan provided to the affiliated shareholders. Finally, the Company has agreed that each of the affiliated shareholders could require that any registration be a shelf registration under Rule 415 under the United States Securities Act of 1933, and to maintain such a shelf registration for the maximum possible time

Note 9 - Accounts Payable – Other

	December 31,	
	2012	**2011**
Government institutions	$ 5,782	$ 5,145
Liabilities relating to employees	15,665	15,370
Advances from customers	196	201
Warranty	573	665
Commissions	1,291	1,857
Accrued expenses	3,584	5,159
	$ 27,091	$ 28,397

Note 10 - Liability in Respect of Employee Severance Payments

Under Israeli law and labor agreements the Company is required to pay severance payments to each employee who was employed by the Company for over one year and has been terminated by the Company or resigned under certain specified circumstances. The Company's liability for these severance payments is covered mainly by deposits with insurance companies in the name of the employee and/or by purchase of insurance policies. The liability related to these severance payments is calculated on the basis of the latest salary of the employee multiplied by the number of years of employment as of the balance sheet date. The liability for employee severance payments included in the balance sheet represents the total amount due for such severance payment, while the assets held for severance benefits included in the balance sheet represents the Company's contributions to insurance policies. The Company may make withdrawals from the funds only upon complying with the Israeli severance pay law or labor agreements. In respect of certain Israeli employees, the Company obtained approval from the Israeli Ministry of Labor and Welfare, pursuant to the terms of Section 14 of the Israeli Severance Pay Law, 1963, according to which the current deposits with the insurance companies exempt the Company from any additional obligation to these employees for whom the said depository payments are made.

Expenses recorded in respect of employees' severance payments for the years ended December 31, 2012, 2011 and 2010 are $1,125, $1,471 and $1,347, respectively.

The U.S. subsidiaries have a defined contribution retirement plan for their employees. Employees are allowed to contribute up to 18% of their salary in any one year, subject to a regulatory limit. The Company contributes 3% of an employee's salary subject to regulatory limits. Employees are vested in the Company's contributions after 30 days of employment. Expenses recorded in respect of the defined contribution retirement plan in the U.S for the years ended December 31, 2012, 2011 and 2010 are $1,089, $1,157 and $804, respectively.

Note 11 - Shareholders' equity

A. Ordinary shares

All of the issued and outstanding Ordinary Shares of the Company are authorized and fully paid. The Ordinary Shares of the Company are not redeemable and have no preemptive rights. The ownership or voting of Ordinary Shares by non-residents of Israel is not restricted in any way by the Company's memorandum or articles of association or the laws of the State of Israel, except that citizens of countries (including corporations incorporated in countries) which are considered under the applicable law as "enemy states" of Israel may not be recognized as owners of Ordinary Shares.

B. Employees' and non employees' stock options

The Company has three active equity plans:

The newest plan is the 2009 Equity Incentive Plan. The 2009 equity plan permits the Company to grant a number of equity instruments, such as options, restricted stock, restricted stock units and stock appreciation rights to eligible employees, directors and consultants. Stock option awards under this plan must be granted at no less than the fair market value of our ordinary shares on the date of the grant and the term of the awards may not exceed ten years. Shares underlying equity awards that have been cancelled or forfeited return to the pool of equity units are also available for grant under the plan. As of December 31, 2012, there were outstanding under this plan 495,117 restricted share units, or RSUs. No other types of equity units are outstanding under the 2009 plan.

Generally, awards vest over a four-year period beginning with the first or second anniversary of the grant. The Company's Compensation and Nominating Committee has the authority to grant awards with different vesting terms and to accelerate the time periods for the vesting of awards. To the extent the awards have vested, they may be exercised in whole or in part from time to time until their expiration.

Upon the termination of employment or service of participating employees and consultants, all unvested awards are cancelled. All vested awards may be exercised within 180 days following termination, except if termination of employment is due to specified circumstances such as death or disability of a plan participant, in which case vested awards may be exercised within one year following termination. All vested awards not exercised within this period are automatically forfeited and cancelled. Unvested awards to non-employee directors whose service is terminated or discontinued for any reason other than for cause and who have been members of our board of directors for more than five years, will automatically vest and become exercisable immediately prior to termination or discontinuation of service. These vested awards may be exercised within 180 days following termination of service, except in cases of where termination or discontinuation of service is a result of statutory requirements, death, disability or other circumstances of forced cessation of service, in which case awards may be exercised at any time until their expiration date. In a case of termination for cause of a plan participant, all awards, whether vested or unvested, are automatically forfeited and cancelled.

Under the 2009 equity plan, in the event of an acquisition, merger or other share exchange in which the Company is not the surviving entity and the acquiring entity does not agree to assume the awards, all outstanding, but unvested, awards of each plan participant having been employed by the Company at least one year, will be accelerated and exercisable, ten days prior to the completion of the acquisition, merger or share exchange. In addition, if the employment of a particular holder of outstanding awards is terminated by the Company as of or during the 12-month period following a change in control (as defined in the 2009 equity plan), all unvested awards of such holder will be automatically accelerated and exercisable, subject to certain adjustments and exceptions.

Awards granted under the 2009 equity plan to Israeli residents may be granted under Section 102 of the Israeli Income Tax Ordinance pursuant to which the awards or the ordinary shares issued upon their exercise must be deposited with a trustee for at least two years following the date of the grant. Under Section 102, any tax payable by an employee from the grant or exercise of the awards is deferred until the transfer of the awards or ordinary shares by the trustee to the employee or upon the sale of the awards or ordinary shares.

Note 11 - Shareholders' equity (cont'd)

B. Employees' and non employees' stock options (cont'd)

Awards granted under Section 102 may qualify for certain tax benefits under the Israeli Tax Ordinance.

Stock options granted under the plan to U.S. residents may also qualify as incentive stock options within the meaning of Section 422 of the U.S. Internal Revenue Code of 1986, as amended. The exercise price for incentive stock options must not be less than the fair market value on the date the option is granted, or 110% of the fair market value if the option holder holds more than 10% of our share capital.

The Company also has an equity plan entitled the 2006 Equity Incentive Plan. The terms of the 2006 plan are identical to the terms of the 2009 equity plan. The Company has reserved for issuance a total of 4,000,000 Ordinary Shares under the 2006 Plan. As of December 31, 2012 there were 3,344,814 options outstanding under the 2006 Plan.

The Company's 2003 stock option plan was materially amended in February 2012 and renamed the Amended and Restated 2003 Equity Incentive Plan, and is currently identical to the 2009 plan. Previously, the 2003 stock option plan only permitted the grant of stock options. The Company has reserved for issuance a total of 2,500,000 Ordinary Shares under the 2003 Plan. As of December 31, 2012, there were outstanding options to purchase 1,396,665 ordinary shares and 315,924 RSUs under the 2003 stock option plan. Stock option awards under this plan had been granted at no less than the fair market value of the Company's ordinary shares on the date of the grant and the term of the awards does not exceed ten years. The 2003 stock option plan has expired on February 12, 2013 and no equity grants will be made under this plan after this date. However, outstanding awards may be exercised until their expiration date.

During 2009 the Company extended the term of outstanding stock options previously granted to 181 employees under the Company's 2006 Plan by two additional years. On June 3, 2009, the shareholders at their Annual General Meeting approved extension of the term of outstanding stock options previously granted to external directors under the Company's 2006 Plan by two additional years.

The incremental cost recorded due to this modification in the consolidated statements of income for the years ended December 31, 2012, 2011 and 2010 was $10, $61 and $721, respectively.

Awards granted to consultants are immaterial.

(In thousands)

Note 11 - Shareholders' equity (cont'd)

B. Employees' and non employees' stock options (cont'd)

Options

The following table summarizes information relating to stock options for Ordinary Shares outstanding, as of December 31, 2012 and 2011:

	Options outstanding as of December 31, 2012	
Exercise prices	**Number outstanding at**	**Weighted Average Remaining contractual life (in years)**
$1 - $10	704,792	1.93
$10.01-$20	1,714,775	1.45
$20.01-$30	1,822,472	1.50
$30.01-$40	499,440	1.90
	4,741,479	

	Options outstanding as of December 31, 2011	
Exercise prices	**Number outstanding at**	**Weighted Average Remaining contractual life (in years)**
$1 - $10	790,080	2.87
$10.01-$20	1,990,864	2.29
$20.01-$30	1,825,172	1.96
$30.01-$40	499,440	2.90
	5,105,556	

The stock option activity under the Plans is as follows:

	Number of shares	Weighted average exercise price	Weighted average grant date fair value
Balance at January 1, 2012	5,105,556	$ 20.48	9.55
Exercised	(350,638)	$ 11.56	7.48
Forfeited	(13,439)	$ 13.04	5.46
Balance at December 31, 2012	4,741,479	$ 21.16	9.70
Exercisable at December 31, 2012	4,538,344	$ 20.78	9.99

(In thousands)

Note 11 - Shareholders' equity (cont'd)

B. Employees' and non employees' stock options (cont'd)

As of December 31, 2012, unrecognized compensation costs related to non-vested options aggregated $685 to be recognized over 0.3 years.

The aggregate intrinsic value of options outstanding as of December 31, 2012, 2011 and 2010 is $8,878 $10,944 and $8,208, respectively. The aggregate intrinsic value of options exercisable as of December 31, 2012, 2011 and 2010 is $7,116 , $6,946 and $4,141, respectively.

The total intrinsic value of options exercised during the year ended December 31, 2012 and 2011, is $2,079 and $3,490, respectively.

RSUs

The following table summarizes information relating to RSUs as of December 31, 2012 and related changes during the year ended December 31, 2012:

Non-vested RSUs	Number of shares	Weighted average grant date fair value
Balance at January 1, 2012	793,517	$ 17.80
Granted	324,924	18.49
Vested	(281,400)	17.31
Forfeited	(26,000)	17.60
Balance at December 31, 2012	811,041	$ 18.30

The aggregate intrinsic value of RSUs granted during 2012, 2011 and 2010 is $ 6,004, $6,600 and $6,942, respectively.

(In thousands)

Note 11 - Shareholders' equity (cont'd)

B. Employees' and non employees' stock options (cont'd)

During 2012 the Company granted 264 ,909 RSUs to employees and non-employees. 50% of the RSUs vest on the second anniversary of the date of grant, and 25% vest on each of the third and fourth anniversaries of the date of the grant. 48,650 RSUs were granted to directors - 100% vest on the first anniversary and 11,365 were garnted to a director, 25% vest on each of four anniversaries. The fair value of the RSUs as of the date of grant is amortized over the vesting period. Unrecognized compensation costs related to the RSUs as of December 31, 2012, to be recognized over a weighted average period of 1.22 years, were $9.5 million, and compensation expenses of $5.3 million and $4.1 million were recognized in the years ended December 31, 2012 and 2011, respectively.

Restricted Shares

On May 30, 2006, the Company issued 100,000 restricted shares to its CEO. The restricted shares vested in four installments over a period of four years, beginning on May 30, 2007. On June 15, 2007 the Company issued 6,000 restricted shares to another one of its officers. These restricted shares vested in three installments over a period of four years, beginning on June 15, 2009. The fair value of the restricted shares as of the date of issue is amortized over the vesting period. As of December 31, 2012 there were no unrecognized compensation costs related to the restricted shares. Compensation expenses related to the restricted shares of $0, $18 and $485 and were recognized for the years ended December 31, 2012, 2011 and 2010, respectively.

Total compensation costs

The following table summarizes the allocation of the stock-based compensation charge for both employee and non-employee stock option grants:

	Year ended December 31,		
	2012	2011	2010
Research and development costs	$ 724	$ 708	$ 428
Selling and marketing expenses	1,985	2,175	1,557
General and administrative expenses	3,449	4,480	6,497
	$ 6,158	$ 7,363	$ 8,482

Note 12 - Revenues

A. Revenues by product lines

	Year ended December 31,		
	2012	2011	2010
Workstations, recorders and software	$ 7,533	$ 9,060	$ 8,120
PillCam SB capsule	116,618	117,561	110,189
PillCam ESO capsule	269	425	539
PillCam Colon capsule	1,981	1,798	1,291
Patency capsules and scanners	906	792	666
Bravo pH monitoring products	17,677	19,746	18,603
GILA manometry and catheters	34,704	28,460	17,913
SmartPill systems and capsules	594	-	-
Services	219	113	488
	$ 180,501	$ 177,955	$ 157,809

(In thousands)

Note 12 – Revenues (cont'd)

B. Revenues by geographic areas

	Year ended December 31,		
	2012	**2011**	**2010**
Americas	$ 115,168	$ 108,745	$ 100,501
Europe, Middle East and Africa (mainly Europe)	42,911	45,122	40,224
Asia Pacific	22,422	24,088	17,084
	$ 180,501	$ 177,955	$ 157,809

Most of the Company's long-lived assets are located in Israel.

Note 13 - Financial Income, net

	Year ended December 31,		
	2012	**2011**	**2010**
Currency gains, net	$ 61	$ 650	$ 1,989
Income from marketable securities and deposits	1,599	1,347	1,165
Other	(813)	(654)	(555)
	$ 847	$ 1,343	$ 2,599

The Company uses forward contracts and option strategies to manage its foreign exchange rate exposures. Contracts with notional amounts of $37.7 million, $64.7 million and $58.5 million and with estimated fair values that totaled $212, $1,431 and $(132) as of December 31, 2012, 2011 and 2010, respectively, were not designated as hedging instruments for accounting purposes. The changes in fair value of these contracts of $ (1,219), $1,563 and $(956) for the years ended December 31, 2012, 2011 and 2010 have been recognized as finance income (loss) in those years among "currency gains, net". The periodic net cash (receipts) settlements totaled $1,995, $1,617 and $1,602 for the years ended December 31, 2012, 2011 and 2010, respectively.

Note 14 - Taxes on Income

A. Israeli Taxation

(1) Israeli income tax is computed on the basis of the Company's results in New Israeli Shekels ("NIS") determined for statutory purposes.

Pursuant to the Encouragement Capital Investments Law -1959 (the "Law"), the Company was awarded "Approved Enterprise" status under the government alternative benefits path ("Alternative Path") beginning in 1999, upon completion of the project as approved by the Investment Center. The program is for investments in the development of infrastructure and for investments in locally produced and imported equipment. The main benefits to which the Company will be entitled, if it implements all the terms of an approved program, are the exemption from tax on income deriving from an Approved Enterprise, and reduced tax rates on dividends originating from this income (if distributed within a certain time limit).

Note 14 - Taxes on Income (cont'd)

A. Israeli Taxation (cont'd)

Under the Alternative Path, the income derived from an Approved Enterprise will be exempt from tax for a ten-year period, commencing on the date that taxable income is first generated by the Approved Enterprise (limited to the earlier of a maximum period of 12 years from the year of commencement of operations or 14 years from the year the approval letter was received).

Dividend distributions originating from income of an Approved Enterprise will be subject to a withholding tax at the shareholders level at the rate of 15%, provided that the dividend is distributed during the period stipulated under Israeli law.

In the event of a dividend distribution (including withdrawals and charges that are deemed to be dividends) out of the income originating from the Approved Enterprise, and on which the Company received a tax exemption, the distribution is subject to corporate taxes at rates varying from 10% - 25% (currently 25%) depending on the percentage of foreign investment holding in the Company as defined by the Law.

If the Company derives income from sources other than the Approved Enterprise during the relevant period of benefits, such income will be taxable at regular corporate tax rates (see (4) below).

In 2005, an amendment to the Law was enacted (the "2005 Amendment"). Provisions of the 2005 Amendment which apply to the Company are as follows:

a. Companies that meet the criteria of the Alternative Path of tax benefits will receive those benefits (now called "Beneficiating Enterprise" benefits) without prior approval. In addition, there will be no requirement to file reports with the Investment Center. Companies will be required to notify the Israeli Income Tax Authorities regarding the implementation of the Alternative Path. Audit will take place via the Income Tax Authorities as part of the tax audits. Request for pre-ruling is possible.

b. Tax benefits of the Alternative Path include lower tax rates or zero tax depending on the investment zone and the path chosen, lower tax rates on dividends and accelerated depreciation.

c. In order to receive benefits in the Grant Path or the Alternative Path, the Industrial Enterprise must contribute to the economic independence of Israel's economy in one of the following ways:

    1. Its primary activity is in the Biotechnology or Nanotechnology fields and pre-approval is received from the head of research and development at the Office of the Chief Scientist;

    2. Its revenue from a specific country is not greater than 75% of its total revenues that year;

    3. 25% or more of its revenues are derived from a specific foreign market of at least 12 million residents.

The 2005 Amendment does not apply retroactively for investment programs having an Approved Enterprise approval certificate from the Investment Center issued up to December 31, 2004 (even when investments under these programs are conducted after January 1, 2005). Consequently, the amendments should not impact an existing Approved Enterprise, which received prior written approval. The new tax regime shall apply for a new Approved Enterprise and for an Approved Enterprise expansion for which the first year of benefits may be as early as 2004. The Company has notified the Israeli Income Tax Authorities as to the expansion of its Approved Enterprise status based on the 2005 Amendment.

Note 14 - Taxes on Income (cont'd)

A. Israeli Taxation (cont'd)

(2) The 2010 Amendment to the Law for the Encouragement of Capital Investments – 1959

On December 29, 2010 an amendment to the Law for the Encouragement of Capital Investments – 1959 was approved (hereinafter – "the 2010 Amendment"). The 2010 Amendment was published in the Official Gazette on January 6, 2011. The 2010 Amendment is effective from January 1, 2011 and its provisions will apply to preferred income derived or accrued in 2011 and thereafter by a preferred company, per the definition of these terms in the 2010 Amendment. Companies can choose to not be included in the scope of the 2010 Amendment and to stay in the scope of the Law before its amendment until the end of the benefits period. The 2012 tax year is the last year companies can choose as the year of election, providing that the minimum qualifying investment began in 2010.

The 2010 Amendment provides that only companies in Development Area A will be entitled to the grants track and that they will be entitled to receive benefits under this track and under the tax benefits track at the same time. In addition, the existing tax benefit tracks were eliminated (the tax exempt track, the "Ireland track" and the "Strategic" track) and two new tax tracks were introduced in their place, a preferred enterprise and a special preferred enterprise, which mainly provide a uniform and reduced tax rate for all the company's income entitled to benefits, such as: for a preferred enterprise – in the 2011-2012 tax years – a tax rate of 10% for Development Area A and of 15% for the rest of the country, in the 2013-2014 tax years – a tax rate of 7% for Development Area A and of 12.5% for the rest of the country, and as from the 2015 tax year – 6% for Development Area A and 12% for the rest of the country. Furthermore, an enterprise that meets the definition of a special preferred enterprise is entitled to benefits for a period of 10 consecutive years and a reduced tax rate of 5% if it is located in Development Area A or of 8% if it is located in a different area.

The 2010 Amendment also provides that no tax will apply to a dividend distributed out of preferred income to a shareholder that is a company, for both the distributing company and the shareholder. A tax rate of 15% shall continue to apply to a dividend distributed out of preferred income to an individual shareholder or foreign resident, subject to double taxation prevention treaties, similar to the provisions of the existing law. Furthermore, the 2010 Amendment provides relief with respect to tax paid on a dividend received by an Israeli company from profits of an approved/alternative/beneficiary enterprise that accrued in the benefits period according to the version of the law before its amendment, if the company distributing the dividend elects to notify the tax authorities by June 30, 2015 that it is applying the provisions of the 2010 Amendment and the dividend is distributed after the date of the notice.

As of the December 31, 2012, the Company has not chosen the election of the Amendment to the law, and therefore is currently not entitled to the available relief described above. Under the Company's current tax status, the Company is eligible for tax exemption through 2021.

(3) As explained above, the Israeli Company is exempt from tax for a ten-year period. Therefore, the Israeli Company has not recorded deferred tax assets and liabilities. Out of the Company's retained earnings as of December 31, 2012, approximately $22.2 million are tax-exempt earnings attributable to its Approved Enterprise and approximately $54.6 million are tax-exempt earnings attributable to its Beneficiating Enterprise. The tax-exempt income attributable to the Approved and Beneficiating Enterprises cannot be distributed to shareholders without subjecting the Company to taxes. If these retained tax-exempt profits are distributed, the Company would be taxed at the reduced corporate tax rate applicable to such profits (currently- 25% pursuant to the implementation of the Investment Law).

According to the 2005 Amendment, tax-exempt income generated under the Beneficiating Enterprise will be taxed upon dividend distribution or complete liquidation, whereas tax exempt income generated under the Approved Enterprise will be taxed only upon dividend distribution (but not upon complete liquidation, as the tax liability will be incurred by the shareholders). As of December 31, 2012, if the income attributed to the Approved Enterprise were distributed as dividend, the Company would incur a tax liability of approximately $5.5 million. If income attributed to the Beneficiating Enterprise were distributed as dividend, or upon liquidation, the Company would incur a tax liability in the amount of approximately $13.6 million. These amounts will be recorded as an income tax expense in the period in which the Company declares the dividend.

Note 14 - Taxes on Income (cont'd)

A. Israeli Taxation (cont'd)

(4) On July 14, 2009, the Knesset (the Israeli parliament) passed the Economic Efficiency Law (Legislation Amendments for Implementation of the 2009 and 2010 Economic Plan) - 2009, which provided, inter-alia, an additional gradual reduction in the regular company tax rate to 18% as from the 2016 tax year. In accordance with the aforementioned amendments, the regular company tax rates applicable as from the 2009 tax year are as follows: in the 2009 tax year- 26%, in the 2010 tax year - 25%, in the 2011 tax year - 24%, in the 2012 tax year - 23%, in the 2013 tax year - 22%, in the 2014 tax year - 21%, in the 2015 tax year - 20% and as from the 2016 tax year the regular company tax rate will be 18%. The aforementioned change in the tax rates had no material impact on the Company's financial position or results of operations, since the Israeli company is currently tax exempt as explained above.

On December 5, 2011 the Knesset approved the Law to Change the Tax Burden (Legislative Amendments) – 2011. According to the law, the tax reduction that was provided in the Economic Efficiency Law, as aforementioned, will be cancelled and the regular company statutory tax rate will be 25% as from 2012.

(5) In 2012, the Company signed a settlement agreement with the Israeli Tax Authorities (ITA) for fiscal years 2008 and 2009 (see also Note 14F below).

(6) As of December 31, 2012, the Company has no tax loss carryforwards in Israel except for capital losses of approximately $37.0 million which are available to offset future taxable capital gains for indefinite period. The Company has not recorded deferred tax assets on behalf of these capital losses, since management believes it is more likely than not that these deferred tax assets will not be realized.

(7) An amendment to the Law, which was enacted on November 12, 2012 (the "Trapped Profits Law") offers reduced corporate income tax rates intended to encourage the distribution of profits derived from tax-exempt income accumulated up to December 31, 2011. The Trapped Profits Law provides a formula, pursuant to which the higher the amount of income a company would be willing to release, the lower would the applicable corporate income tax rate be for that company with respect to such income (the tax rate may be reduced to a minimum of 6%). A company opting to utilize the Trapped Profits Law would be required to meet certain conditions, including, among others, an obligation of the company to invest in an Industrial Enterprise. As of December 31, 2012, the Company has not utilized the accommodations of the Trapped Profits Law.

(In thousands)

Note 14 - Taxes on Income (cont'd)

B. Foreign subsidiaries

As of December 31, 2012, the Company's subsidiaries had accumulated net operating loss carryforwards totaling approximately $37,144. Operating loss carryforwards in the Japanese subsidiary, totaling approximately $19,649, will expire through 2021. Operating loss carryforwards in the German and French subsidiaries amounted to approximately $11,266 and $3,915, respectively, and can be carried forward indefinitely.

C. Profit before tax and income tax benefit (expense) included in the consolidated statements of income

	Year ended December 31,		
	2012	**2011**	**2010**
Profit before taxes on income and non controlling interest:			
Israel	$ 9,231	$ 6,598	$ 8,232
Foreign jurisdiction	5,485	7,729	1,318
	14,716	14,327	9,550
Current tax benefit (expense):			
Israel	84	(1,002)	(294)
Foreign jurisdiction	(2,338)	(1,565)	(1,195)
	(2,254)	(2,567)	(1,489)
Deferred taxes (see Note 14D):			
Israel	-	-	-
Foreign jurisdiction	1,795	409	127
	1,795	409	127
Income tax expense	$ (459)	$ (2,158)	$ (1,362)

D. Deferred taxes

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers projected future taxable income and tax planning strategies in making this assessment.

Based upon projections for future taxable income over the periods in which the deferred tax assets are deductible, management believes it is more likely than not that the Company will realize the benefits of these deductible differences, net of the existing valuation allowances at December 31, 2012. The amount of the deferred tax asset considered realizable, however, could be reduced in the near term if estimates of future taxable income during the carryforward period are reduced.

(In thousands)

Note 14 - Taxes on Income (cont'd)

D. Deferred taxes (cont'd)

The tax effects of significant items comprising the Company's deferred taxes:

	December 31,	
	2012	**2011**
Deferred tax assets:		
Tax loss carryforwards of subsidiaries	$ 12,120	$ 13,123
Other timing differences	2,643	1,550
Total gross deferred tax assets	14,763	14,673
Valuation allowance	(12,117)	(13,135)
Net deferred tax assets (presented among current assets)	$ 2,646	$ 1,538
Long term deferred tax liabilities - intangible assets acquired in business combination (see Note 16B)	$ (4,675)	$ (5,362)

The net changes in the total valuation allowance for the years ended December 31, 2012, 2011 and 2010 are $ (1,018), $(1,976) and $1,898, respectively. For the year ended December 31, 2012, the net change in valuation allowance included a tax benefit of $239 which was due to a change in judgment about the realizability of the related deferred tax in future years, in the Company's Australian subsidiary. The remaining net change in the valuation allowance, and the net change in valuation allowance in the year ended December 31, 2011 are mainly due to utilization of operating loss carryforwards.

E. Reconciliation of statutory tax expense to actual income tax expense

	Year ended December 31,		
	2012	**2011**	**2010**
Profit before taxes on income	$ 14,716	$ 14,327	$ 9,550
Tax rate	25%	24%	25%
Computed expected tax	(3,679)	(3,438)	(2,388)
Tax benefits arising from approved enterprises (*)	2,717	1,584	2,058
Changes in unrecognized tax benefits	48	(1,471)	(57)
Permanent difference and other	(77)	(311)	64
Change in valuation allowance	1,018	1,976	(1,898)
Foreign tax rate differential	(486)	(498)	859
Income tax expense	$ (459)	$ (2,158)	$ (1,362)
(*) Net earnings per share – amounts of the benefit resulting from the Approved Enterprises:			
Basic	$ 0.07	$ 0.05	$ 0.07
Diluted	$ 0.07	$ 0.05	$ 0.07

(In thousands)

Note 14 - Taxes on Income (cont'd)

F. Accounting for income tax uncertainties

The Company and its subsidiaries file income tax returns in Israel, the U.S and other foreign jurisdictions. The U.S. subsidiary files income tax returns in federal jurisdictions, and various states within the U.S. The Company is no longer subject to U.S. federal, state and local, or non-U.S. income tax examinations by tax authorities for years before 2008.

A reconciliation of the beginning and ending amount of unrecognized tax benefits based on the provisions of FASB ASC Subtopic 740-10, is as follows:

	2012	2011	2010
Balance at January 1	$ 5,301	$ 3,991	$ 3,974
Additions based on tax positions related to the current year	236	1,479	635
Reductions for tax positions of prior years	(204)	(169)	(618)
Settlements	(1,540)	-	-
Balance at December 31	$ 3,793	$ 5,301	$ 3,991

Unrecognized tax benefits in the amount of $3,793, if recognized, would affect the effective tax rate of the Company. The Company does not expect unrecognized tax benefits to change significantly over the next 12 months.

During the years ended December 31, 2012, 2011 and 2010 the Company recorded approximately $(80), $161 and $76, respectively in interest relating to unrecognized tax benefits in the consolidated statements of income and accrued $405 and $485 in the balance sheets as of December 31, 2012 and 2011, respectively.

(In thousands)

Note 15 - Fair Value of Financial Instruments

The level in the fair value hierarchy within which a fair measurement in its entirety falls is based on the lowest level input that is significant to the fair value measurement in its entirety.

The following table presents the placement in the fair value hierarchy of assets and liabilities that are measured at fair value on a recurring basis (including items that are required to be measured at fair value and items for which the fair value option has been elected) at December 31, 2012 and 2011:

	December 31, 2012	In active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Short-term investments	$ 2,446	$ 2,446	$ -	$ -
Long-term marketable securities	30,188	30,188	-	-
Derivatives	212		212	-
	32,846	32,634	212	-
Liabilities – contingent consideration	(1,038)			(1,038)
Total At December 31, 2012	$ 31,808	$ 32,634	$ 212	$ (1,038)

	December 31, 2011	In active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Short-term investments	$ 3,794	$ 3,794	$ -	$ -
Long-term marketable securities	16,003	16,003	-	-
Derivatives	1,431	-	1,431	-
Total At December 31, 2011	$ 21,228	$ 19,797	$ 1,431	$ -

Foreign Exchange Contracts

The Company and its subsidiaries complete transactions in currencies other than their functional currencies. The Company's primary objective with respect to currency risk is to reduce net income volatility that would otherwise occur due to exchange-rate fluctuations. In order to minimize the risk of gain or loss due to exchange rates, the Company uses foreign currency derivatives. As of December 31, 2012, the Company held foreign currency forward contracts aggregating $2,715 hedging Australian dollar, $8,209 hedging Euro, $6,377 hedging Yen and $20,430 hedging Israeli Shekel. Such instruments had a combined fair value gain of $212 and $1,431 as of December 31, 2012 and 2011, respectively, based on quotations from financial institutions. The Company does not apply hedge accounting. Gains /losses on these instruments are recognized in the consolidated statement of income.

Note 16 - Acquisitions and Investment

A. Investment in the Japanese Subsidiary

On January 1, 2011, the Company's share in Given Imaging K.K. ("GIKK") was 93% of the total issued and outstanding shares of GIKK.

In March 2012, the Company purchased all of the remaining shares held by the non-controlling shareholders in GIKK for a total consideration of $658. As a result of this share purchase the Company holds 100% of GIKK.

As to impairment of goodwill, see Note 17.

B. Acquisition of GILA (formerly Sierra)

On April 1, 2010, as part of the Company's strategy of expanding its product offerings, the Company completed the acquisition of GILA, a leading provider of specialty diagnostic device for the gastrointestinal tract (the "**GILA Acquisition**"). Under the terms governing the GILA Acquisition, on the closing date of the GILA Acquisition (the "GILA Closing Date"), th Company paid $34.8 million in cash for all of the issued and outstanding shares of GILA's common stock. Transaction costs in connection with the GILA Acquisition, in the amount of $93 were recorded as expenses in the Company's consolidated statement of income for the year ended December 31, 2010.

The Company accounted for the GILA Acquisition using the purchase method of accounting. The following table represents the final allocation of the purchase price of GILA:

	$ in thousands
Current assets	$ 7,967
Property, plant and equipment	533
Other long-term assets	65
Identifiable intangible assets:	
In-process research and development	5,306
Technological intellectual property (1)	7,562
Backlog	612
Business-related intellectual property (2)	3,711
Goodwill	20,523
Total assets acquired	46,279
Current liabilities	(4,761)
Deferred tax liability	(6,759)
Other non-current liabilities	(9)
Total liabilities assumed	(11,529)
Net assets acquired	$ 34,750

(1) Amortized over a period of 8 years.
(2) Amortized over periods ranging from 8 to 15 years.

Note 16 - Acquisitions and Investment (cont'd)

B. Acquisition of GILA (cont'd)

The goodwill is attributable to the significant synergies expected to arise after the Company's acquisition of GILA.

The operations of GILA have been included in the consolidated financial statements of the Company from April 1, 2010. The acquisition of GILA contributed revenues of $17.9 million and net loss of $716 to the Company for the period from April 1, 2010 to December 31, 2010.

Below are certain unaudited pro forma, combined statements of income data for the year ended December 31, 2010, presented as if the GILA Acquisition had occurred on January 1, 2009, after giving effect to: (a) purchase accounting adjustments, including the increase in amortization of identifiable intangible assets; and (b) estimated decrease in interest income due to the deduction of interest income on the Company's cash, cash equivalents and marketable securities used as cash consideration in the acquisition. This unaudited pro forma financial information is not necessarily indicative of the combined results that would have been attained had the acquisition actually taken place at the beginning of 2009, nor is it necessarily indicative of future results.

	Year ended December 31 2010
	$ in millions (except earnings per share) (unaudited)
Net sales	$ 162.5
Net income	$ 9.9
Net income attributable to shareholders*	$ 10.2
Earnings per share:	
Basic	$ 0.34
Diluted	$ 0.33

* Includes net amortization in the amount of approximately $766 and decrease in interest income of approximately $88. In addition, transaction costs of $936 were eliminated.

C. Marketing Subsidiary in Brazil

In January 2012, the Company paid $390 in a combination of cash and cancellation of a credit line in connection with setting up a sales and marketing subsidiary in Brazil. Under the terms of the agreement, the Company paid additional $210 in January 2013. The Company may be obligated to pay up to an additional $390 if certain conditions and performance milestones are achieved between January 2014 and December 31, 2015.

Note 16 - Acquisitions and Investment (cont'd)

D. Acquisition of SmartPill Corporation

In October 2012, as part of the Company's strategy of expanding its product offerings, the Company acquired from the SmartPill Corporation, a U.S. based-company, the assets related to the SmartPill® GI Monitoring Systems for $6 million. The purchase agreement also includes an earn-out component, based on sales of the SmartPill product between 2013 and 2016.

The fair value of the contingent consideration arrangement of $1,038 was estimated based on future earn-out payments discounted to the valuation date using the weighted average cost of capital of 15.2%. That measure is based on significant inputs that are not observable in the market, which ASC Section 820-10-35 refers to as Level 3 inputs. Key assumptions include management's estimation about future sales. As of December 31, 2012, only the time-factor had affected the remaining contingent consideration; the range of outcomes and the assumptions used to develop the estimates had not changed.

The Company accounted for the transaction as a business combination. The following table represents the final allocation of the purchase price:

	$ in thousands
Current assets	$ 595
Property, plant and equipment	183
Identifiable intangible assets:	
In-process research and development	-
Technological intellectual property (1)	3,105
Business-related intellectual property (2)	302
Goodwill(3)	2,853
Total assets acquired	7,038
Current liabilities	
Deferred tax liability	-
Other non-current liabilities	(1,038)
Total liabilities assumed	(1,038)
Net assets acquired	$ 6,000

(1) Amortized over a period of 15 years.
(2) Amortized over a period of 7 years.
(3) The goodwill arising from the acquisition represents, inter alia, the synergies between the technology acquired and the Company's existing operational, R&D and sales and marketing infrastructure. The goodwill recognized is expected to be deductible for income tax purposes.

In the fourth quarter of 2012 Company recorded revenues of $594 related to SmartPill.

Pro-forma financial statements for SmartPill acquisition have not been furnished as they are immaterial to the understanding of future operations.

(In thousands)

Note 17 - Goodwill

Goodwill reflects the excess of the purchase price of Smart Pill, GILA and Bravo pH monitoring business acquired in December 2012, April 2010 and December 2008 , respectively, over the fair value of net assets (see note 16) and the excess of the cash invested over the fair value of the Company's share in the net assets of its subsidiary in Japan.

Based on the annual impairment tests performed relating to the goodwill in the Japanese subsidiary, the Company recorded impairment losses of $20 in 2010, as a result of ongoing operating losses. The Company recognized the impairment losses as part of the Operating expenses - other. All the goodwill related to the Japanese subsidiary has been written off.

The Company has set its annual impairment testing date for Smart Pill, GILA and for Bravo operations at December 31 of each year and no impairment charge was recognized.

The changes in the carrying amount of goodwill for the years ended December 31, 2012 and 2011 are as follows:

	December 31,	
	2012	**2011**
Balance as of January 1		
Goodwill	$ 24,089	$ 24,998
Accumulated impairment losses	-	(909)
	24,089	24,089
Goodwill acquired during the year	2,853	-
Impairment loss	-	-
Balance as of December 31		
Goodwill	26,942	24,998
Accumulated impairment losses	-	(909)
	$ 26,942	$ 24,089

Exhibit 4.13

AMENDMENT NO. 1

GIVEN IMAGING LTD.
AMENDED AND RESTATED 2003 EQUITY INCENTIVE PLAN

WHEREAS, Given Imaging Ltd. (the "Company") sponsors the Given Imaging Ltd. Amended and Restated 2003 Equity Incentive Plan (the "Plan");

WHEREAS, the Company desires to amend the Plan.

NOW, THEREFORE, pursuant to the power reserved to it in Section 11.1 of the Plan, the Company hereby amends the Plan as follows:

1. Section 2.9 of the Plan is hereby deleted and the following substituted therefor:

2.9 "Change of Control" shall mean, unless otherwise defined in an Award Agreement, the occurrence of an event described in paragraph (a) or (b) below:

(a) The acquisition by any Person of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of more than 30% of the then outstanding Shares; provided, however, that for purposes of this subsection (a), the following acquisitions shall not constitute a change of control:

(i) Any acquisition directly from the Company;

(ii) Any acquisition by the Company or by any affiliate (as defined in Rule 405 under the Securities Act) of the Company as of February 12, 2003;

(iii) Any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company; or

(iv) Any acquisition by any corporation pursuant to a transaction which complies with clauses (i) and (ii) of subsection (b) below.

(b) Consummation of a reorganization, merger or consolidation involving the Company or its Subsidiaries or a sale or other disposition of all or substantially all of the assets of the Company and its Subsidiaries on a consolidated basis (a "Business Combination") unless, following such Business Combination:

(i) All or substantially all of the individuals and entities who were the beneficial owners, respectively, of the outstanding Shares immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the then outstanding voting securities entitled to vote generally in the election of directors of the Company or its successor (including, without limitation, an entity which as a result of such transaction owns the Company or all or substantially all of the assets of the Company either directly or through one or more Subsidiaries); and

(ii) No Person (excluding any corporation resulting from such Business Combination or any employee benefit plan (or related trust) of the Company or its successor resulting from such Business Combination) beneficially owns, directly or indirectly, more than 30% of the then outstanding voting securities of the Company or corporation (including, without limitation, an entity which as a result of such transaction owns the Company or all or substantially all of the assets of the Company either directly or through one or more Subsidiaries) except to the extent that such ownership existed prior to the Business Combination.

(c) Notwithstanding paragraphs (a) or (b) above, with respect to Restricted Stock Units that constitute "non-qualified deferred compensation" within the contemplation of Section 409A of the Code and that are granted to Participants who are subject to U.S. income tax, a transaction described in paragraphs (a) or (b) above shall constitute a "Change of Control" for purposes of the distribution or settlement of such Restricted Stock Units only to the extent it also qualifies as a "change of control event" within the meaning of Section 409A of the Code.

Adopted: September 27, 2012

Exhibit 4.14

AMENDMENT NO. 1

GIVEN IMAGING LTD.
AMENDED AND RESTATED 2006 EQUITY INCENTIVE PLAN

WHEREAS, Given Imaging Ltd. (the "Company") sponsors the Given Imaging Ltd. Amended and Restated 2006 Equity Incentive Plan (the "Plan");

WHEREAS, the Company desires to amend the Plan.

NOW, THEREFORE, pursuant to the power reserved to it in Section 11.1 of the Plan, the Company hereby amends the Plan as follows:

1. Section 2.9 of the Plan is hereby deleted and the following substituted therefor:

2.9 "Change of Control" shall mean, unless otherwise defined in an Award Agreement, the occurrence of an event described in paragraph (a) or (b) below:

(a) The acquisition by any Person of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of more than 30% of the then outstanding Shares; provided, however, that for purposes of this subsection (a), the following acquisitions shall not constitute a change of control:

(i) Any acquisition directly from the Company;

(ii) Any acquisition by the Company or by any affiliate (as defined in Rule 405 under the Securities Act) of the Company as of November 1, 2011;

(iii) Any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company; or

(iv) Any acquisition by any corporation pursuant to a transaction which complies with clauses (i) and (ii) of subsection (b) below.

(b) Consummation of a reorganization, merger or consolidation involving the Company or its Subsidiaries or a sale or other disposition of all or substantially all of the assets of the Company and its Subsidiaries on a consolidated basis (a "Business Combination") unless, following such Business Combination:

(i) All or substantially all of the individuals and entities who were the beneficial owners, respectively, of the outstanding Shares immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the then outstanding voting securities entitled to vote generally in the election of directors of the Company or its successor (including, without limitation, an entity which as a result of such transaction owns the Company or all or substantially all of the assets of the Company either directly or through one or more Subsidiaries); and

(ii) No Person (excluding any corporation resulting from such Business Combination or any employee benefit plan (or related trust) of the Company or its successor resulting from such Business Combination) beneficially owns, directly or indirectly, more than 30% of the then outstanding voting securities of the Company or corporation (including, without limitation, an entity which as a result of such transaction owns the Company or all or substantially all of the assets of the Company either directly or through one or more Subsidiaries) except to the extent that such ownership existed prior to the Business Combination.

(c) Notwithstanding paragraphs (a) or (b) above, with respect to Restricted Stock Units that constitute "non-qualified deferred compensation" within the contemplation of Section 409A of the Code and that are granted to Participants who are subject to U.S. income tax, a transaction described in paragraphs (a) or (b) above shall constitute a "Change of Control" for purposes of the distribution or settlement of such Restricted Stock Units only to the extent it also qualifies as a "change of control event" within the meaning of Section 409A of the Code.

Adopted: September 27, 2012

Exhibit 4.15

AMENDMENT NO. 1

GIVEN IMAGING LTD.
AMENDED AND RESTATED 2009 EQUITY INCENTIVE PLAN

WHEREAS, Given Imaging Ltd. (the "Company") sponsors the Given Imaging Ltd. Amended and Restated 2009 Equity Incentive Plan (the "Plan");

WHEREAS, the Company desires to amend the Plan.

NOW, THEREFORE, pursuant to the power reserved to it in Section 11.1 of the Plan, the Company hereby amends the Plan as follows:

1. Section 2.9 of the Plan is hereby deleted and the following substituted therefor:

2.9 "Change of Control" shall mean, unless otherwise defined in an Award Agreement, the occurrence of an event described in paragraph (a) or (b), or (c) below:

(a) The acquisition by any Person of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of more than 30% of the then outstanding Shares; provided, however, that for purposes of this subsection (a), the following acquisitions shall not constitute a change of control:

(i) Any acquisition directly from the Company;

(ii) Any acquisition by the Company or by any affiliate (as defined in Rule 405 under the Securities Act) of the Company as of July 2, 2009;

(iii) Any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company; or

(iv) Any acquisition by any corporation pursuant to a transaction which complies with clauses (i) and (ii) of subsection (b) below.

(b) Consummation of a reorganization, merger or consolidation involving the Company or its Subsidiaries or a sale or other disposition of all or substantially all of the assets of the Company and its Subsidiaries on a consolidated basis (a "Business Combination") unless, following such Business Combination:

(i) All or substantially all of the individuals and entities who were the beneficial owners, respectively, of the outstanding Shares immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the then outstanding voting securities entitled to vote generally in the election of directors of the Company or its successor (including, without limitation, an entity which as a result of such transaction owns the Company or all or substantially all of the assets of the Company either directly or through one or more Subsidiaries); and

(ii) No Person (excluding any corporation resulting from such Business Combination or any employee benefit plan (or related trust) of the Company or its successor resulting from such Business Combination) beneficially owns, directly or indirectly, more than 30% of the then outstanding voting securities of the Company or corporation (including, without limitation, an entity which as a result of such transaction owns the Company or all or substantially all of the assets of the Company either directly or through one or more Subsidiaries) except to the extent that such ownership existed prior to the Business Combination.

(c) Notwithstanding paragraphs (a) or (b) above, with respect to Restricted Stock Units that constitute "non-qualified deferred compensation" within the contemplation of Section 409A of the Code and that are granted to Participants who are subject to U.S. income tax, a transaction described above shall constitute a "Change of Control" for purposes of the distribution or settlement of such Restricted Stock Units to the extent it also qualifies as a "change of control event" within the meaning of Section 409A of the Code.

Adopted: September 27, 2012

Exhibit 12.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER UNDER SECTION 302 OF THE SARBANES-OXLEY ACT

I, Nachum Shamir, certify that:

1. I have reviewed this annual report on Form 20-F of Given Imaging 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 officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting;

5. The company's other certifying officers 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 7, 2013

/s/ Nachum Shamir
Nachum Shamir
President and Chief Executive Officer

Exhibit 12.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER UNDER SECTION 302 OF THE SARBANES-OXLEY ACT

I, Yuval Yanai, certify that:

1. I have reviewed this annual report on Form 20-F of Given Imaging 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 officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting;

5. The company's other certifying officers 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 7, 2013

/s/ Yuval Yanai
Yuval Yanai
Chief Financial Officer

Exhibit 13.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER UNDER SECTION 906 OF THE
SARBANES-OXLEY ACT

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Given Imaging Ltd. (the "Company") hereby certifies, to such officer's knowledge, that:

(i) the accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2012 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Dated: March 7, 2013

/s/ Nachum Shamir
Nachum Shamir
President and Chief Executive Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 13.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER UNDER SECTION 906 OF THE
SARBANES-OXLEY ACT

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Given Imaging Ltd. (the "Company") hereby certifies, to such officer's knowledge, that:

(i) the accompanying Annual Report on Form 20-F of the Company for the year ended December 31, 2012 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Dated: March 7, 2013

/s/ Yuval Yanai
Yuval Yanai
Chief Financial Officer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors
Given Imaging Ltd:

We consent to the incorporation by reference in the registration statements (Nos. 333-145474, 333-134739, 333-118473, 333-107630, 333-73732 and 333-161506) on Form S-8 of Given Imaging Ltd. (the "Company") of our reports dated March 7, 2013, with respect to the consolidated balance sheets of the Company as of December 31, 2012 and 2011, and the related consolidated statements of income and comprehensive income, changes in equity and cash flows for each of the years in the three-year period ended December 31, 2012 and the effectiveness of internal control over financial reporting as of December 31, 2012, which reports appear in the December 31, 2012 annual report on Form 20-F of the Company.

Somekh Chaikin
Certified Public Accountants (Israel)
Member firm of KPMG International

Haifa, Israel
March 7, 2013