

10-013 January 2017

Udi Aharoni Erez Cohn Orion Avidan

Given Imaging: The Quest for a Quantum Leap

" and they shall beat their swords into plowshares, and their spears into pruning hooks..."

Book of Isaiah, Chapter II, Verse IV

Introduction and the Main Dilemma

During the 1990s Rafael, a major Israeli defense company specializing in technological development, looked for ways to leverage military technology for civilian use. Several companies were set up as a result of this effort, all of them based on the ideas and knowledge of Rafael's scientists. One of these companies, incorporated in 1998, was named Given Imaging, and it captured the imagination of many people with its product. The technology, once used for military defense, has now found a new purpose in medical diagnosis. It was scaled down from a heavy duty system mounted on airplanes and used to visualize items many kilometers away, to a miniature visualization system for the human body, encapsulated in a standard size pill even a ten year old child can swallow, used to visualize an item from within.

Given has become the world's technological pioneer and leader of the capsule endoscopy field, a subset of the gastrointestinal (GI) tract market. In the US alone the GI tract device supplier market is valued at approximately \$1.2 bn in 2007 and is expected to grow to \$1.6 bn by 2011. Given develops, manufactures and markets innovative GI tract diagnostic systems based on capsule endoscopes.

The capsule endoscope is a capsule roughly the size of a vitamin pill that contains a miniature camera, a light source, batteries, an RF transmitter and an antenna. This system was the first to allow full access to the small bowel and it represents a significant increase in patient comfort.

Udi Aharoni from the Faculty of Management, The Eli Hurvitz Institute for Strategic Management, prepared this case with the assistance of Erez Cohn and Orion Avidan as the basis for a case competition.

The case does not intend to illustrate effective or ineffective handling or business processes or decisions.

©2008 Tel Aviv University, Faculty of Management, The Leon Recanati School of Business Administration.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means—electronic, mechanical, photocopying, recording or otherwise without written permission from the Coller School of Management, Tel Aviv University.

Given is based in Yokneam, in the north of Israel, where it has a production site and carries out the majority of its R&D effort. As of December 31, 2007, the company and its subsidiaries employed 458 employees of whom 232 are based in Israel, 150 in the US, 50 in Europe, 13 in Japan and 13 in Asia-Pacific. Given's revenues were \$95,029 thousand in 2006 and \$112,868 thousand in 2007. Given has been trading on the NASDAQ exchange (GIVN) since 2001, and at the end of 2007 had a market capitalization of \$680 m.

While the company has experienced substantial growth over the last few years, there is a clear need for a breakthrough. Given's goals are to reach sales of \$300 m-\$350 m by 2012 with an operating profit above 10%, while facing growing competition and new entrants into the industry.²

The company plans to use its positioning as a market leader in the GI medical devices market to make the transition from an R&D orientation, to a mass market one, through organic growth. This will create significant value for the shareholders in the coming years and will position Given Imaging as a leading global Israeli company.

The GI Tract (Exhibit 1)

The human body receives essential nutrients and water through the digestion of food which takes place throughout the GI tract. The principal organs in the GI tract are the mouth, esophagus, stomach, small bowel and colon. Essential for survival, the digestive process uses 25%-30% of the blood's volume continually. Digestion starts in the mouth when food is chewed. Food is then pushed down the esophagus, a tube approximately 25 centimeters long, that connects the throat and the stomach. In the stomach, a sac-like organ, food is broken down by enzymes. The stomach passes its content to the small bowel in controlled amounts. The small bowel, a hollow organ approximately 6.5 meters long, is primarily responsible for absorption of food components. It is divided to three areas—the upper third is called duodenum, the middle section is the jejunum and the lower third is called ileum. What remains at the end of the small bowel is passed to the colon for water absorption and waste extraction.

Approximately 70 million³ Americans suffer from digestive and gastrointestinal conditions and diseases each year. The GI tract, a complex system of vital importance to the body, is susceptible to various disorders from annoying heartburn to life threatening bleeding and cancer. Colorectal cancer, a cancer of the colon, is the most common cause of death associated with GI diseases. It was recently estimated that every year about 150,000 Americans are diagnosed with colorectal cancer and approximately 55,000 die from it annually. About 90% of deaths can be prevented by early screening. In Europe these figures are higher and it is estimated that 400,000 people are diagnosed each year, and over 200,000 die of it. Other colonic disorders, including inflammatory bowel diseases such as ulcerative colitis and Crohn's colitis, diverticulosis and lower gastrointestinal hemorrhage also cause many deaths.

The small bowel is another major source of GI tract ailment. Approximately 19 million Americans suffer from numerous disorders of the small bowel, including bleeding, Crohn's disease, celiac disease, chronic diarrhea, irritable bowel syndrome and small bowel cancer. The esophagus is not as susceptible to diseases and relatively few conditions affect it. Still, there are approximately nine million physician office visits in the US each year diagnosing GERD, a reflux disorder of the esophagus. It is estimated that approximately 10%-15% of patients with GERD symptoms have Barrett's esophagus⁵, a pre-cancerous condition.

The mortality from most GI tract conditions can be greatly reduced with early detection since modern medicine has a plethora of prevention and early treatment techniques. Screening capabilities for major conditions do exist yet most cases are diagnosed too late. Late diagnosis is due to both the nature of the conditions which are hard to diagnose, and patients' low compliance, since traditional screening tests are highly uncomfortable. Colorectal cancer is a typical example. US⁶ guidelines, as well as many other health care institutions worldwide recommend that any person, regardless of gender, over the age of 50 undergo a screening test called colonoscopy every ten years, as should anyone with risk factors. These guidelines call for approximately 12.5 million people to be screened annually; yet patient compliance is only around 50%. Compliance rates in Europe are believed to be even lower, estimated at 25% in Western Europe and as low as 10% in Eastern Europe (Exhibit 2). The awareness and investment in GI diagnostics is closely correlated to a country's overall economic wealth and expenditure on health (Exhibit 22).

Gastroenterology is considered a conservative field of specialization requiring extensive knowledge and experience, with relatively few medical students specializing in it. Practicing gastroenterologists have gained significant hands-on experience in all aspects of their specialization, including the use of the different diagnostic devices. Diagnosis and treatment are done in hospitals, either in an outpatient hospital setting, or during regular hospitalization, and in the private clinics of gastroenterologists who possess the relevant equipment.

Traditional diagnostics

Diagnosis of the GI tract is based, in many cases, on allowing the gastroenterologist to view the actual situation inside the relevant section of the GI tract. With the advancement of technology in the 20th century this has been achieved with reduced invasiveness. Nowadays the traditional and common methods for detection of gastrointestinal disorders, including disorders of the small bowel, are endoscopy and radiological imaging.

Endoscopy is the preferred diagnostic method. A traditional endoscope is a device consisting of a flexible tube and an optical system (Exhibit 3). It can perform both diagnostic and limited treatment functions. It is inserted through the mouth for upper endoscopy (for the esophagus, stomach and duodenum), or through the anus for colonoscopy (colon and ileum). The traditional endoscopic procedures can not reach the entire small bowel. This has led to the development of a modified endoscope, the "double balloon endoscope", which allows the gastroenterologist a view of the entire small bowel. This new procedure is even more uncomfortable for the patient and requires high skill and experience from the physician.

Traditional endoscopy is a very time consuming and uncomfortable semi-invasive procedure for the patient, requiring preparation such as fasting and enema, as well as sedation. It has side effects and involves potential complications. There is a significant difference in the timing and preparation between upper and lower endoscopy. Usually, upper endoscopy is a quick procedure, lasting no more than 10-15 minutes, and involves a low level of sedation, seven hours of fasting, and few hours of recovery. Lower endoscopy, i.e., colonoscopy, is a longer procedure. Preparation procedures require more than 12 hours (including cleansing liquids to clean the colon), fasting is longer, sedation is deeper, and therefore recovery is much longer.

This procedure also allows the physician to control the movement of the endoscope through the gastrointestinal tract, to stop the endoscope and more closely examine a particular area in the gastrointestinal tract, and to take a tissue sample or seal a bleeding site using the endoscope.

An alternative to endoscopy is radiological imaging. In this procedure the physician can't perform minor surgical activities, such as obtaining tissue samples or sealing bleeding sites. During a radiological imaging examination, the patient swallows a contrast medium (such as barium), which is a dense liquid that coats the internal organs and makes them appear on x-ray film. While this procedure doesn't provide clear or detailed visualization, it is uncomfortable (barium has an unpleasant chalky taste), can induce vomiting and can result in blockage that is associated with morbidity in elderly patients. It also increases the risk of exposure to ionizing radiation.

These diagnostic tests disrupt the patient's routine as they require time for preparation, execution and recovery that is significantly longer that a regular doctor's visit or laboratory test.

Reimbursement method (Exhibit 4)

Once a patient is suspected of having a GI disorder, a diagnosis is required. The physician or hospital will define the diagnostic procedure so that they are assured that all expenses will be covered and profit can be made. Medical procedures are usually covered by local government or through different methods of heath or medical insurance, and sometimes are paid for privately by the patient. Third-party payers reimburse the physician or the hospital for their time and the technical expenses incurred. The reimbursement rate is set by the third-party payer and there may be differences in coverage of procedures, patient qualification and rates between payers.

There are several models of private, public and state owned health insurance. Different models can be operated in parallel at one place, and there are instances where neighboring provinces have opposite systems. To illustrate this variance, in the US there are around 80 third-party payers, both private insurers and state owned Medicare and Medicaid insurers. In France, Japan, Australia and other countries around the world, the health system is based on extensive coverage by the state. In Israel, health management organizations, which are the main third-party payers, are subject to extensive reimbursement regulations set by the government. Other private insurers exist and sell private extensions to improve coverage.

The legal environment

Just like medicines, medical devices are strictly regulated by different agencies around the world, the main reason being the need to protect patients as some devices can be harmful. Some regulation processes require proof of safety (proof that the device is safe), and efficacy (proof that the device is as effective as a comparable device). Only devices that have been approved through these processes can be marketed in the geographical jurisdiction of the authorizing body. Therefore, medical device manufacturers need to survive long, rigorous and expensive processes of testing and regulation in order to get products to the market. Once the technology is ready the product goes into clinical trials to prove its safety and efficacy. These studies are time consuming and expensive. In the EU and US the average cost of a participant in a medical device clinical study is \$1000-\$2,000, and a study will have 60-100 participants (compared to \$2,500-\$3000 per participant, and over a thousand participants in medicine trials). In Japan studies cost much more and can reach \$10,000 per participant for medicine trials. The trials are indication specific and need to be repeated with many changes and upgrades to the product. When enough data has been collected applications can be made to the relevant agencies to clear the product for marketing. The major approval processes are FDA clearance in the US and the CE mark in the EU. These processes are independent of each other and have a major influence on the approval processes in other locations. Around

the world the legal requirements vary from country to country. Australia will approve any device which carries either FDA approval or CE mark; Japan prefers devices that have both.

In order to obtain the CE mark the company must prove that the device is in compliance with ISO 13485 definitions—regulatory regulation for medical devices. The company files claims that are backed by research showing expectable risk factors and similarity to existing devices. Approval is granted within days. Obtaining FDA approval for class two devices (not life-critical) is often done through the 510(K) process, in which the device is compared to a "predicate device". The process costs \$3,000 and the submission review takes 90 days. It can take another 90 days to resolve any questions that arise from the review. Obtaining PMDA (the Japanese equivalent to the FDA) approval takes about one year, and if further answers regarding the product are needed, it can take an additional six months. In some cases it can even take as long as two to three years before PMDA approval is granted.

The device manufacturer can market the device only for such indications that have been approved. Physicians and third-party payers can expand the usage and coverage of the device to other indications as they see fit.

Going to market

Regulatory approval is a legal barrier to entering a market. Once obtained, the device can be sold in the relevant market. At this point devices that are new to the market start penetration and market development. First, physicians must learn of the device and start using it. Then third-party payers need to be convinced to add the device to their approved procedures. This is done through more clinical trials which are then published in peer-reviewed publications and through standard marketing processes such as trade shows and conferences, training, medical representative work, lobbying and more.

The success of novel devices depends in large part on convincing physicians to replace the existing technology with the newer one. This is done with the help of key opinion leaders, usually renowned experts that have led the early clinical trials. These experts report their positive findings and opinions in peer-reviewed journals, conferences and trade shows which encourage early adopters to learn about the device. In gastroenterology, a conservative field of medicine where physicians are often satisfied with existing devices, this is a very long process. Gastroenterologists will only accept devices that make their life easier, significantly improve their diagnostic ability and are sure to have a positive impact on income. Decisions on which device to use are at the physician's discretion, and patients' preferences are a secondary consideration. Approaching the patients with data about new and singular devices in an effort to influence physicians' decision making is considered a very risky tactic that can backfire with physicians boycotting the device.

The time it takes to get third-party payers to include a device in their reimbursement plan varies greatly between countries and in some cases between regions within a country. For example, in the US a major step to getting third-party reimbursement is getting a Current Procedural Terminology (CPT) code which facilitates claims for reimbursement. This process can be lengthy, typically taking at least two years before the new code is effective. While the process is long it is not always necessary to wait for the full reimbursement process before physicians start using the device, as there are general and temporary codes. In other places, France and Japan as examples, there are no shortcuts and reimbursement becomes available only at the end of the process.

Given Imaging

Historical Background

Dr. Gabi (Gavriel) Iddan, a scientist from Rafael's missiles division, conceived the idea for capsule endoscopy. Dr. Iddan proved the model using a chicken from a retail store for the tests. In 1997 a patent request for the technology was awarded. The idea was commercialized with the assistance of Rafael Development Corporation (RDC), which appointed Gavriel Meron to research business prospects for it. Mr. Meron, who became the first CEO, concluded it was commercially viable, noting that given the choice between a pill and an endoscope, the preference would be obvious. In January 1998, Given Imaging Ltd. was incorporated.

Given's first development was aimed at the small bowel, since it was the part of the GI tract that traditional endoscopy could not serve well. The first product, PillCam SB was awarded CE approval in May 2001, and FDA approval in August 2001. It was followed by products for other parts of the GI tract. The system is currently available worldwide, marketed in the US, EU, Australia, Japan, Israel and in more than 60 other countries. Over 750,000 people suffering from various small bowel disorders have been diagnosed using the PillCam SB. Today, Given's portfolio of PillCam capsules covers the esophagus, small bowel and the colon. Given sells a complete solution that includes software and hardware for the proprietary workstation and data recorders, and a patency pill, a dissolving pill used to ensure there is safe passage for the PillCam SB.

Technology (Exhibits 5,6,7,8)

Given's principal product is the Given System, a proprietary wireless imaging system that uses the disposable video capsule, referred to as the PillCam capsule, a portable data recorder and a workstation with the proprietary RAPID software.

The PillCam capsule contains a miniaturized disposable color video camera, light-emitting diodes, batteries, transmitter and an antenna, all encased in a plastic shell. After the patient ingests the capsule with a small amount of water, the capsule passes naturally through the gastrointestinal tract, without discomfort, while wirelessly transmitting to the portable recorder, enabling the gastroenterologist to view high quality video images and data on the workstation. The friendly and painless procedure is usually administered on an outpatient basis and requires only a brief visit to the clinic. The PillCam capsules are excreted naturally from the body, usually within less than a day, without pain or discomfort.

The PillCam SB capsule can provide images of the entire small bowel, produces higher diagnostic rates and appears to be cost effective from a third-party payer point of view. During the recording process, which lasts around eight hours, the patient can go on with daily activities, while wearing a belt with a data recorder. Most of the small bowel indications relevant for the PillCam SB are covered by governmental and commercial reimbursement policies in the US, Australia, many EU countries and Japan. Several reimbursement policies cover small bowel capsule endoscopy as a primary diagnostic tool. PillCam SB2, an improved version of PillCam SB, has been approved for marketing in all major locations except Japan.

The PillCam ESO capsule, used for visualization of the esophageal mucosa, has a 15-minute recording process. It is currently used primarily for esophageal varices, which is not a prevalent condition in the general population. A significant increase in sales is expected if and when there is clinical data and reimbursement coverage to support and cover the use of this capsule for GERD patients.

PillCam Colon capsule is the latest addition to the portfolio. It has received the CE mark but did not get FDA approval through the 510(K) procedure, as it was not proved to be compatible enough with the specific procedure it was compared to. An additional process is required by the company to obtain FDA approval for the PillCam Colon in order to market it in the US. Small scale sales are expected until enough clinical data is published. Given expects that the large potential of this product will come from colorectal cancer screening.

PillCam SB and PillCam ESO technologies appear mature with opportunities for incremental improvements. PillCam Colon capsule is still quite new and shows opportunities for technological breakthroughs.

All PillCam capsules work with the same data recorder and workstation. The patient wears a belt with the data recorder during the test and returns it to the clinic after the examination is finished. In the clinic the data recorder is connected to the workstation that downloads the captured images. One workstation can support many data recorders so that a single workstation is usually sufficient even when there is high demand. Once the images are stored in the workstation the physician has to analyze them and reach a prognosis. With the assistance of the Given System, a trained physician can complete analyzing the video in less than 30 minutes for a small bowel scan. The Given workstations use proprietary software, called RAPID, which supports the physician's understanding of the resulting video. The software helps the physician locate the part of the GI tract being viewed and shortens viewing time by highlighting suspicious spots and using multi-frame viewing, and by using a bank of thousands of clinical images called RAPID Atlas in the diagnostics.

In addition, the company developed the AGILE Patency capsule which is a dissolvable capsule that enables the physician to determine whether there are obstructions or strictures in the gastrointestinal tract that may prevent the safe passage of the PillCam SB capsule. This capsule is mainly used to clear high risk patients for the use of the PillCam SB.

Manufacturing

PillCam capsule manufacturing is subject to the quality and safety regulations of medication as well as those of medical devices. Medication regulations require a clean and sterile environment, while the electrical and RF components require an anti-static environment. Both medication and medical device regulations require extensive documentation and tracking. The PillCam capsule assembly line is located at Given's headquarters in Yokneam. The assembly is done in a sterile, anti-static clean room in which special protective gear is worn at all times and only approved personnel can enter. This environment is constantly monitored by automatic controllers and the data is recorded. All this is in compliance with the different regulations of the FDA, the CE and other regulating bodies around the world. Each capsule is numbered sequentially and tracked from the assembly and testing process, through shipping and all the way to the customer. Each and every capsule goes through quality tests to ensure it is working properly.

The Given workstation and data recorder are also assembled and tested at the Yokneam facility, mainly from standard computer equipment which is then equipped with the proprietary software. This is done in a regular computer laboratory environment and is documented to comply with FDA, CE and other regulatory controls.

As of December 31, 2007 Given employed 232 employees in Israel, mostly in R&D, clinical affairs and manufacturing.

Marketing & Distribution (Exhibits 9,10,11)

Markets and customers

The Given System is sold to hospitals, out-patient clinics and private clinics all over the world in a razor and razor blade model. The first sale involves the capital equipment, the workstation and the RAPID software, as well as a data recorder and at least 10 PillCam capsules. By the end of 2007 Given has a significant install base of 4,250 systems placed worldwide. Subsequent sales are for repeat purchases of PillCam capsules and sometimes include sales of data recorders to improve workstation utilization.

The sales and marketing operations are organized in three geographical regions with separate subsidiaries: Americas (US, Canada, Latin America), EMEA (Europe, Middle East, Africa) and Asia-Pacific. Given has two kinds of marketing and sales efforts: direct sales by Given employed sales representatives in its major markets, and distributors and representatives elsewhere. Sales to the major markets (Australia, France, Germany, the US and Israel), managed directly by Given through fully owned subsidiaries, accounted for 78.2% of 2007 revenues. The US is the biggest direct market both in terms of sales and in terms of sales force. Around 70 salespeople, 80% of Given's direct sales force, work in the US. In Japan, also a major market, Given sells its products through an exclusive domestic distributor. As of December 31, 2007, this distributor held 15% of Given's Japanese subsidiary.

In mature markets that are familiar with the company's products, such as the US, Europe and Australia, the marketing strategy focuses on increasing the utilization of PillCam capsules by each account and consequently increasing reorder of capsules. In new markets, such as Japan, the initial focus is on driving the placement of Given Systems in order to expand market penetration in gastroenterology physician offices and gastroenterology departments within hospitals. At the same time market development activities, such as clinical trials, working with payers to obtain appropriate reimbursement and educational activities, take place.

Given is a relatively small company in a market of big players, which have larger financial resources, sales forces and networks of connections. In addition to this, hospital buyers tend to prefer large suppliers with a full product spectrum, since larger orders enjoy better discounts. Private clinics buy small volume, in comparison, but tend to prefer larger suppliers as these are sometimes considered to have less logistic and administrative procedures.

Direct and indirect competition (Exhibits 12,13,14)

Capsule endoscopy entered the market as a secondary small bowel diagnosis tool targeting areas traditional endoscopes had difficulty coping with.

Several companies control the major share of the traditional gastrointestinal endoscopy market worldwide—Olympus, Hoya, Fujinon and Boston Scientific. These companies have marketed and sold flexible endoscopic equipment for many years; they have substantial financial resources, an established reputation and worldwide distribution channels for medical instruments to gastroenterologists. There are R&D efforts by these companies and others, to develop and bring to market imaging capsules or other minimally invasive imaging techniques.

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, Toshiba Corporation and Shimadzu Corporation.

Following the successful market penetration of the PillCam SB capsule endoscope, other players have entered the market for small bowel capsule endoscopy. The major competitor is Olympus Medical Systems from Japan. Olympus has a long history as a leader in the endoscopy market. It specializes in major capital equipment sales to hospitals. These sales are characterized by long sale cycles, big and complicated contracts, high financial value, and little, if any, repeated sales of consumables. Olympus has been marketing and selling a capsule endoscopy system for the small bowel, Endo Capsule endoscope, in Europe and Australia since October 2005. In September 2007, it received FDA clearance to market its capsule endoscopy system in the US. Olympus is also seeking regulatory clearance to market its capsule endoscopy system in Japan.

The two other competitors in the market are small companies: IntroMedic, a South Korean company, introduced the MiroCam capsule endoscopy system, and Chongqing Jinshan Science & Technology, a Chinese company, introduced the Omom capsule endoscopy system. IntroMedic began selling the MiroCam system in Korea, Europe and Australia in 2007. This system is priced below the Given's system and in many cases the capital equipment is not paid for but rather is placed with the customer for appraisal. The Omom System is sold in China as a low cost alternative to the Given System. This system has been presented at industry trade shows outside of China.

The effect of competition from Olympus and other possible direct competitors is uncertain. On the one hand, it may lead to loss of market share, price competition and delays in completing sales as a result of a longer decision making process. On the other hand, the entry of Olympus into the capsule endoscopy market validates the market opportunity for the PillCam platform and may result in greater market acceptance of the PillCam products, due to the advantages they have over competing products.

Capsule Endoscopy Reimbursements (Exhibits 15,16)

PillCam procedures were the first capsule endoscopy procedures approved in the world, and as such did not have any third-party payment procedures in place. Over the years Given has worked with the different payers around the world and has slowly gained ground. PillCam SB, the first capsule endoscope introduced was first approved as a secondary or third diagnostic tool. This means that it was approved for use only after an endoscopy (upper, lower, or both) did not produce enough data to allow diagnosis. Over the years the clinical data and the experience accumulated have started a shift towards capsule endoscopy as a primary diagnostic tool. This means that more third-party payers are now willing to pay for a capsule endoscopy as the first diagnostic test done. Currently in the US general coverage has been expanded to most indications, barring new ones, and around 30 million US citizens are covered for PillCam SB as a primary diagnostic tool. As of October 2007, all the adult population of Japan is covered for PillCam SB capsule endoscopy.

IP and the Hitchhiker Dilemma

Being the first to introduce capsule endoscopy technology and products into the market, Given had the first mover advantage. However, it also had to incur significant costs and risks that were involved in market penetration, such as clinical studies, conferences, supporting articles, physician recruitment and so on. Since capsule endoscopy represents a complete change in the way endoscopies are performed, the entire market needed to be educated. Regulation bodies had to define the correct approval process. Physicians had to learn of uses, techniques, indications and procedures, and had to define their needs from the product so that it could be improved accordingly. Third-party payers had to learn of the benefits of the procedures and how they rank, with regard to cost, in comparison to existing procedures. This was achieved through clinical trials, supporting publications, conferences and training. The Given System is supported by many clinical trials, a vast amount of publications, its own conference and training programs, and much more besides.

Competition coming into this market needs to invest much less in order to reach similar results. As soon as a competitor proves that its device is similar to the Given System and the relevant PillCam capsule in the relevant parameters, it can move forward. By doing so the competition benefits from Given's investments, such as the approval of capsule endoscopy as a first line diagnostic procedure, without incurring similar costs.

Given is to a certain degree protected by its installed base and by the intellectual property of 91 issued patents and 500 pending patents globally. However, arguably, patents provide a more effective protection against smaller competitors who do not have the financial resources to undergo lengthy and expensive legal disputes.

Given's Competitive Advantage

Given is a technological leader in the GI tract diagnostics market. As the pioneer of capsule endoscopy it enjoys the first mover's advantage through the volume of clinical data gathered using its system, the installed base of users and the professionals loyal to its brand. Given is ahead of the competition in portfolio development, since it has already brought to market an esophagus capsule and a colon capsule, thus providing physicians with a complete solution, which is further enhanced by the AGILE patency pill. Having been in actual use, the Given System also has far more developed supporting algorithms which means physicians' reading time is significantly reduced compared to other systems.

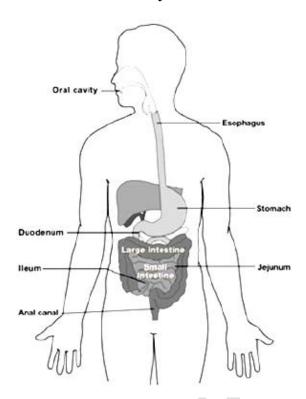
The Next Step—Crossing the Chasm

As 2008 begins, Given is at a crossroads, facing both great prospects and great threats. All of its products seem to be gaining momentum as good clinical trial results lead to better market penetration. PillCam SB is gaining ground as a primary diagnostic tool in the US, gaining market share in Japan and is heading for the final approval of reimbursement in France. PillCam ESO is gaining ground with physicians in preparation for the GERD indication approval. PillCam Colon, while still not a significant contributor, seems to have the largest potential market of the three. Yet Given is still a small company playing in a high risk field among such giants as Boston Scientific and Olympus. New capsule endoscopy systems launched in recent years are moving aggressively into Given's major markets. New technological developments are announced regularly, promising to bring to the market within years new and improved capsule endoscopy capabilities. There is so much to do and the resources are limited.

Having proven the technology in the market, Given is no longer considered a startup. However, in order to survive and prosper it must grow and grow fast. The time has come to define what will be the growth engines for the company in the coming years and the means to achieve these goals.

Appendices

Exhibit 1: GI in Human Body



Source: Company data

Exhibit 2: Colon Cancer Screening

Country	All	Unscreened	Screened
US ¹	90	45M	45M
U.S	90	(50%)	(50%)
Germany ²	30M	23M	7M
Germany	30101	(75%)	(25%)
France ²	20M	11M	9M
Trance	201 VI	(55%)	(45%)
Japan ²	50M	26M	25M
Japan	30101	(52%)	(48%)

1 American Cancer Society

2 Company estimates

Exhibit 3: Traditional Endoscopy



Exhibit 4: Reimbursement for Small Bowel Capsule Endoscope 2007, estimate

No. of People Covered (Millions)
169.0
40.0
209.0
58.0
42.0
10.0
8.8
8.4
8.0
7.5
7.0
5.4
4.3
159.0
7.0
105
19.3
~500

Exhibit 5: The PillCam Platform









Exhibit 6: PillCam SB

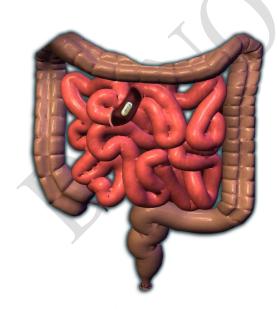
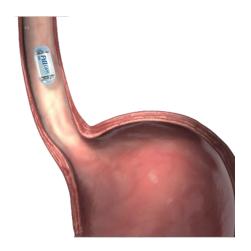


Exhibit 7: PillCam ESO



Source: Company Data

Exhibit 8: PillCam COLON



Exhibit 9: Given Revenue Breakdown, in thousands of \$US

Product	Year		% of annual revenues			
	2005	2006	2007	2005	2006	2007
Workstations and data recorders	17,831	14,104	15,267	20.5	14.8	13.5
PillCam SB capsule	62,528	76,360	90,614	72.1	80.4	80.3
PillCam COLON capsule	N/A	N/A	1,106	N/A	N/A	1.0
PillCam ESO capsule	4,384	1,438	1,012	5.1	1.5	0.9
Patency system and capsule	174	353	523	0.2	0.4	0.4
Service	1,859	2,774	4,346	2.1	2.9	3.9
Total	\$86,776	\$95,029	\$112,868	100%	100%	100%

Exhibit 10: Total Number of Sold Given PillCam SB

	2005	2006	2007
Total number of PillCam SB capsules sold	134,500	165,100	191,800
US	100,000	123,600	139,900
EMEA		32,500	39,800
APAC		9,000	12,100
ROW	34,500		
Number of PillCam SB capsule sales representing customer reorders	128,760	155,840	177,000
% of revenues from capsule sales that represent customer reorders	95%	94.4%	92.3%

Source: company data

Exhibit 11: Given Sales—Geographical Breakdown

7	2005	2006	2007
Americas	75%	71%	66%
EMEA	19%	23%	24%
APAC	6%	6%	10%
Total	100%	100%	100%

Exhibit 12: Leading competitors in the GI Market, US, 2006

Company	Estimated Market
	Share%
Boston Scientific	32.7
Olympus	25.3
Wilson Cook	9.7
Pentax	8.0
Given Imaging	6.4
CONMED	5.5
Others	12.4
Total	100.0

Exhibit 13: Main Competitors in GI Market

Boston Scientific

Boston Scientific is the world's largest medical device company dedicated to less-invasive medicine. Boston Scientific's mission is to improve the quality of patient care and the productivity of health care delivery through the development and advocacy of less-invasive medical devices and procedures. With more than 25,000 employees, \$8.35 bn sales (2007), and 26 manufacturing, distribution & technology centers around the world, the company delivers over 13,000 products in more than 45 countries. According to company figures Boston Scientific had invested nearly \$6 bn in new technologies over the past five years, and enrols tens of thousands of patients in pre- and post-approval clinical studies.

Boston Scientific engages in the development, manufacture, and marketing of medical devices that are used in various interventional medical specialties worldwide. The company offers its products in three groups: Cardiovascular, Endosurgery, and Neuromodulation. The Endosurgery group includes esophageal, gastric, and duodenal intervention products; colorectal, pancreatico-biliary, and pulmonary intervention devices; and products for urinary tract intervention and bladder disease, prostate intervention, pelvic floor reconstruction and urinary incontinence, genecology, and oncology. Within the GI field Boston Scientific is the largest company, holding almost 33% of the estimated market, and is also a market leader in many fields such as biopsy devices, ERCP devices, hemostasis, esophageal dilation balloons, GI stents and polypectomy snares. Boston's products do not compete with Given directly.

Olympus

Olympus Corporation, headquartered in Tokyo, Japan, develops and manufactures products based on optical and electronic technology for the consumer, scientific, healthcare and industrial markets. The company's medical devices cover endoscopy, minimally-invasive

surgery and biomaterials. Olympus, established in 1919, currently operates within five divisions; Medical Systems, Imaging Systems, Life Science, Information & Communication and Other, which includes its biomaterials operations.

The main focus of this profile is Olympus Medical Systems, its largest operating division accounting for 29% of the company's \$10 bn revenue in fiscal 2007. The division is a leading manufacturer of gastrointestinal and surgical endoscopes, endotherapy products, endoscopic ultrasound systems and related products. Products are organised within two areas: gastrointestinal endoscopes and minimally-invasive products, with the latter mainly comprising surgical endoscopy products and endotherapy devices.

Gastrointestinal endoscopes are Olympus Medical Systems' largest product area, accounting for 69% of its total revenue in fiscal 2007. The company is the global market leader for these products, claiming to hold over 70% of the global market. This product line includes endoscopic video imaging systems, fiberscope systems, bronchoendoscopes, endoscopic ultrasound systems, ultrasound probes, ultrasound-guided needle puncture systems, cleaning, disinfecting and sterilisation systems, medical treatment peripherals and ancillary products. Olympus has made several key product introductions in this area over the past year, including endoscopes designed to enhance image quality and enable the visualisation of smaller details. In addition Olympus has been marketing and selling a capsule endoscopy system in Europe and Australia since October 2005. In the US Olympus launched its Endo Capsule endoscope, following FDA clearance for the small bowel in September 2007, making it the second such product available in this market. It is also seeking regulatory clearance to market its system in Japan.

Cook Group Incorporated

The company, one of the world's largest privately held medical device firms, was founded by Chairman William Cook in 1963. This US based group holds almost 10% of the GI devices' worldwide market. The Cook group includes medical device manufacturing companies that produce various products. The company's flagship subsidiary, Cook Incorporated, makes catheters, wire guides, stents, and other devices used in minimally invasive cardiac procedures. Cook Group operates a host of other medical manufacturing subsidiaries that make urological and gynecological devices, endoscopic accessories, and vascular products. Additionally, industrial parts manufacturers Sabin and K-Tube make plastic parts used for medical and other industrial applications, and Cook Pharmica offers contract manufacturing services to the biotech industry. In addition to the medical field the Cook Group affiliates offer commercial enterprises such as transportation, travel, real estate, and retail services. The group, which employs 6,300 people, posted revenues of \$1.5 bn in 2006. Cook Group products do not compete with Given directly.

Hoya

Hoya, headquartered in Japan, was founded in 1941 as Japan's first specialty manufacturer of optical glass and since has diversified into new business areas that exploit the potential of advanced optics technologies. The company has continued to grow as a global enterprise through the expansion of its diverse business activities, which encompass electro-optics, photonics, vision care, healthcare and crystal products. Revenues at the end of 2006 totalled \$3 bn, of which around 70% originated in Japan.

Hoya acquired Pentax, a pioneering leader in the camera industry, which also makes technologically innovative digital cameras and lenses. Other products include surveying instruments, medical instruments and equipment such as endoscopes and ceramics and endoscopy products. Pentax 2007 sales were \$1.3 bn.

Fujinon

Fujinon Inc. is a wholly owned subsidiary of Fujinon Corporation of Saitama City, Japan, one of 165 global subsidiaries of the Fuji Photo Film Co., LTD (FUJIFILM), a world leader in imaging technology. Fujinon Inc. was established in Wayne, New Jersey, in 1973, as the sole distributor of high-quality lens products for the North American market. The New Jersey based organization is comprised of four divisions: Medical, TV/Broadcast Lens, Industrial, and Binocular. The Medical Division is specifically responsible for sales and service of high-resolution, cost effective integrated endoscopic solutions in North America. It is estimated that Fujinon holds 4.5% of the GI endoscopic market, equivalent to 1.4% of the total GI market.

Fujinon is currently a partner of Given following a cooperation agreement signed with Given in March 2007. Under the terms of the agreement the companies could build closer collaboration in R&D, component sourcing, marketing and product distribution world wide, except Japan. In addition Fujinon received non-exclusive distribution rights for Given products in certain countries world wide.

Exhibit 14: Direct Competitors in the PillCam Market

IntroMedic

IntroMedic, a South Korean medical engineering company, began manufacturing its MiroCam capsules at the end of 2006, claiming to have a capsule endoscope with superior image quality in comparison to the Given PillCam capsules. The MiroCam Capsule Endoscope for the small bowel received the Korean FDA approval in April 2007, clearing the way for sales of MiroCam within the Korean market. It has also obtained the CE mark and is selling its system in Australia and the EU. IntroMedic claims that the MiroCam system offers significant advantages over other endoscopes enabling physicians to perform more complete, thorough and effective diagnosis of the small bowel.

Chongqing Jinshan Science & Technology (Group) Co., Ltd.

Headquartered in Jinshan, China, established in 2006, the company manufactures two main products: a capsule endoscope and a Silicon Micro-pump. It markets a capsule endoscopy system (OMOM) in China at low prices and has presented its systems at trade shows outside of Asia. There are claims by the company that the system can examine the stomach, small intestine and large intestine by swallowing a single capsule endoscope.

Exhibit 15: PillCam Reimbursement Success

Worldwide Covered Live					
Year	2003	2004	2005	2006	2007
No. of people (millions)	206	327	347	395	495

Exhibit 16: US National Average Global Fee Paid for Capsule Endoscope

Payment Type	2007 Payment	% Change 2006 –7	2008 Planned Payment
SB in physician's office	\$955	-3.2%	\$944
SB in outpatient hospital setting	\$180 for interpretation \$583 for technical component	-4.8%	\$178 for interpretation \$607 for technical component
ESO in physician's office	\$743		\$756
ESO in outpatient hospital setting	\$53 for interpretation \$511 for technical component		\$55 for interpretation \$541 for technical component

Exhibit 17: Given Imaging Consolidated Statement of Income, thousands of \$US

	31/12/2005	31/12/2006	31/12/2007
Revenues	86,776	95,029	112,868
Cost of revenues	(22,070)	(24,154)	(29,721)
Early repayment of royalty bearing government grants			(4,843)
Gross profit	64,706	70,875	78,304
	74.6%	74.6%	69.4%
Operating expenses			
Research and development gross	(8,833)	(12,678)	(12,847)
Royalty-bearing government grants	1,244	1,867	1,242
Research and development, net	(7,589)	(10,811)	(11,605)
Sales and marketing	(43,281)	(50,732)	(55,446)
General and administrative *	(9,657)	(16,027)	(20,981)
Termination of marketing agreement			22,860
Other			(422)
Total operating expenses	(60,527)	(77,570)	(65,594)
Operating profit (loss)	4,179	(6,695)	12,710
	4.8%	n/a	11.3%
Financial income	762	3,980	5,520
Profit (loss) before taxes on income and minority share	4,941	(2,715)	18,230
	5.7%	n/a	16.2%
Income tax benefit (expense)	286	(127)	(4,548)
Profit (loss) before minority share	5,227	(2,842)	13,682
Minority share in losses of subsidiary	1,116	1,334	1,503
Net profit (loss)	6,343	(1,508)	15,185
	7.3%	n/a	13.4%

^{*} Expenses for the years 2006 and 2007 include \$1.1m and \$5.2m respectively related to company litigation with Olympus. This dispute was resolved in April 2008.

^{**} As of 1.1.2006 the company adopted FAS123R which resulted in a \$5.2m and \$5.6m expense in Y2006 and Y2007 respectively.

Exhibit 18: Given Imaging Ltd. Balanced Sheets, thousands of \$US

		31/12/2007
31/12/2005	31/12/2000	31/12/2007
65 356	44 510	37,103
	·	23,191
200	17,213	23,171
18 325	18 887	23,315
		10,385
		15,960
		190
		1,350
		1,289
· · · · · · · · · · · · · · · · · · ·		112,783
		892
		3,007
21,664	34,769	41,629
13,862	14,811	15,422
2,517	3,075	3,583
149,110	158,177	177,316
11	13	121
5,529	5,550	7,275
3,333	3,871	9,379
· ·	·	37,787
,	,	,
22,172	20.411	
		448
		3490
24.246	22.838	3,938
		41,725
17,000	10,072	11,720
61	3 499	1,996
	3,133	1,550
327	335	343
		166,819
		2,166
(49 404)	(50.917)	133 ///
(49,404) 102,044	(50,912) 107,786	(35,727) 133,595
	31/12/2005 65,356 288 18,325 6,264 16,172 332 1,219 1020 108,976 401 1,690 21,664 13,862 2,517 149,110 11 5,529 13,886 3,333 22,759 22,172 34 2,040 24,246 47,005	65,356 44,510 288 17,245 18,325 18,887 6,264 1,463 16,172 18,168 332 82 1,219 1,374 1020 1,340 108,976 103,069 401 469 1,690 1,984 21,664 34,769 13,862 14,811 2,517 3,075 149,110 158,177 11 13 5,529 5,550 13,886 14,620 3,333 3,871 22,759 24,054 22,172 20,411 34 20 2,040 2,407 24,246 22,838 47,005 46,892

Exhibit 19: Given Inventory, thousands of \$US

	2006	2007
Raw materials and components	7,721	7,733
Work in progress	3,533	2,941
Finished goods	6,914	5,286
Total	18,168	15,960

Exhibit 20: Given Intangible Assets, thousands of \$US

	2006	2007
Patents and trademarks	4,594	5,545
Web site applications	922	1,165
Intangible assets at cost	5,516	6,710
Accumulated amortization	(2,441)	(3,127)
Intangible assts, at cost, less accumulated amortization	3,075	3,583

Source: company data

Exhibit 21: Given Commitments to Israel Chief Scientist

Until December 2007, the company's research and development efforts have been partly financed through grants from the Office of the Chief Scientist of the Israeli Ministry of Industry and Trade (the "OCS"). In return for the OCS's participation the company was committed to pay royalties to the Israeli Government at the rate of 3% of the sales of its product for each of the first three years following the launch of a product and, from the fourth year, at the rate of 3.5% and up to 100% of the grant amount plus LIBOR interest. The company was entitled to the grants only upon incurring research and development expenditures. There were no future performance obligations related to the grants received from the OCS.

During December 2007, the company made an early repayment of all its outstanding royalty obligations and accrued interest of \$4,843 thousand to the OCS. This repayment resulted in a one-time charge of \$4,843 thousand presented as an early repayment of royalty bearing government grants in the company's consolidated statement of operations.

The company continues to participate in other non-royalty bearing programs of the OCS.

Exhibit 22: Population, GDP, Healthcare Exposure per Country

	Per capita total expenditure on health at average exchange rate (US\$), 2005	Per capita government expenditure on health at average exchange rate (US\$), 2005	Population (in thousands) ,2006	Population annual growth rate (%), 2006	Gross national income per capita (PPP international \$), 2006
Location Africa		(004), 2000			
Algeria	108	81	33,351	1.5	6,900
Angola	36	30	16,557	2.8	2,360
Benin	28	15	8,760	3.1	1,160
Botswana Burkina Faso	431 27	338 16	1,858 14,359	1.2	12,250 1,330
Burundi	3	1	8,173	3.9	710
Cameroon	49	14	18,175	2.1	2,370
Cape Verde	114	93	519	2.3	5,980
Central African Republic	13 22	<u>5</u>	4,265 10,468	1.7	1,280
Chad Comoros	14	8	818	3.1 2.5	1,230 2,010
Congo	31	15	3,689	2.2	270
Cote d'Ivoire	34	7	18,914	1.8	1,550
Democratic Republic of the Congo	5	2	60,644	3.2	720
Equatorial Guinea	211	166	496	2.4	10,150
Eritrea Ethiopia	<u>8</u>	4	4,692 81,021	3.6 2.5	1,090 1,190
Gabon	276	205	1,311	1.5	5,310
Gambia	15	10	1,663	2.8	1,970
Ghana	30	10	23,008	2.1	2,640
Guinea	21	2	9,181	2	2,410
Guinea-Bissau	10	3	1,646	3	830
Kenya Lesotho	24 41	11	36,553	2.6 0.7	1,300
Liberia	10	23	1,995 3,579	3.9	4,340
Madagascar	9	6	19,159	2.7	960
Malawi	19	14	13,571	2.6	720
Mali	28	14	11,968	3	1,130
Mauritania Mauritius	17	11	3,044	2.7	2,600
Mauritius Mozambique	218 14	112 9	1,252	0.8	13,510
Mozambique Namibia	14 165	108	20,971 2,047	1.3	1,220 8,110
Niger	9	5	13,737	3.5	830
Nigeria	27	8	144,720	2.4	1,050
Rwanda	19	11	9,464	2.5	1,270
Sao Tome and Principe	49	41	155	1.6	1,490
Senegal Seychelles	38 557	12 402	12,072 86	2.5 0.7	1,840 16,560
Sierra Leone	8	402	5,743	2.8	
South Africa	437	182	48,282	0.7	11,710
Swaziland	146	94	1,134	0.8	5,170
Togo	18	5	6,410	2.7	1,490
Uganda	22	6	29,899	3.2	1,490
United Republic of Tanzania Zambia	17 36	9	39,459 11,696	2.5 1.9	740 1,000
Zimbabwe	21	9	13,228	0.8	1,000
Americas					
Antigua and Barbuda	503	339	84	1.3	
Argentina	484	213	39,134	1	15,390
Bahamas Barbados	1,224 725	613 461	327 293	1.2 0.3	
Barbados Belize	198	112	282	2.2	6,650
Bolivia	71	44	9,354	1.9	2,890
Brazil	371	164	189,323	1.3	8,800
Canada	3,430	2,410	32,577	0.9	34,610
Chile	397	204	16,465	1	11,270
Colombia Costa Rica	201 327	170 248	45,558 4,399	1.4 1.6	7,620 10,770
Cuba	310	281	11,267	0.1	10,770
Dominica	288	186	68	-0.3	6,490
Dominican Republic	197	61	9,615	1.5	8,290
Ecuador	147	59	13,202	1.1	4,400
El Salvador Grenada	177 342	95 224	6,762	1.4 0.3	5,340 7,810
Grenada Guatemala	132	50	106 13,029	2.5	
Guatemaia	60	50	739	-0.1	4,680
Haiti	28	14	9,446	1.6	1,490
Honduras	91	46	6,969	2	
Jamaica Movice	170	83	2,699	0.6	
Mexico Nicaragua	474 75	215 37	105,342 5,532	1.3	11,410 4,010
Panama	351	242	3,288	1.3	7,680
Paraguay	92	34	6,016	1.9	
Peru	52				6,080
Saint Kitta and Navia	125	61	27,589	1.1	
Saint Kitts and Nevis	125 478	61 301	50	1.3	12,690
Saint Lucia	125 478 323	61 301 181	50 163	1.3 1.1	6,970
Saint Lucia Saint Vincent and the Grenadines	125 478 323 218	61 301 181 137	50 163 120	1.3 1.1 0.5	6,970 7,010
Saint Lucia	125 478 323	61 301 181	50 163	1.3 1.1	6,970 7,010 8,120
Saint Lucia Saint Vincent and the Grenadines Suriname	125 478 323 218 209	61 301 181 137 99	50 163 120 455	1.3 1.1 0.5 0.6 0.4	6,970 7,010 8,120
Saint Lucia Saint Vincent and the Grenadines Suriname Trinidad and Tobago United States of America Uruguay	125 478 323 218 209 513 6,350 404	61 301 181 137 99 275 2,862 172	50 163 120 455 1,328 302,841 3,331	1.3 1.1 0.5 0.6 0.4 1	6,970 7,010 8,120 16,260 44,260 11,150
Saint Lucia Saint Vincent and the Grenadines Suriname Trinidad and Tobago United States of America Uruguay Venezuela	125 478 323 218 209 513 6,350	61 301 181 137 99 275 2,862	50 163 120 455 1,328 302,841	1.3 1.1 0.5 0.6 0.4	6,970 7,010 8,120 16,260 44,260 11,150
Saint Lucia Saint Vincent and the Grenadines Suriname Trinidad and Tobago United States of America Uruguay Venezuela Eastern Mediterranean	125 478 323 218 209 513 6,350 404 247	61 301 181 137 99 275 2,862 172 112	50 163 120 455 1,328 302,841 3,331 27,191	1.3 1.1 0.5 0.6 0.4 1 1 0.2 1.7	6,970 7,010 8,120 16,260 44,260 11,150
Saint Lucia Saint Vincent and the Grenadines Suriname Trinidad and Tobago United States of America Uruguay Venezuela Eastern Mediterranean Afghanistan	125 478 323 218 209 513 6,350 404 247	61 301 181 137 99 275 2,862 172 112	50 163 120 455 1,328 30,2841 3,331 27,191	1.3 1.1 0.5.5 0.6 0.4 1 1 0.2.2 1.7	6,970 7,010 8,120 16,260 44,260 11,150 7,440
Saint Lucia Saint Vincent and the Grenadines Suriname Trinidad and Tobago United States of America Uruguay Venezuela Eastern Mediterranean	125 478 323 218 209 513 6,350 404 247	61 301 181 137 99 275 2,862 172 112	50 163 120 455 1,328 302,841 3,331 27,191	1.3 1.1 0.5 0.6 0.4 1 1 0.2 1.7	6,970 7,010 8,120 16,260 44,260 11,150 7,440
Saint Lucia Saint Vincent and the Grenadines Suriname Trinidad and Tobago United States of America Uruguay Venezuela Eastern Mediterranean Afghanistan Bahrain Djibouti Egypt	125 478 323 218 209 513 6,350 404 247 20 710 61	61 301 181 137 99 275 2,862 172 112 4 472 46	50 163 120 455 1,328 30,2,841 3,331 27,191 26,088 739 819 74,166	1.3 1.1 0.5.5 0.6 0.4 1.1 0.2 1.7 4 1.9 1.8	6,970 7,010 8,120 16,260 44,260 11,150 7,440
Saint Lucia Saint Vincent and the Grenadines Suriname Trinidad and Tobago United States of America Uruguay Venezuela Eastern Mediterranean Afghanistan Bahrain Djibouti Egypt Iran (Islamic Republic of)	125 478 323 218 209 513 6,350 404 247 20 710 61 78 212	61 301 181 137 99 275 2,862 172 112 4 472 46 30 119	50 163 120 455 1,228 302,841 3,331 27,191 26,088 739 819 74,166 70,270	1.3 1.1 0.5 0.6 0.6 0.4 1 0.2 1.7 4 1.9 1.8 1.8	6,970 7,010 8,120 16,260 44,260 11,150 7,440 2,540 4,690 8,490
Saint Lucia Saint Vincent and the Grenadines Suriname Trinidad and Tobago United States of America Uruguay Venezuela Eastern Mediterranean Afghanistan Bahrain Djibouti Egypt Iran (Islamic Republic of)	125 478 323 218 209 513 6,350 404 247 20 710 61 78 212 59	61 301 181 137 99 275 2,862 172 112 4 472 46 30 119	50 163 120 455 1,328 30,2,841 3,331 27,191 26,088 739 819 74,166 70,270 28,506	1.3 1.1 0.5 0.6 0.4 1 1 0.2 1.7 4 1.9 1.8 1.8 1.8	6,970 7,010 8,120 16,260 44,260 11,150 7,440 2,540 4,690 8,490
Saint Lucia Saint Vincent and the Grenadines Suriname Trinidad and Tobago United States of America Uruguay Venezuela Eastern Mediterranean Afghanistan Bahrain Djibouti Egypt Iran (Islamic Republic of) Iraq Jordan	125 478 323 218 209 513 6,350 404 247 20 710 61 78 212 59 241	61 301 181 137 99 275 2,862 172 112 4 4 472 46 30 119 44	50 163 120 455 1,328 30,2,841 3,331 27,191 26,088 739 8119 74,166 70,270 28,506 5,729	1.3 1.1 0.5 0.6 0.4 1 1 0.2 1.7 4 1.9 1.8 1.8 1.8 3.3	6,970 7,010 8,120 16,260 44,260 11,156 7,440 2,540 4,690 8,490 6,210
Saint Lucia Saint Vincent and the Grenadines Suriname Trinidad and Tobago United States of America Uruguay Venezuela Eastern Mediterranean Afghanistan Bahrain Djibouti Egypt Iran (Islamic Republic of) Iraq Jordan Kuwait	125 478 323 218 209 513 6,350 404 247 20 710 61 78 212 59 241	61 301 181 137 99 275 2,862 172 112 4 472 46 30 119 44 109	50 163 120 455 1,328 302,841 3,331 27,191 26,088 739 819 74,166 70,270 28,506 5,729 2,779	1.3 1.1 0.5 0.6 0.6 0.4 1 1 0.2 1.7 4 1.9 1.8 1.8 1.8 1.2 2.9 3.3 3.3	6,970 7,010 8,120 16,260 44,260 11,150 7,440 2,540 4,690 8,490 6,210
Saint Lucia Saint Vincent and the Grenadines Suriname Trinidad and Tobago United States of America Uruguay Venezuela Eastern Mediterranean Afghanistan Bahrain Djibouti Egypt Iran (Islamic Republic of) Iraq Jordan	125 478 323 218 209 513 6,350 404 247 20 710 61 78 212 59 241	61 301 181 137 99 275 2,862 172 112 4 4 472 46 30 119 44	50 163 120 455 1,328 30,2,841 3,331 27,191 26,088 739 8119 74,166 70,270 28,506 5,729	1.3 1.1 0.5 0.6 0.4 1 1 0.2 1.7 4 1.9 1.8 1.8 1.8 3.3	6,970 7,010 8,120 16,260 44,260 11,150 7,440 2,540 4,690 8,490 6,210
Saint Lucia Saint Vincent and the Grenadines Suriname Trinidad and Tobago United States of America Uruguay Venezuela Eastern Mediterranean Afghanistan Bahrain Djibouti Egypt Iran (Islamic Republic of) Iraq Jordan Kuwait Lebanon Libyan Arab Jamahiriya Morocco	125 478 323 218 209 513 6,350 404 247 20 710 61 78 212 59 241 687 460 223	61 301 181 137 99 275 2,862 172 112 4 4 472 46 30 119 44 109 530 200	50 163 120 455 1,328 302,841 3,331 27,191 26,088 7399 819 74,166 70,270 28,506 5,729 2,779 4,055 6,039 30,853	1.3 1.1 0.5 0.6 0.6 0.4 1.1 0.2 1.7 4 1.9 1.8 1.8 1.2 1.8 2.9 1.1.1	6,970 7,010 8,120 16,260 44,260 11,150 7,440 2,540 4,690 8,490 6,210
Saint Lucia Saint Vincent and the Grenadines Suriname Trinidad and Tobago United States of America Uruguay Venezuela Eastern Mediterranean Afghanistan Bahrain Djibouti Egypt Iran (Islamic Republic of) Iraq Jordan Kuwait Lebanon Libyan Arab Jamahiriya Morocco Oman	125 478 323 218 209 513 6,350 404 247 20 710 61 78 212 59 241 687 460 223 89	61 301 181 137 99 275 2,862 172 112 4 472 46 30 119 44 109 530 200 155 33 266	50 163 120 455 1,328 30,2,841 3,331 27,191 26,088 739 74,166 70,270 28,506 5,729 2,779 4,055 6,039 30,853 2,554	1.3 1.1 0.5 0.6 0.6 0.4 1.1 0.2 1.7 4 1.9 1.8 1.8 2.9 1.1.1 2.1.2 1.6 1.6	6,970 7,010 8,120 16,260 44,260 11,150 7,440 2,540 4,690 8,490 6,210 5,460 5,000
Saint Lucia Saint Vincent and the Grenadines Suriname Trinidad and Tobago United States of America Uruguay Venezuela Eastern Mediterranean Afghanistan Bahrain Djibouti Egypt Iran (Islamic Republic of) Iraq Jordan Kuwait Lebanon Libyan Arab Jamahiriya Morocco	125 478 323 218 209 513 6,350 404 247 20 710 61 78 212 59 241 687 460 223	61 301 181 137 99 275 2,862 172 112 4 4 472 46 30 119 44 109 530 200	50 163 120 455 1,328 302,841 3,331 27,191 26,088 7399 819 74,166 70,270 28,506 5,729 2,779 4,055 6,039 30,853	1.3 1.1 0.5 0.6 0.6 0.4 1.1 0.2 1.7 4 1.9 1.8 1.8 1.2 1.8 2.9 1.1.1	6,970 7,010 8,120 16,260 44,260 11,150 7,440 2,540 4,690 8,490 5,460 5,000

Complia	0		0.445	1 2	T
Somalia Sudan	8 29	4	8,445 37,707	3 2.2	2,160
Syrian Arab Republic	61	31	19,408	2.7	3,930
Tunisia	158	70	10,215	1.1	8,490
United Arab Emirates Yemen	833 39	597 16	4,248 21,732	3.5	920
Europe	50	10	21,702	J	020
Albania	169	68	3,172	0.6	5,840
Andorra	2,589 88	1,825 29	74 3,010	-0.3	5,890
Armenia Austria	3,788	2,869	8,327	-0.3	35,130
Azerbaijan	62	15	8,406	0.6	5,960
Belarus	204	155	9,742	-0.5	8,810
Belgium	3,451 243	2,465 143	10,430 3,926	0.3	35,090 6,780
Bosnia and Herzegovina Bulgaria	272	165	7,693	-0.7	10,140
Croatia	651	530	4,556	0.1	13,680
Cyprus	1,350	571	846	1.1	25,060
Czech Republic	868 4,350	769 3,658	10,189 5,430	0.2	21,470 36,460
Denmark Estonia	4,330 516	3,038	1,340	-0.3	17,540
Finland	2,824	2,196	5,261	0.3	35,150
France	3,819	3,050	61,330	0.6	33,740
Georgia	123 3,628	24 2,790	4,433 82,641	-0.9	3,690 31,830
Germany Greece	2,580	1,105	11,123	0.2	24,560
Hungary	855	606	10,058	-0.3	18,290
Iceland	5,154	4,254	298	0.9	36,560
Ireland Israel	3,993 1,533	3,173 1,019	4,221 6,810	1.9	35,900 23,840
Italy	2,692	2,061	58,779	0.2	30,550
Kazakhstan	148	95	15,314	0.7	7,780
Kyrgyzstan	28	11	5,259	1.1	1,990
Latvia Lithuania	443 448	268 302	2,289 3,408	-0.6 -0.5	15,350 14,930
Luxembourg	6,330	5,740	3,408	-0.5	59,560
Malta	1,235	956	405	0.5	20,990
Monaco	6,128	4,587	33	0.3	
Montenegro Netherlands	299 3,560	225 2,311	601 16,379	-1.1 0.3	8,930 37,580
Norway	5,910	4,940	4,669	0.6	43,820
Poland	495	343	38,140	-0.1	14,830
Portugal	1,800	1,301	10,579	0.5	21,580
Republic of Moldova Romania	58 250	32 176	3,833 21,532	-1.1 -0.4	2,880 9,820
Russian Federation	277	170	143,221	-0.5	11,630
San Marino	3,490	2,991	31	1.4	,
Serbia	212	153	9,851	-0.1	
Slovakia Slovenia	626 1,495	466 1,083	5,388 2,001	0.1	17,600 23,970
Spain	2,152	1,538	43,887	1.1	28,030
Sweden	3,727	3,044	9,078	0.4	35,070
Switzerland	5,694	3,398	7,455	0.4	40,930
Tajikistan The former Yugoslav Republic of Macedonia	18 224	4 158	6,640 2,036	1.4	1,410 7,610
Turkey	383	274	73,922	1.3	9,060
Turkmenistan	156	104	4,899	1.4	
Ukraine	128	68	46,557	-0.8 0.4	7,520
United Kingdom Uzbekistan	3,064 26	2,668	60,512 26,981	1.4	35,580 2,250
South-East Asia					-,,-
Bangladesh	12	3	155,991	1.8	2,340
Bhutan Democratic People's Republic of Korea	52	<1.0	649 23,708	1.8	5,690
India	<1.0	7	1,151,751	1.5	3,800
Indonesia	26	12	228,864	1.2	3,950
Maldives	316	270	300	1.7	4,740
Myanmar	4 16	<1.0	48,379 27,641	0.9	1.000
Nepal Sri Lanka	51	24	19,207	0.5	1,630 5,010
Thailand	98	63	63,444	0.7	9,140
Timor-Leste	45	39	1,114	4.3	
Asia Pacific Australia	3,181	2,132	20,530	1.1	34,060
Brunei Darussalam	519	413	382	2.1	49,900
Cambodia	29	7	14,197	1.7	2,920
China Cook kalanda	81	31	1,328,474	0.6	7,740
Cook Islands Fiji	466 148	426 105	14 833	-2.5 0.6	6,200
Japan	2,936	2,412	127,953	0.0	33,150
Kiribati	118	109	94	1.7	8,970
Lao People's Democratic Republic	18	4	5,759	1.7	2,050
Malaysia Marshall Islands	222 294	99 286	26,114 58		11,300 8,040
Micronesia (Federated States of)		265	111	0.5	7,830
	290		2,605	0.9	2,280
Mongolia	35	27		. 0.2	1
Mongolia Nauru	35 567	302	10	0.2	27 222
Mongolia Nauru New Zealand	35 567 2,403	302 1,860	4,140	1	27,220
Mongolia Nauru New Zealand Niue Palau	35 567 2,403 1,082 690	302 1,860 1,067 627	4,140 2 20	1 -2.2 0.5	14,340
Mongolia Nauru New Zealand Niue Palau Papua New Guinea	35 567 2,403 1,082 690	302 1,860 1,067 627 30	4,140 2 20 6,202	1 -2.2 0.5 2.2	14,340 2,410
Mongolia Nauru New Zealand Niue Palau Papua New Guinea Philippines	35 567 2,403 1,082 690 34 37	302 1,860 1,067 627 30 14	4,140 2 20 6,202 86,264	1 -2.2 0.5 2.2 2	14,340 2,410 5,980
Mongolia Nauru New Zealand Niue Palau Papua New Guinea Philippines Republic of Korea	35 567 2,403 1,082 690 34 37 973	302 1,860 1,067 627 30 14 515	4,140 2 20 6,202 86,264 48,050	1 -2.2 0.5 2.2 2 0.4	14,340 2,410 5,980 23,800
Mongolia Nauru New Zealand Niue Palau Papua New Guinea Philippines	35 567 2,403 1,082 690 34 37 973 113	302 1,860 1,067 627 30 14 515 91	4,140 2 20 6,202 86,264 48,050 185 4,382	1 -2.2 0.5	14,340 2,410 5,980 23,800 6,400 31,710
Mongolia Nauru New Zealand Niue Palau Papua New Guinea Philippines Republic of Korea Samoa Singapore Solomon Islands	35 567 2,403 1,082 690 34 37 973 113 944 28	302 1,860 1,067 627 30 14 515 91 301	4,140 2 20 6,202 86,264 48,050 185 4,382 484	1 -2.2 -0.5 -0.5 -0.5 -0.5 -0.5 -0.5 -0.5 -0.5	6,400 31,710 2,170
Mongolia Nauru New Zealand Niue Palau Papua New Guinea Philippines Republic of Korea Samoa Singapore Solomon Islands Tonga	35 567 2,403 1,082 690 34 37 973 113 944 28	302 1,860 1,067 627 30 14 515 91 301 26 79	4,140 2 20 6,202 86,264 48,050 185 4,382 484 100	1 -2.2 0.5.5 2.2 2 0.4.4 0.8 1.3 2.4	14,340 2,410 5,980 23,800 6,400 31,710 2,170 8,580
Mongolia Nauru New Zealand Niue Palau Papua New Guinea Philippines Republic of Korea Samoa Singapore Solomon Islands	35 567 2,403 1,082 690 34 37 973 113 944 28	302 1,860 1,067 627 30 14 515 91 301	4,140 2 20 6,202 86,264 48,050 185 4,382 484	1 -2.2 0.5.5 2.2 2 0.4.4 0.8 1.3 2.4	14,340 2,410 5,980 23,800 6,400 31,710 2,170 8,580

Source: WHO

Business Communication Company, Inc. research data.

Survey 2001 American Gastroenterology Association (AGA).

⁵ AGA study.

⁶ Guidelines of professional associations survey.

Millennium Research Group's (MRG) US Markets for Gastrointestinal (GI) Endoscopy report.

This goal is defined by the case writers for purposes of this case study and does not intend to illustrate effective or ineffective handling of business processes or decisions.