Check-Cap Ltd
Form F-1/A
February 18, 2015

As filed with the Securities and Exchange Commission on February 18, 2015.

Registration No. 333-201250

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

AMENDMENT NO. 6
TO
FORM F-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

CHECK-CAP LTD.
(Exact name of Registrant as specified in its charter)

| Israel | 3844 | Not Applicable |
|---|---|---|
| (State or other jurisdiction of incorporation or organization) | (Primary Standard Industrial Classification Code Number) | (I.R.S. Employer Identification Number) |

Check-Cap Building
Abba Hushi Avenue
P.O. Box 1271
Isfiya, 30090
Mount Carmel, Israel
+972-4-8303400

(Address, including zip code, and telephone number,
including area code, of Registrant's principal executive offices)

Puglisi & Associates
850 Library Avenue, Suite 204
Newark, Delaware 19711
302-738-6680

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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| | | | |
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| New York, New York 10154<br>(212) 407-4000 - Telephone<br>(212) 407-4990 - Facsimile | 3 Daniel Frisch Street<br>Tel Aviv, 6473104, Israel<br>+972 3 6944111 - Telephone<br>+972 3 6091116 - Facsimile | New York, New York 10022<br>(212) 521-5400 - Telephone<br>(212) 521-5450 - Facsimile | Tel Aviv 67775, Israel<br>+972 3 568 9000<br>Telephone<br>+972 3 568 9001<br>Facsimile |

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, or the Securities Act, check the following box. T

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. £

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. £

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. £

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Calculation of Registration Fee

| Title of Each Class of Securities to be Registered | Proposed Maximum Aggregate Offering Price (1) | Amount of Registration Fee (1)(11) |
|---|---|---|
| Units of ordinary shares, par value NIS 0.20 and Series A Warrants (2)(3)(4) | $18,400,000 | $2,138.10 |
| Ordinary shares included in the Units (7)(9) | -- | -- |
| Series A Warrants included in the Units (9) | -- | -- |
| Ordinary shares underlying the Series A Warrants included in the Units (5)(7) | $11,500,000 | $1,336.50 |
| Long Term Incentive Warrants to be issued with the units (2)(3)(4)(9) | -- | -- |
| Ordinary shares underlying the Long Term Incentive Warrants to be issued with the units(6)(7) | $31,740,000 | $3,688.20 |
| Underwriter warrants(8)(9) | -- | -- |
| Ordinary shares underlying the underwriter warrants(7)(10) | $1,000,000 | $116.20 |
| TOTAL | $62,640,000 | $7,279 |

(1) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(o) under the Securities Act.

(2) Each unit will consist of one ordinary share and one-half of a Series A Warrant to purchase one ordinary share. Each unit will be issued with one and one-half non-transferrable Long Term Incentive Warrants.

(3) Includes units and Long Term Incentive Warrants initially offered and sold outside the United States that may be resold from time to time in the United States either as part of their distribution or within 40 days after the later of the effective date of this registration statement and the date the units (and accompanying Long Term Incentive Warrants) are first bona fide offered to the public, and also includes units that may be purchased by the underwriters pursuant to an option to purchase additional units to cover over-allotments, if any. Neither the units nor the Long Term Incentive Warrants are being registered for the purpose of sales outside the United States.

(4) Estimated pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the aggregate offering price of an additional 300,000 units (together with the accompanying 450,000 Long Term Incentive Warrants) the underwriters have the option to purchase in this offering to cover over-allotments, if necessary.

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(5) We have calculated the proposed maximum aggregate offering price of the ordinary shares underlying the Series A Warrants by assuming that such warrants are exercisable to purchase ordinary shares at a price per share equal to $10.00.

(6) We have calculated the proposed maximum aggregate offering price of the ordinary shares underlying the Long Term Incentive Warrants by assuming that such warrants are exercisable to purchase ordinary shares at a price per share equal to $9.20.

(7) Pursuant to Rule 416 of the Securities Act, the securities being registered hereunder include such additional securities as may be issued after the date hereof as a result of share splits, share dividends or similar transactions.

(8) We have agreed to issue, upon closing of this offering, compensation warrants exercisable commencing on a date which is one year after the effective date of this registration statement and expiring four years following the effective date of this registration statement representing 5% of the aggregate number of ordinary shares included in the units issued in the offering but not including the over-allotment option, or the "underwriter warrants," to Chardan Capital Markets, LLC. Resales of the underwriter warrants on a delayed or continuous basis pursuant to Rule 415 under the Securities Act are registered hereby. Resales of ordinary shares issuable upon exercise of the underwriter warrants are also being similarly registered on a delayed or continuous basis hereby. See "Underwriting."

(9) No fee required pursuant to Rule 457(g) under the Securities Act.

(10) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(g) under the Securities Act. We have calculated the proposed maximum aggregate offering price of the ordinary shares underlying the underwriters' warrants by assuming that such warrants are exercisable to purchase ordinary shares at a price per ordinary share equal to 125% of the price per ordinary share sold in this offering.

(11) The Registrant previously paid $7,279 in connection with the filing of this Registration Statement.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall hereafter become effective in accordance with Section 8(a) of the Securities Act or until the registration statement shall become effective on such date as the Commission acting pursuant to said section 8(a), may determine.

The information contained herein is subject to completion or amendment. A registration statement relating to these securities has been filed with the U.S. Securities and Exchange Commission. These securities may not be sold until the registration statement becomes effective. This prospectus is not an offer to sell and is not a solicitation of an offer to buy in any jurisdiction in which an offer, solicitation, or sale is not permitted.

PRELIMINARY PROSPECTUS — SUBJECT TO COMPLETION, DATED FEBRUARY 18, 2015

Check-Cap Ltd.
2,000,000 Units

Each Unit Consisting of One Ordinary Share and One-Half of a
Series A Warrant to Purchase One Ordinary Share
Together with
3,000,000 Long Term Incentive Warrants to Purchase Ordinary
Shares to be Issued with the Units

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This is the initial public offering of securities of Check-Cap Ltd. We are offering to sell 2,000,000 units, each unit consisting of one ordinary share and one-half of a Series A Warrant to purchase one ordinary share. Each unit will be issued with one and one-half non-transferrable Long Term Incentive Warrants. Each whole Series A Warrant entitles the holder to purchase one ordinary share at an exercise price of $ (125% the offering price per unit, subject to adjustment as described herein). Each whole Series A Warrant will become exercisable 45 days after the date of this prospectus and will expire on , 2020. Upon vesting, each Long Term Incentive Warrant will entitle the holder to purchase one ordinary share at an exercise price of $ (115% of the offering price per unit, subject to adjustment as described herein). One-third of the Long Term Incentive Warrants held by each holder who has held the ordinary shares underlying the units issued in this offering for a period of one year following the closing date of this offering will vest and become exercisable on the first anniversary of the closing date of this offering. The remaining two-third of the Long Term Incentive Warrants held by each holder who has held the ordinary shares underlying the units issued in this offering for a period of two years following the closing date of this offering will vest and become exercisable on the second anniversary of the closing date of this offering. The Long Term Incentive Warrants will not be transferrable and will expire on , 2022. We currently expect the initial public offering price to be between $6.00 and $8.00 per unit.

Prior to this offering, there has been no public market for our securities. We have applied for the listing of our ordinary shares, our units and our Series A Warrants on the NASDAQ Capital Market under the symbols “CHEK,” “CHEKU” and “CHEKW,” respectively. There is no assurance that our applications will be approved. The Long Term Incentive Warrants will not be listed on any national securities exchange or other trading market.

The Series A Warrants and ordinary shares will trade together as units only during the first 45 days following the date of this prospectus, and thereafter, the units will automatically separate and the ordinary shares and Series A Warrants will trade separately, unless Chardan Capital Markets, LLC, as representative of the underwriters, determines that an earlier date is acceptable based upon, among other things, its assessment of the relative strengths of the securities markets and small capitalization companies in general, and the trading pattern of, and demand for, our securities in particular.

Concurrently with this offering, we expect to complete a private placement of approximately 1,714,286 units, or the Private Placement, at a purchase price per unit equal to the public offering price in accordance with Regulation S under the Securities Act of 1933, as amended, or the "Securities Act" or Regulation D under the Securities Act, to certain investors including certain of our affiliates. Each unit sold in the Private Placement will be issued with one and one-half non-transferrable Long Term Incentive Warrants. The issuance and sale of such units and Long Term Incentive Warrants will not be registered under the Securities Act. We expect to receive approximately $10,900,000 in aggregate net proceeds from the Private Placement. See "Summary-Recent Developments-Credit Line Agreement; Private Placement." The closing of the Private Placement is conditioned upon the completion of the offering to which this prospectus relates. However, the completion of the offering to which this prospectus relates is not conditioned upon the closing of the Private Placement.

We are an "emerging growth company" under applicable U.S. federal securities laws and may elect to comply with reduced public company reporting requirements. See "Implications of Being an Emerging Growth Company" on page 6 of this prospectus.

Investing in our securities involves a high degree of risk. You should read carefully the "Risk Factors" beginning on page 17 of this prospectus before investing in our securities that are the subject of this offering.

Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of the disclosures in this prospectus. Any representation to the contrary is a criminal offense.

| | Per Unit | Total |
|---|---|---|
| Public offering price | $ | $ |
| Underwriting discount and commissions (1) | $ | $ |
| Proceeds, before expenses, to us | $ | $ |

(1) We have also agreed to issue, upon closing of this offering, compensation warrants to Chardan Capital Markets, LLC as representative of the underwriters, entitling it to purchase up to 100,000 ordinary shares. For a description of other terms of the compensation warrants and a description of the additional compensation to be received by the underwriters see "Underwriting."

The underwriters have an option exercisable within 45 days from the date of this prospectus to purchase up to 300,000 of additional units (together with the accompanying 450,000 Long Term Incentive Warrants) from us at the public offering price, less the underwriting discount, solely to cover over-allotments. The units and Long Term Incentive Warrants issuable upon exercise of the underwriters' over-allotment option have been registered under the registration statement of which this prospectus forms a part. In addition to the underwriting discount, we have agreed to pay certain of the expenses of underwriters incurred in connection with this offering, see "Underwriting" beginning on page 162 of this prospectus.

The underwriters expect to deliver the units to purchasers on or about , 2015.

Joint Book-Running Managers

Chardan Capital Markets, LLC Maxim Group LLC

Co-Manager

Feltl and Company

, 2015

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You should rely only on the information contained in this prospectus, any amendment or supplement to this prospectus or any free writing prospectus prepared by us or on our behalf. We have not, and the underwriters have not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer of these securities, or soliciting any offers to buy these securities, in any jurisdiction where the offer or solicitation is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our securities.

Neither we nor any of the underwriters has done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required other than the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of our securities set forth in, and the possession and distribution of, this prospectus outside of the United States.

We obtained statistical data, market data and other industry data and forecasts used throughout this prospectus from market research, publicly available information and industry publications. While we believe that the statistical data, industry data and forecasts and market research are reliable, we have not independently verified the data.

PROSPECTUS SUMMARY

The following summary does not contain all of the information you should consider before investing in our securities. You should read the following summary together with the entire prospectus carefully, including the "Risk Factors" section beginning on page 17 and the financial statements and the accompanying notes to those financial statements beginning on page F-1 before making an investment decision. Unless otherwise indicated, all information in this prospectus assumes no exercise of the underwriters' over-allotment option and no exercise of the underwriter warrants. Unless the context otherwise requires, references to "we," "our," "us," "our company," and "Check-Cap" refer to Check-Cap Ltd., an Israeli company. The terms "dollar," "US$" or "$" refer to U.S. dollars, the lawful currency of the United States, and the term "NIS" refers to New Israeli Shekels, the lawful currency of the State of Israel. Unless otherwise indicated, U.S. dollar translation of NIS amounts presented in this prospectus are translated using the rate of $1.00 = NIS 3.4380, the exchange rate published by the Bank of Israel on June 30, 2014, and U.S. dollar translation of Euro amounts presented in this prospectus are translated using the rate of $1.00 = Euro 1.3693, the exchange rates published by the Wall Street Journal on June 30, 2014.

Our Company

We are a clinical stage medical diagnostics company engaged in the development of an ingestible imaging capsule that utilizes low-dose X-rays for the screening for colorectal cancer, or CRC. While CRC is the second leading cause of death from cancer in the United States and is largely preventable with early detection, about one-half of Americans over the age of 50 do not undergo any form of CRC screening due in large part to the pain, discomfort and embarrassment related to current screening methods. Unlike other structural screening methods that are designed to generate structural information of the colon for the detection of pre-cancerous polyps, such as optical colonoscopy, computed tomographic colonography, or CTC, and other capsule-based technology, our imaging capsule is designed to be ingested without any cleansing of the colon and to travel through the gastrointestinal tract naturally while the patient continues his or her normal daily routine. Furthermore, unlike the procedures for CRC imaging devices currently on the market, all of which

require the patient to fast for several hours prior to administration, the procedure for the Check-Cap device is designed to enable patients to continue eating normally. We believe that this solution will be attractive to both physicians and patients, thereby increasing the number of people willing to undergo screening for CRC.

Our imaging capsule is being designed to create a reconstructed three-dimensional image of the colon and to enable detection of clinically significant polyps with a high degree of sensitivity. Colon polyps are fleshy growths that occur on the lining of the colon. Polyps in the colon are extremely common, and when certain types of polyps grow large enough they can become cancerous.

Our imaging capsule will be swallowed by the patient and propelled by natural motility through the gastrointestinal tract and excreted naturally with no need for retrieval for data collection. Unlike other CRC screening methods, this process should not disrupt a patient's normal activities or require fasting. Our imaging capsule employs X-rays, which allow it to image the lining of the colon even when surrounded by intestinal content. As such, we believe that patients using our imaging capsule will not be required to undergo any prior bowel cleansing. The Radiation Safety Division of the Soreq Nuclear Research Center found, as set forth in its report of November 2010, that was prepared at our request and based on the information provided by us and the relevant methods and principles known at such time, or the Report, that the radiation dose to the patient in the proposed screening procedure utilizing the imaging device developed by us at that time in routine operation and normal conditions is low relative to the radiation dose involved in conventional imaging procedures using X-rays (such as fluoroscopy and CT) and is also low when compared to the radiation dose involved in established screening procedures such as mammography, all as more fully described in the Report.

Our imaging capsule is being designed to transmit the data it collects to an external data recorder that will be worn by the patient. The external data recorder is being designed to enable the transfer of the data to physicians, who will then utilize our data viewer software application to analyze the data collected by our imaging capsule. We intend for physicians to be able to review the colon's inner images at any location at any time, in less time than is required to perform an optical colonoscopy.

In order to enable a complete view of capsule positioning and motility, we have designed a Capsule Positioning

System, or CPS, which is mounted on the patient's back throughout the entire procedure. The CPS is being designed to provide the physician with accurate localization data aligned with a reconstructed image.

In the event that polyps are identified through our imaging capsule, the patient would be required to undergo a subsequent traditional colonoscopy procedure to examine, remove and biopsy the polyps. For those patients who require a subsequent polypectomy, concerns regarding pain, discomfort and embarrassment may still remain with respect to the subsequent polypectomy. We do not, however, believe that these concerns will make the use of our imaging capsule any less attractive to doctors and patients. Although patients who are initially screened utilizing a traditional colonoscopy could avoid the need for a second procedure if polyps are discovered because they could undergo a polypectomy during the initial screening, if necessary, we believe that our imaging capsule will still be attractive to doctors and patients since a large majority of patients who are screened will not require a subsequent polypectomy. According to a review published by the Agency for Healthcare Research and Quality in October 2008, out of 100 adults aged 50-75, only 25-30 persons have one or more polyps and only 15 persons have significant (10+mm) polyps.

A clinical proof-of-concept study, which was based on a 10-case study conducted at Tel Aviv Medical Center in Israel and used a prior version of our imaging capsule, did not identify any material safety or feasibility issues. The study demonstrated the applicability of our imaging technology to the human colon, generating images taken in the colon without any prior bowel-cleansing. All subjects ingested the capsule easily with smooth passage within the designated transit time, on average, within two to three days. There were no reported device-related adverse events. Mild effects on bowel movements were noted, which were determined to be related to the contrast agent and passed within one to two days after the capsule was excreted.

Another objective of the 10-case study was to estimate total radiation exposure for each case study. This was calculated using standard established factors for calculating effective radiation exposure, such as the duration of the capsule inside the body, and was based on the activity of the radiation source inside the imaging capsule and radiation energy, both of which were measured for each case study. The average calculated exposure for the entire procedure in the 10-case study, from ingestion of the capsule to excretion, was 0.03 mSv (STD 0.007 mSv). This level of radiation exposure is similar to a single chest X-ray (approximately 0.06mSv) and two orders of magnitude less than a CTC.

The 10-case clinical proof-of-concept study focused on assessing the safety and feasibility of the Check-Cap imaging system. The 10-case study is the first part of a multi-center, prospective clinical feasibility study to establish the safety, functionality and preliminary efficacy of the Check-Cap imaging system in patients eligible for CRC screening, by comparing results from the clinical feasibility study with those from non-invasive, low-sensitivity fecal occult blood tests, or FOBTs, and fecal immunochemical tests, or FITs, as well as from optical colonoscopies. The feasibility study is designed to include approximately 60 subjects. The study is being conducted in Israel at the Tel Aviv Medical Center and Laniado Hospital and is planned to also be conducted at the Erasmus University Medical Center in the Netherlands. The clinical feasibility study will evaluate the image resolution generated by the capsule in an unprepped human colon, will assess polyp imaging in various shapes and in different segments of the colon and will evaluate the safety of the device in terms of total and segmental transit time and analyze the effects of the presence of polyps and variable colon dimensions on these parameters. The study will seek to create a clinical atlas of images that will enable comparisons between images acquired by different CRC screening modalities. During the feasibility study we will collect data about the overall imaging of the colon's internal surfaces during the passage of the capsule to support the development of a correlation map of polyps identified through our imaging system with polyps imaged by optical colonoscopy and CTC. Additionally, the feasibility study will measure total radiation exposure and the distribution of contrast material within the colon.

Following the successful completion of the broader multi-center, prospective clinical feasibility study, we plan to submit during 2015 a request for CE marking for the marketing and sale of our capsule in the European Union. We expect to perform post-marketing studies in Europe following CE marking for the purpose of collecting additional clinical data to support market adoption. Subject to regulatory approval and available capital, we anticipate launching our product commercially in Europe during 2016.

We plan to conduct a second pre-IDE meeting, now referred to as a pre-submission meeting, with the U.S. Food and Drug Administration, or FDA, in late 2015, and subsequently to submit a request for the approval of an investigational device exemption, or IDE, for a pivotal study in the United States to (i) demonstrate device safety as evidenced by a lack of device-related serious adverse events; and (ii) provide efficacy data concerning our imaging capsule's sensitivity and specificity. We anticipate that FDA approval for the pivotal study will be subject to our providing sufficient clinical data from the multi-center, prospective clinical feasibility study. We also intend to pursue clinical trials for regulatory approvals in Japan and China in parallel to the U.S. pivotal study. Pivotal studies are expected, among other things, to compare the images of polyps identified by our imaging system with the same

polyps detected by traditional optical colonoscopy and CTC in instances where patients were referred after positive exam results. These clinical findings will be analyzed in comparison with results obtained from FOBTs and FITs. Subject to the successful completion of our clinical trials and the receipt of initial FDA approval for the marketing of our imaging capsule in the United States, we anticipate launching our product commercially in the United States during 2017.

We have submitted patent applications covering our technology in the United States, member states of the European Patent Organisation, Australia, Brazil, Canada, China, Hong Kong, India, Israel, Japan and South Korea. We have been granted patents for our core patent by the U.S. Patent and Trademark Office as well as from the European Patent Office, Australia, China, Hong Kong, Israel, India and Japan. We also filed patent applications describing the use of our imaging technology in several other medical applications.

Since our formation, we have not generated any revenue. We do not anticipate generating any revenue for the foreseeable future and we do not yet have any specific launch dates for our product. For the six months ended June 30, 2014, we had a total comprehensive loss of $2.2 million. For the year ended December 31, 2013, we had a total comprehensive loss of $4.0 million. As of June 30, 2014, we had an accumulated deficit of $24.7 million and a total shareholders' deficit of $998,000.

Industry Background

According to the American Cancer Society, or the ACS, CRC is the third most common cancer diagnosed and the second leading cause of death from cancer in the United States. The ACS estimates that in 2014, in the United States approximately 136,830 people are expected to be diagnosed with CRC and approximately 50,310 people will die from CRC. According to the World Health Organization, or the WHO, in 2012, in Europe there were an estimated 471,000 cases of CRC and approximately 228,000 died from the disease, and in Japan there were an estimated 112,675 cases of CRC and approximately 49,345 died from the disease. According to the WHO, in 2020 the expected numbers of cases of CRC are estimated to be 159,972 in the United States, 528,481 in Europe, 128,346 in Japan and 1,678,127 worldwide.

CRC screening can reduce death rates from CRC by detecting polyps at an earlier, more treatable stage. CRC is one of the few cancers that can be prevented through screening because pre-cancerous polyps, from which colon cancers often develop, can be identified and removed. Moreover, the five-year survival rate is greater than 90% for CRC patients diagnosed at an early, localized stage. However, less than 40% of cases are currently diagnosed at that stage. According to the Centers for Disease Control and Prevention, or the CDC, at least 6 out of every 10 deaths from CRC could be prevented if every adult age 50 years or older was screened regularly and approximately 30,000 lives could be saved each year in the United States if the screening recommendations were followed. The ACS' goal is to have 80% of those 50 years and older who are covered by the program screened by 2018.

Today, there is a range of options for CRC screening in the average risk population, with current technology falling into two general categories: (i) structural exams, such as optical colonoscopy, sigmoidoscopy, CTC and optical capsules (all of which require aggressive bowel preparation), which are invasive exams that enable physicians to visualize the colon for abnormalities; and (ii) stool tests, such as FOBTs, FITs and stool DNA tests, which test for blood and irregularities in DNA. Notwithstanding the many CRC screening alternatives, the fact that the tests are encouraged by clinicians and insurers and the clinical value of screening for CRC, a large portion of the population are still reticent to undergo CRC screening and are not satisfied with the currently available alternatives.

The ACS recommends that men and women over the age of 50 undergo an optical colonoscopy every 10 years or other structural tests, such as sigmoidoscopy or virtual colonoscopy, every five years or alternatively, a FOBT should be performed every year. According to the U.S. Census Bureau, as of mid-2014, there were projected to be approximately 91 million Americans aged 50-75 years. Assuming the longest screening interval of 10 years, the addressable annual U.S. patient population is at least 9.1 million.

Optical colonoscopy is currently considered the most reliable method for detecting disorders of the colon and is the standard screening tool for early detection of colon cancer. Optical colonoscopy demonstrates a high degree (approximately 95%) of sensitivity (i.e., detection of individuals with cancer) and specificity (i.e., avoiding false negative results). Optical colonoscopy involves the insertion of a flexible colonoscope, which is an approximately160 centimeters long endoscope, by a physician into a patient's colon through the anus in order to visually inspect the interior of the colon. Air must be pumped in through the rectum in a process called "insufflation." Sigmoidoscopy, or FSIG, is an endoscopic procedure that examines the lower part of the colon lumen. The exam may be performed

with a variety of endoscopic instruments, including a standard 60 centimeter sigmoidoscope. FSIG is typically performed without sedation and with a more limited bowel preparation than a standard optical colonoscopy. An optical colonoscopy and sigmoidoscopy can perform both diagnostic and limited treatment functions, by allowing for the removal of polyps and adenomas during the course of the procedure. However, both of these procedures carry some risks of bowel perforations and bleeding and related limitations as they require prior cleansing of the bowel, insufflation and sedation, involve potential complications and may cause patient anxiety, discomfort and, in some cases, pain. In addition, a patient's normal daily routine is disrupted for one or two days.

CTC, or virtual colonoscopy, is an imaging procedure that results in cross-sectional, two- or three-dimensional views of the entire colon with the use of a special X-ray machine linked to a computer. Here, as well, a flexible tube is inserted into the rectum in order to allow air or carbon dioxide to open the colon. The patient then passes through the CT scanner, which creates multiple images of the colon interior. This method does not allow for treatment and the subject is exposed to a high dose of radiation. A full bowel cleansing is currently necessary for a successful examination by CTC.

FOBT is based on an analysis of stool samples and is currently the most widely used non-invasive screening test. It has a lower sensitivity in detecting polyps (measured by the percentage of polyps being found). According to the CDC, in 2012, only approximately 10.6% of men and 10.2% of women in the United States underwent the procedure due to its inconvenience and unreliable performance. FOBT is being replaced by a more sensitive blood stool technology FIT, but it is also not designed to detect the majority of non-bleeding polyps.

In 2009, optical capsule endoscopy became commercially available in Europe for CRC screening. In early 2014, the FDA granted approval for optical capsule endoscopy procedure to be used for CRC screening for use in patients who have had an incomplete optical colonoscopy. However, this technology requires bowel cleansing to a greater degree than is required for a regular optical colonoscopy, which can result in dehydration and in turn can lead to cancellation of the procedure in certain cases. Moreover, because this procedure must be completed within several hours in order to maintain a clean colon and to accommodate the capsule's limited battery life, patients are required to drink large amounts of liquid so that the capsule can flow through the gastrointestinal tract during the time allotted. Furthermore, camera-based optical capsule endoscopy procedures generate a large number of images, often requiring more physician time to analyze the images than to conduct an optical colonoscopy.

Several companies are developing technologies based on molecular diagnostics (from blood and other bodily fluids), or MDx, tests that investigate the link between genes and the function of metabolic pathways, drug metabolism and disease development with a primary focus on the study of DNA, RNA and proteins. Genetic markers can be traced within stool samples in minute quantities. For example, a special collecting kit for stool samples and an analyzer to diagnose CRC based on these stool-based markers has been developed and recently approved by the FDA. While the method of screening for CRC using stool DNA testing has been endorsed by several societies, this test does not generate structural information on the colon and therefore, does not detect most pre-cancerous polyps.

Our Solution

We believe that our imaging capsule could represent a potential breakthrough in CRC screening by providing a structural exam without the pain, discomfort and embarrassment experienced by some patients undergoing a traditional optical colonoscopy and other currently available screening methods by offering the following benefits:

- eliminating the need for fasting and prior bowel cleansing, which would differentiate our imaging capsule from every other currently available structural screening exam;
- providing patients with a procedure that requires them to swallow our capsule and small amounts of a contrast agent, thereby minimizing any disruption to their normal activities;
- eliminating the need to sedate patients;
- obviating the requirement for the insufflation (the forcing of air into the gastrointestinal tract) of patients;
- administering our technology on an outpatient basis;
- providing digital reporting, storage and remote consulting capabilities; and

- enabling a physician to analyze the results in approximately 10 minutes, which would be less time than is required to conduct an optical colonoscopy.

Although our imaging capsule utilizes radiation that is considered low dose, we believe that the risks associated with such radiation exposure are low compared to risks associated with other procedures such as perforation, bleeding or sedation related effects (optical colonoscopy and sigmoidoscopy) and dehydration and damage to kidneys (optical capsules). Unlike FOBTs, FITs and stool DNA tests, our capsule-based imaging modality generates structural information on the colon, which could assist in the detection of pre-cancerous polyps. We therefore do not believe that the low dose radiation in our imaging capsule will make our imaging capsule less attractive to physicians and patients than other less effective products that do not employ any radiation.

We believe that gastroenterologists will embrace our technology and encourage the use of our imaging capsule. This may increase the number of people undergoing CRC screening and may cause more people with polyps to obtain polypectomy – a therapeutic procedure during which polyps are removed and which currently receives different reimbursement coverage.

Our imaging capsule and CPS are intended to be prescribed to patients by physicians. Just prior to swallowing our capsule, a patient will begin drinking small amounts of a radio opaque contrast agent (such as barium sulfate or iodine) with his or her meals, which enhances the contrast of the colon surface. The capsule is propelled by natural motility through the gastrointestinal tract. As it makes its way through the gastrointestinal tract, information is transmitted to a receiving device worn by the patient that stores the information for offline analysis. After our imaging capsule is expelled from a patient's body, the CPS data will be transferred to physicians, who will then utilize our data viewer software application to analyze the data collected by our imaging capsule. Our proprietary software is being designed to process the data and produce a two- and three-dimensional visualization of the colon. A physician will then analyze the visualization to determine whether any anatomical anomalies are present on the surface of the colon.

Our imaging capsule consists of an X-ray source and several X-ray detectors. The X-ray source is contained in a rotating radiation shield, enabling the generation of 360-degree angular scans. The collection of successive angular scans enables the virtual reconstruction of a portion of the colon. During movement of our imaging capsule longitudinally through the colon, successive images of portions of the colon are collected to enable the three-dimensional reconstruction of the colon. Our imaging capsule is also intended to enable identification of polyps, which protrude inward into the colon, through the detection of irregularities in the topography of the colon.

Image for illustration purpose only

Our Strategy

Our goal is to become a leading supplier of CRC screening technology and, subject to the successful completion of the development of our technology and the receipt of the requisite regulatory approvals, to establish our technology as a leading CRC screening method. Key elements of our strategy include:

- obtaining CE marking for the marketing and sale of our imaging capsule in the European Union, followed by obtaining regulatory approvals for the use of our imaging capsule initially in the United States and Japan. In Europe and Japan, we intend to offer our imaging capsule as an imaging and screening tool for the general population. In the United States, we may first seek to obtain regulatory approvals for our imaging capsule as an adjunct tool to FOBTs and FITs, and after we have conducted more extensive clinical studies, we anticipate applying to the FDA for the use of our imaging capsule as an initial screening tool;
- obtaining third-party reimbursement for our technology;
- enhancing our existing technology portfolio and developing new technologies; and
- successfully marketing our product to establish a large customer base.

Our Challenges

Because we are still in the clinical and development stage, we are subject to certain challenges, including, among others, that:

- our technology has been tested on a limited basis and therefore we cannot assure the product's clinical value;
- we need to CE mark the devices in the European Union and obtain the requisite regulatory approvals in the United States, Japan and other markets where we plan to focus our commercialization efforts;
- we need to raise an amount of capital sufficient to complete the development of our technology, obtain the requisite regulatory approvals and commercialize our current and future products;
- we need to obtain reimbursement coverage from third-party payors for procedures using our imaging capsule;
- we need to increase our manufacturing capabilities; and
- we need to establish and expand our customer base while competing against other sellers of capsule endoscopes as well as other current and future CRC screening technologies and methods.

Our ability to operate our business and achieve our goals and strategies is subject to numerous risks as described more fully in "Risk Factors."

Implications of Being an Emerging Growth Company

As a company with less than $1.0 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" pursuant to the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth

company may take advantage of certain exemptions from specified disclosure and other requirements that are otherwise generally applicable to public companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements for the assessment of our internal control over financial reporting provided by Section 404 of the Sarbanes-Oxley Act of 2002;
- not being required to comply with any requirements adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation or a supplement to the auditor's report in which the auditor would be required to provide additional information about the audit and our financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a nonbinding advisory vote on executive compensation or seek shareholder approval of any golden parachute payments not previously approved.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. However, we have elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted for public companies. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which our total annual gross revenues exceed $1.0 billion; (ii) the last day of the fiscal year in which the fifth anniversary of the date of the first sale of securities under this registration statement occurs; (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (iv) the date on which we are deemed to be a "large accelerated filer" under the Securities Exchange Act of 1934, as amended, or the Exchange Act. When we are no longer deemed to be an emerging growth company, we will not be entitled to rely on the exemptions provided in the JOBS Act discussed above. We may choose to take advantage of some, but not all, of the exemptions available to emerging growth companies. We have taken advantage of some of the reduced reporting exemptions in this prospectus. Accordingly, the information contained herein and in future filings with the U.S. Securities and Exchange Commission may be different from the information provided by other public companies in similar filings.

Concurrent Private Placement

Concurrent with this offering, we expect to complete a Private Placement utilizing the $12.0 million in proceeds from the credit line agreement, dated August 20, 2014, described below, of approximately 1,714,286 units at a purchase price per unit equal to the public offering price in accordance with Regulation S under the Securities Act or Regulation D under the Securities Act, to certain investors including certain of our affiliates. Each unit sold in the Private Placement will be issued with one and one-half non-transferrable Long Term Incentive Warrants. The issuance and sale of such units and Long Term Incentive Warrants will not be registered under the Securities Act. We expect to receive $12.0 million in gross proceeds from the Private Placement. The closing of the Private Placement is conditioned upon the completion of the offering to which this prospectus relates. However, the completion of the offering to which this prospectus relates is not conditioned upon the closing of the Private Placement.

Corporate Information

We were incorporated as a limited liability private company under the laws of the State of Israel on April 5, 2009, and on May 31, 2009, we acquired all of the business operations and substantially all of the assets of Check-Cap LLC, a Delaware limited liability company formed in December 2004. Our principal executive offices are located at Check-Cap Building, Abba Hushi Avenue, P.O. Box 1271, Isfiya, 30090, Mount Carmel, Israel. Our telephone number is +972-4-8303400. Our website address is www.check-cap.com. Information contained on, or accessible through, our website does not constitute part of this prospectus and is not incorporated by reference herein.

Throughout this prospectus we refer to the trademark "CHECK-CAP" that we use in our business. Furthermore, we received a notice of allowance for the "CHECK-CAP" mark and design logo in the United States and hold a registered trademark for the "CHECK-CAP" design logo in Europe. Other trademarks and service marks appearing in this prospectus are the property of their respective holders.

Recent Developments

Credit Line Agreement; Private Placement

On August 20, 2014, we entered into a certain credit line agreement, pursuant to which we obtained a credit line in an aggregate principal amount of $12 million from certain lenders and existing shareholders, or the Lenders. The credit line amount was deposited in an escrow account at the closing, which was consummated on October 14, 2014.

We issued to each Lender at closing a warrant, collectively referred to as the Credit Line Warrants, to purchase a number of our ordinary shares constituting 2% of our share capital on a fully diluted basis (assuming conversion of all of our convertible securities into ordinary shares at a 1:1 conversion rate) as of the closing for each $1 million (or portion thereof) extended by such Lender. We issued Credit Line Warrants to purchase in the aggregate 2,658,463 of our ordinary shares. The Credit Line Warrants are exercisable for a period of ten years at an exercise price of NIS 0.20 per share, and may be exercised on a net issuance basis.

Under the terms of the agreement, if we intend to consummate (as defined in the credit line agreement) an initial public offering of our securities, or an IPO, on or prior to February 18, 2015, or if we consummate (as defined in the credit line agreement) an IPO on or prior to February 18, 2015, we will be entitled to direct that all or any portion of the credit line amount be invested in securities in a private placement transaction that is exempt from the registration requirements of the Securities Act at a price equal to the public offering price in the IPO. The agreement provides that in the event that we direct that less than the full credit line amount be invested in the Private Placement, the amount to be invested by each Lender in the Private Placement will be equal to its pro rata share of the total credit line amount. We intend to direct that the full credit line amount be invested in the Private Placement. If we consummate (as defined in the credit line agreement) an IPO on or prior to February 18, 2015, any part of the credit line amount not so invested in the Private Placement will be released to the Lenders. The consummation of any of the transactions contemplated by the credit line agreement, including, without limitation, the Private Placement, is not a condition to our obligation or the obligation of the underwriters to consummate the transactions contemplated by the underwriting agreement.

If we do not consummate (as defined in the credit line agreement) an IPO on or prior to February 18, 2015, we may "call" the credit line amount (i.e., direct that such funds be released from the escrow account to us) at any time thereafter until April 14, 2016, subject to certain conditions. Any part of the credit line amount not so called by us on or prior to such date will be released to the Lenders. If we call the credit line amount from the escrow account on or prior to April 14, 2016, the amount called will bear interest at the annual rate of 7%; provided that the aggregate interest rate will not be less than 5%. The called credit line amount (and, at our option, the interest accrued thereon) will automatically convert into shares of our company upon the earlier of a qualified financing round (which includes a public offering, including an IPO), an M&A Event (i.e., as defined in the credit line agreement as an acquisition with or into another entity, the sale or license of all or substantially all of our assets or intellectual property or all or substantially all of our issued and outstanding share capital, or any other transaction having the same effect of any of the foregoing) and April 14, 2016, and the Lenders may elect to convert the entire called credit line amount (and, at our option, the interest accrued thereon) upon a non-qualified financing round, all under the terms and conditions set forth in the credit line agreement. In the event that the qualified financing round is an IPO, in lieu of automatic conversion, we are entitled, to the extent permitted by law, to deposit in trust an amount equal to 133% of the called credit line amount (and, at our option, the interest accrued thereon) and irrevocably instruct the trustee to submit an offer, on behalf of each Lender, for the purchase of the IPO shares at the IPO price determined by the lead underwriters.

Israel-United States Binational Industrial Research and Development Foundation Grant

On July 13, 2014, we entered into a Cooperation and Project Funding Agreement with the Israel-United States Binational Industrial Research and Development Foundation, or the BIRD Foundation, and Synergy Research Inc., or Synergy, pursuant to which the BIRD Foundation has agreed to award a grant in the maximum amount of the lesser of (i) $900,000; and (ii) 50% of the actual expenditures for the funding of a project entitled "Collection & Analysis of Gastrointestinal Images for Diagnostic Adenomatic Polyps and Colorectal Cancer." The development work is expected to be performed over a 24 month period by Synergy (or a subcontractor on its behalf) and us. Of the total

grant amount, we are expected to receive an aggregate of $567,000 to fund our expenditures for the project, in five installments. We received our first advance payment from the BIRD Foundation of $68,000 in July 2014. Our research and development expenses, net is presented net of the differences between the fair value of the liability and the grant amount received from the BIRD Foundation.

We are required to repay the total sum granted to us and Synergy by the BIRD Foundation, linked to the U.S. Consumer Price Index from date of receipt of each payment, up to 100%, 113%, 125%, 138% and 150% of the linked sum granted by the BIRD Foundation if repaid within one year, two years, three years, four years and five or more years, respectively, of the original project completion date in accordance with the project proposal. Repayments are made at the rate of 5% of gross revenues derived from the product funded by the project. Under the terms of the agreement, if any portion of the product funded by the project is sold outright to a third party prior to full repayment of the grant to the BIRD Foundation, one-half of the sale proceeds will be applied to the repayment of the grant. If the funded product is licensed to a third party, 30% of all payments received under the respective license agreement must be paid to the BIRD Foundation in repayment of the grant.

Bank Leumi Credit Facility

On January 4, 2015, we entered into a credit line agreement with Bank Leumi le-Israel B.M., or Bank Leumi, pursuant to which we may obtain a credit line in the principal amount of up to $1,000,000, or the Bank Leumi Credit Facility. The Bank Leumi Credit Facility is to be repaid in full by us no later than April 1, 2015 and Bank Leumi's consent is required for early repayment. The drawn portion of the Bank Leumi Credit Facility bears interest at an annual rate of LIBOR plus 5.25% on the basis of a 365-day year, until repayment in full. The undrawn portion of the Bank Leumi Credit Facility shall bear interest at an annual rate of 1.0% on the basis of a 365-day year, until repaid in full. We have drawn the entire $1,000,000 Bank Leumi Credit Facility. We paid Bank Leumi a facility fee of $20,000. Under the terms of the agreement, we are required to maintain a cash balance of not less than $400,000 in our account at Bank Leumi so long as the Bank Leumi Credit Facility has not been repaid in full. The Bank Leumi Credit Facility would become due and payable upon certain events, including (among others) upon a change of control, other than in the event of a public offering of our securities. Pursuant to the agreement, a merger would require the prior written consent of Bank Leumi.

To secure the repayment of the Bank Leumi Credit Facility, we granted Bank Leumi (i) a first ranking fixed charge over our goodwill; and (ii) a first ranking floating charge over all of the assets and rights of any type whatsoever, which we now have or may acquire in the future, subject to the rights of the Office of the Chief Scientist of the Ministry of Economy (formerly named the Ministry of Industry, Trade and Labor), or the OCS, and the BIRD Foundation and the rights under existing and future liens in favor of the First Intentional Bank of Israel Ltd. securing debt or indentures of up to an aggregate amount of $100,000. Under the terms of the Bank Leumi Credit Facility, we undertook to instruct the underwriters in this offering to transfer to our bank account at Bank Leumi any proceeds from this offering to be transferred to us. In addition, we have irrevocably instructed the escrow agent for the credit line agreement dated August 20, 2014, to transfer to our bank account at Bank Leumi any funds that should be transferred to us pursuant to the escrow agreement. We intend to repay all amounts outstanding under the Bank Leumi Credit Facility with the proceeds of this offering and the concurrent Private Placement. The Company intends to repay all amounts outstanding under the Bank Leumi Credit Facility with the proceeds of this offering.

Reverse Stock Split

On January 15, 2015, our shareholders approved the adoption of our Amended and Restated Articles of Association which reflect a 1-for-20 reverse stock split of our ordinary shares subject to and effective immediately prior to the consummation of this offering. Unless otherwise indicated in this prospectus, all numbers are reflected on a post-split basis.

Conversion of Preferred Shares

On January 15, 2015, our shareholders approved the conversion on a 1:1 basis, of each and every class and series of our authorized and outstanding preferred shares into our pre-split ordinary shares and the conversion on a 1:1 basis of all outstanding preferred share warrants into pre-split ordinary share warrants, in each case, subject to and effective immediately prior to the consummation of this offering.

Election of Directors

On January 15, 2015, our shareholders approved the continued service of Tomer Kariv, Alon Dumanis, Yoav Kimchy, Guy Neev, Walter Robb and Richard Stone as directors of our company following the consummation of this

offering. In addition, subject to the consummation of this offering, our shareholders approved the election of Steven Hanley as a director of our company effective as of the consummation of this offering and the election of Yuval Yanai as an external director (within the meaning of the Israeli Companies Law, 5759-1999, or the Israeli Companies Law) for an initial three-year term commencing on March 15, 2015, subject to the ratification of his election by our shareholders within three months following the consummation of this offering.

On February 12, 2015, our shareholders approved the election of XiangQian (XQ) Lin as a director of the Company subject to and effective as of the consummation of this offering.

The Offering

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| Issuer | Check-Cap Ltd. |
| Securities offered by us in this offering | 2,000,000 units, each consisting of one ordinary share and one-half of a Series A Warrant to purchase one ordinary share. Each unit will be issued with one and one-half non-transferrable Long Term Incentive Warrants to purchase ordinary shares, for a total of 3,000,000 Long Term Incentive Warrants. |
| Over-allotment option | The underwriters have an option for a period of 45 days to purchase up to 300,000 additional units (together with an accompanying 450,000 Long Term Incentive Warrants) to cover over-allotments, if any. |
| Ordinary shares outstanding immediately prior to the offering | 6,137,580 ordinary shares |
| Securities to be issued in the concurrent Private Placement | 1,714,286 units, each consisting of one ordinary share and one-half of a Series A Warrant to purchase one ordinary share. Each unit will be issued with one and one-half Long Term Incentive Warrants for a total of 2,571,429 Long Term Incentive Warrants. |
| Ordinary shares to be outstanding immediately after the offering and the concurrent Private Placement(1) | 9,851,866 ordinary shares (or 10,151,866 ordinary shares if the underwriters exercise in full their option to purchase additional units (together with the accompanying Long Term Incentive Warrants)) |
| Terms of the Series A Warrants | Exercise price: $8.75 per ordinary share, which is equal to 125% of the offering estimated price of the units in this offering.<br><br>Exercisability: Each whole Series A Warrant is exercisable for one ordinary share, subject to adjustment as described herein. Series A Warrants will not be rounded up to the next whole Series A Warrant and only whole Series A Warrants will be exercisable for full ordinary shares.<br><br>Exercise period: Each Series A Warrant will be exercisable 45 days after the date of this prospectus and will expire on , 2020; provided in each case that we have an effective registration statement under the Securities Act covering the |

ordinary shares issuable upon exercise of the Series A Warrants and a current prospectus in respect thereof is available, and such shares are registered, qualified or exempt from registration under the securities laws of the state of residence of the holder. We have agreed to use our reasonable best efforts to maintain the effectiveness of the registration statement and current prospectus relating to ordinary shares issuable upon exercise of the Series A Warrants at any time that the Series A Warrants are exercisable. During any period that we fail to have maintained an effective registration statement covering the ordinary shares underlying the Series A Warrants, the holder may exercise the Series A Warrants on a cashless basis.

See “Description of Share Capital and Securities Offered Hereby” for more information.

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| Terms of the Long Term Incentive Warrants | Exercise price: $8.05 per ordinary share, which is equal to 115% of the estimated price of the units in this offering<br><br>Exercisability: Upon vesting, each whole Long Term Incentive Warrant will entitle the holder to purchase one ordinary share, subject to adjustment as described herein. Long Term Incentive Warrants will not be rounded up to the next whole Long Term Incentive Warrant and only whole Long Term Incentive Warrants will be exercisable for full ordinary shares. One-third of the Long Term Incentive Warrants held by each holder who has held the ordinary shares underlying the units purchased by such holder in this offering for a period of one year following the closing date of this offering will vest and become exercisable on the first anniversary of the closing date of this offering. The remaining two-thirds of the Long Term Incentive Warrants held by each holder who has held the ordinary shares underlying the units purchased by such holder in this offering for a period of two years following the closing date of this offering will vest and become exercisable on the second anniversary of the closing date of this offering. The Long Term Incentive Warrants will not be transferrable and will expire on , 2022. Any transfer of the Long Term Incentive Warrants will be null and void.<br><br>In addition to the vesting conditions described above, for a holder of Long Term Incentive Warrants to be able to exercise its Long Term Incentive Warrants, such holder must, within 120 days of the closing of the offering, register the ordinary shares underlying the units purchased by such holder in the offering in its name and not in "street name."<br><br>If the Long Term Incentive Warrant holder fails to timely register the ordinary shares underlying the units purchased by such holder in the offering, the Long Term Incentive Warrants held by such holder will automatically expire. In addition, if the Long Term Incentive Warrant holder transfers all or any portion of the ordinary shares underlying the units purchased by such holder in the offering during the one and two year vesting periods described above (other than by way of a "permitted transfer" (defined elsewhere in this prospectus)), the holder will forfeit a pro rata portion of the Long Term Incentive Warrants held by such holder. By way of example, if the Long Term Incentive Warrant holder purchases 100 units in the offering and transfers 50 ordinary shares in an unpermitted transfer or series of transfers during the first two years following the offering, such holder will forfeit one-half of its unvested Long Term Incentive Warrants.<br><br>Exercise period: Each Long Term Incentive Warrant will be exercisable upon vesting, provided in each case that we have an effective registration statement under the Securities Act covering the ordinary shares issuable upon exercise of the Long Term Incentive |

Warrants and a current prospectus in respect thereof is available, and such shares are registered, qualified or exempt from registration under the securities laws of the state of residence of the holder, and will expire on , 2022. We have agreed to use our reasonable best efforts to maintain the effectiveness of the registration statement and current prospectus relating to ordinary shares issuable upon exercise of the Long Term Incentive Warrants at any time that the Long Term Incentive Warrants are exercisable. During any period that we fail to have maintained an effective registration statement covering the ordinary shares underlying the Long Term Incentive Warrants, the holder may exercise the Long Term Incentive Warrants on a cashless basis.

Transferability: The Long Term Incentive Warrants are not transferrable.

See “Description of Share Capital and Securities Offered Hereby” for additional information.

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| Separation of ordinary shares and Series A Warrants issued as part of the units | The units will begin trading on, or promptly after, the date of this prospectus. The units will automatically separate and each of the ordinary shares and Series A Warrants underlying the units will begin trading separately on the 45th day after the date of this prospectus, unless Chardan Capital Markets, LLC, as representative of the underwriters, determines that an earlier date is acceptable (based upon, among other things, its assessment of the relative strengths of the securities markets and small capitalization companies in general, and the trading pattern of, and demand for, our securities in particular). If Chardan Capital Markets, LLC permits separate trading of the ordinary shares and Series A Warrants prior to , 2015, we will issue a press release and file a Current Report on Form 6-K with the Securities and Exchange Commission announcing when such separate trading will begin. |
| Use of Proceeds | We estimate that the net proceeds from our issuance and sale of 2,000,000 units in this offering will be approximately $11.7 million, based on the offering price of $7.00 per unit, and after deducting underwriting discounts and commissions and offering expenses payable by us. If the representative of the underwriters exercises the over-allotment option in full, we estimate that the net proceeds from this offering will be approximately $13.6 million, based on the offering price of $7.00 per unit, and after deducting underwriting discounts and commissions and offering expenses payable by us. We will also expect to receive net proceeds of approximately $10.9 million from the sale of 1,714,286 units in the concurrent Private Placement after deducting commissions and estimated expenses payable by us. We currently expect to use the net proceeds from this offering and the concurrent Private Placement as follows:<br><br>· approximately $5.3 million on research and development;<br><br>· approximately $4.0 million on regulatory submissions for approvals of our product, including approximately $3.5 million on clinical trials in Europe and the United States;<br><br>· approximately $0.6 million to build our manufacturing capabilities for the clinical phase;<br><br>· approximately $1.1 million for the repayment of indebtedness incurred under the Bank Leumi Credit Facility; and<br><br>· the balance, if any, for other general corporate purposes. |

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| | See "Use of Proceeds" beginning on page 52 of this prospectus. |
| Private Placement | Concurrent with this offering, we expect to complete a Private Placement of 1,714,286 units at a purchase price per unit equal to the public offering price in accordance with Regulation S under the Securities Act or Regulation D under the Securities Act, to certain investors including certain of our affiliates. Each unit sold in the Private Placement will be issued with one and one-half non-transferrable Long Term Incentive Warrants. The issuance and sale of such units and Long Term Incentive Warrants will not be registered under the Securities Act. We expect to receive $10.9 million in aggregate net proceeds from the Private Placement. The closing of the Private Placement is conditioned upon the completion of the offering to which this prospectus relates. However, the completion of the offering to which this prospectus relates is not conditioned upon the closing of the Private Placement. See "Summary—Recent Developments—Credit Line Agreement; Private Placement." |
| Underwriter Warrants | We will issue to Chardan Capital Markets, LLC as representative of the underwriters, upon closing of this offering, warrants entitling the underwriter to purchase 5% of the aggregate number of ordinary shares included in the units issued in this offering, but not including the over-allotment option. The underwriter warrants may be exercised commencing on a date which is one year after the effective date of this Registration Statement and expire four years following the date of effectiveness of the Registration Statement on Form F-1 of which this prospectus forms a part. |

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| Dividend Policy | We do not anticipate declaring or paying any cash dividends on our ordinary shares following this offering. |
| Transfer Agent and the Registrar | American Stock Transfer & Trust Company LLC |
| Risk Factors | Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 17 of this prospectus and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities. |
| Proposed Symbols and Listing | We have applied for the listing our ordinary shares on the NASDAQ Capital Market under the symbol "CHEK." We intend to apply for the listing of our units and warrants on the NASDAQ Capital Market under the symbols "CHEKU" and "CHEKW," respectively. |

(1) The number of ordinary shares to be outstanding after our initial public offering and the concurrent Private Placement is based on 6,137,580 ordinary shares outstanding as of February 17, 2015, and excludes:

- 948,000 ordinary shares issuable upon the exercise of outstanding warrants to purchase preferred shares (comprised of (i) warrants to purchase 41,822 Series C-1 preferred shares; (ii) warrants to purchase 50,399 Series C-2 preferred shares; (iii) warrants to purchase 25,196 Series D-1 preferred shares; and (iv) warrants to purchase 830,583 Series D-2 preferred shares, following their conversion into warrants to purchase ordinary shares immediately prior to the closing of this offering) with a weighted average exercise price of $8.97 per ordinary share;

- 203,489 ordinary shares issuable upon the exercise of outstanding warrants, which will become exercisable in full, for no consideration, upon the exercise by Mr. Guy Neev of his options to purchase 99,774 ordinary shares, or the Neev Options, immediately prior to the closing of this offering;

- 10,587 ordinary shares issuable upon the exercise of outstanding warrants, which will be automatically exercised, for no consideration, following the exercise by Mr. Guy Neev of the Neev Options immediately prior to the closing of this offering in proportion to the number of warrants held by the optionee with respect to which such warrants were granted that are exercised by the optionee from time to time;

- 2,712,740 ordinary shares issuable upon the exercise of outstanding warrants, of which (i) warrants to purchase 2,491,201 ordinary shares have an exercise price of NIS 0.20 per ordinary share and are fully vested; (ii) warrants to purchase 110,770 ordinary shares have an exercise price of NIS 0.20 per ordinary share and will become fully vested upon the closing of this offering; and (iii) warrants to purchase 110,769 ordinary shares have an exercise price per share equal to the effective price per share of the ordinary shares underlying the units sold to the public in this offering, which will become fully vested upon the closing of this offering;

- 616,198 ordinary shares issuable upon the exercise of outstanding options with a weighted average exercise price of $3.30 per ordinary share, granted under our 2006 Unit Option Plan;
- 373,849 ordinary shares issuable upon the exercise of outstanding options granted under our 2006 Unit Option Plan, which will become fully vested upon the closing of this offering, of which (i) 83,078 options have an exercise price of NIS 0.20 per ordinary share; and (ii) 290,771 options will be exercisable at the effective price per share of the ordinary shares underlying the units sold to the public in this offering;
- 38,473 ordinary shares issuable upon the exercise of options with an exercise price of $4.96 per ordinary share, under our 2006 Unit Option Plan, which we have agreed that certain executive officers will be entitled to upon completion of an equity financing, which includes this offering;
- a number of ordinary shares constituting 4% of our fully-diluted share capital (including the option pool) immediately following the consummation of this offering that will be available for future option grants under our 2006 Unit Option Plan;
- the ordinary shares issuable upon the exercise of warrants to be issued to certain finders in connection with the credit line agreement if either (i) the credit line amount extended to us is invested in units in a private placement on or prior to February 18, 2015; or (ii) if we do not consummate an IPO on or prior to February 18, 2015 and we call the credit line amount, upon conversion of the credit line amount into ordinary shares in accordance with the terms of the credit line agreement;
- 15,000 ordinary shares issuable upon the exercise of warrants with an exercise price per ordinary shares equal to the effective price per share of the ordinary shares underlying the units sold to the public in this offering to be issued to our U.S. legal counsel as partial compensation for services rendered in connection with the offering;
- the ordinary shares issuable upon the exercise of the Series A Warrants included in the units offered hereby;
- the ordinary shares issuable upon the exercise of the Long Term Incentive Warrants; and
- 100,000 ordinary shares issuable upon exercise of the underwriter warrants to be issued in connection with this offering.

Except as otherwise indicated, information in this prospectus reflects or assumes:

- the adoption of our amended and restated articles of association immediately prior to the closing of this offering, which will replace our articles of

association currently in effect;.

- a 1-for- 20 reverse split of our ordinary shares, which will occur immediately prior to the closing of this offering;
- 1,152,138 ordinary shares outstanding as of the date hereof;
- the conversion of all outstanding preferred shares on a 1:1 basis into an aggregate of 4,338,998 ordinary shares immediately prior to the closing of this offering;
- the issuance of 99,774 ordinary shares to Mr. Guy Neev upon the exercise immediately prior to the closing of this offering of the Neev Options;
- the issuance of 171,715 ordinary shares under warrants that will be automatically exercised, for no consideration, upon the exercise by Mr. Guy Neev of the Neev Options immediately prior to the closing of this offering;
- the issuance of an aggregate of 167,262 ordinary shares to certain lenders under the credit line agreement dated August 20, 2014 upon the exercise, immediately prior to the closing of this offering, of warrants granted to them at the closing of the credit line agreement;
- the issuance of an aggregate of 207,693 ordinary shares to certain of our executive officers upon the exercise of options immediately prior to the closing of this offering;
- the issuance of 1,714,286 units in the Private Placement at the initial public offering price per unit;
- an initial public offering price of $7.00, which is the mid-point of the range set forth of the front cover of this prospectus; and
- that the underwriters do not exercise their over-allotment option.

Summary Financial Data

You should read the following summary financial information in conjunction with our financial statements and related notes, "Selected Financial Information" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

The following tables set forth our summary financial data. You should read the following summary financial data in conjunction with, and it is qualified in its entirety by reference to, our historical financial information and other information provided in this prospectus, including "Selected Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes appearing elsewhere in this prospectus.

The summary statements of comprehensive loss data for the years ended December 31, 2012 and 2013, and the statements of financial position data as of December 31, 2013 are derived from our audited financial statements appearing elsewhere in this prospectus. The summary statements of comprehensive loss data for the six-month periods ended June 30, 2013 and 2014, and the statements of financial position data as of June 30, 2014 are derived from our unaudited financial statements appearing elsewhere in this prospectus. The unaudited financial statements have been prepared on the same basis as the audited financial statements and, in the opinion of management, reflect all adjustments necessary to present fairly our financial position as of June 30, 2014 and our results of operations for the six months ended June 30, 2013 and 2014. The historical results set forth below are not necessarily indicative of the results to be expected in future periods. Our financial statements have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board.

Statements of Comprehensive Loss Data

| | Year Ended December 31, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2013 | 2012 | 2014 | 2013 |
| | (US$ in thousands, except per share data) | | | |
| | | | (Unaudited) | |
| Research and development expenses, net(1) | $ 2,662 | $ 2,692 | $ 1,640 | $ 1,364 |
| General and administrative expenses | 1,090 | 1,203 | 564 | 520 |
| Other expenses (income) | (10) | 13 | -- | -- |
| Operating loss | 3,742 | 3,908 | 2,204 | 1,884 |
| Finance income | (63) | (416) | (60) | (45) |
| Finance expenses | 316 | 229 | 85 | 230 |
| Finance expenses (income), net | 253 | (187) | 25 | 185 |
| Loss and total comprehensive loss for the period | 3,995 | 3,721 | 2,229 | 2,069 |
| Loss per ordinary share of NIS 0.20 par value, basic and diluted(2) | 3.66 | 3.49 | 1.97 | 1.87 |
| Weighted average number of ordinary shares outstanding – basic and diluted (in thousands)(2) | 1,627 | 1,627 | 1,627 | 1,627 |
| Pro forma loss per ordinary share of NIS 0.20 par value(3) | | | | |
| Basic and diluted (unaudited)(2) | $ 0.67 | $ 0.62 | $ 0.37 | $ 0.35 |
| Pro forma weighted average number of | 5,966 | 5,966 | 5,966 | 5,966 |

| | |
|---|---|
| ordinary shares outstanding - basic and diluted (in thousands) (unaudited)(2) | |

| Statements of Financial Position Data | As of December 31, 2013 | As of June 30, 2014 | | |
|---|---|---|---|---|
| | | Actual | Pro forma(3) | Pro forma as adjusted(4) |
| | | (US$ in thousands) Unaudited | | |
| Cash and cash equivalents | $ 4,975 | $ 2,794 | $ 2,822 | $ 25,392 |
| Working capital(5) | 4,131 | 1,990 | 2,018 | 24,588 |
| Total assets | 5,375 | 3,276 | 3,304 | 25,874 |
| Capital stock | 23,676 | 23,716 | 23,744 | 46,314 |
| Total shareholders' equity (deficit) | $ 1,191 | $ (998) | $ (970) | $ 21,600 |

(1) Research and development expenses, net is presented net of the differences between the amount of grants received from the OCS and the fair value of their financial liability. The effect of the participation by the OCS totaled $0.4 million and $0.2 million for the years ended December 31, 2013 and 2012, respectively. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Financial Operations Overview—Research and Development, Expenses, Net" for more information.

(2) Basic and diluted loss per ordinary share is computed based on the basic and diluted weighted average number of ordinary shares outstanding during each period. For purposes of these calculations, the following ordinary shares are deemed to be outstanding: (i) the 99,774 ordinary shares issuable to Mr. Guy Neev upon exercise of the Neev Options; and (ii) the 375,204 ordinary shares issuable under warrants that will be automatically exercised, for no consideration (unless the holder thereof objects to such exercise), upon the exercise by Mr. Guy Neev of the Neev Options, of which 171,715 options will be exercised immediately prior to the closing of this offering upon the exercise by Mr. Guy Neev of the Neev Options. For additional information, see Note 17 to our financial statements for the year ended December 31, 2013 included elsewhere in this prospectus.

(3) On a pro forma basis to give effect to the conversion immediately prior to the completion of this offering of all of our outstanding preferred shares into 4,338,998 ordinary shares and to the increase in shareholders capital due to the exercise of the Neev Options and certain other options and warrants and the receipt by us of the aggregate proceeds of $28,000 upon such exercise.

(4) On a pro forma as adjusted basis to give further effect to (i) the issuance and sale of units by us in this offering at an assumed initial public offering price of $7.00 per unit, the midpoint of the estimated initial public offering price range set forth on the cover of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, together with the accompanying Long Term Incentive Warrants; and (ii) the issuance and sale of units by us in the concurrent Private Placement at an assumed price of $7.00 per unit, the estimated public offering price, after deducting commissions and estimated expenses payable by us in connection with the concurrent Private Placement, together with the accompanying Long Term Incentive Warrants.

(5) Working capital is defined as total current assets minus total current liabilities.

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# RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the following risk factors and all other information contained in this prospectus, including the financial statements and the related notes appearing at the end of this prospectus, before purchasing our securities. If any of the following risks actually occur, they may materially harm our business and our financial condition and results of operations. In any such event, the market price of our securities could decline and you could lose all or part of your investment

## Risks Related to Our Business

### We have a history of losses, may incur future losses and may not achieve profitability.

We are a clinical and development-stage medical diagnostics company with a limited operating history. We have incurred net losses in each fiscal year since we commenced operations in 2009. We incurred net losses of $3.7 million in 2012, $4.0 million in 2013 and $2.2 million in the six months ended June 30, 2014. As of June 30, 2014, our accumulated deficit was $24.7 million. Our losses could continue for the foreseeable future as we continue our investment in research and development and clinical trials to complete the development of our technology and to attain regulatory approvals, begin the commercialization efforts for our imaging capsule, increase our marketing and selling expenses, and incur additional costs as a result of being a public company in the United States. The extent of our future operating losses and the timing of becoming profitable are highly uncertain, and we may never achieve or sustain profitability.

### We may not succeed in completing the development of our product, commercializing our product and generating significant revenues.

Since commencing our operations, we have focused on the research and development and limited clinical trials of our imaging capsule. Our product is not approved for commercialization and has never generated any revenues. Our ability to generate revenues and achieve profitability depends on our ability to successfully complete the development of our product, obtain market approval and generate significant revenues. The future success of our business cannot be determined at this time, and we do not anticipate generating revenues from product sales for the foreseeable future. In addition, we have no experience in commercializing our imaging capsule and face a number of challenges with respect to our commercialization efforts, including, among others, that:

- we may not have adequate financial or other resources to complete the development of our product;
- we may not be able to manufacture our products in commercial quantities, at an adequate quality or at an acceptable cost;
- we may not be able to establish adequate sales, marketing and distribution channels;
- healthcare professionals and patients may not accept our imaging capsule;
- we may not be aware of possible complications from the continued use of our imaging capsule since we have limited clinical experience with respect to the actual use of our imaging capsule;
- technological breakthroughs in CRC screening, treatment and prevention may reduce the demand for our imaging capsule;
-

changes in the market for CRC screening, new alliances between existing market participants and the entrance of new market participants may interfere with our market penetration efforts;

- third-party payors may not agree to reimburse patients for any or all of the purchase price of our imaging capsule, which may adversely affect patients' willingness to purchase our imaging capsule;

- uncertainty as to market demand may result in inefficient pricing of our imaging capsule;

- we may face third-party claims of intellectual property infringement;

- we may fail to obtain or maintain regulatory approvals for our imaging capsule in our target markets or may face adverse regulatory or legal actions relating to our imaging capsule even if regulatory approval is obtained; and

- we are dependent upon the results of ongoing clinical studies relating to our imaging capsule and the products of our competitors.

If we are unable to meet any one or more of these challenges successfully, our ability to effectively commercialize our imaging capsule could be limited, which in turn could have a material adverse effect on our business, financial condition and results of operations.

Our early clinical experience to date may not have revealed certain potential limitations of the technology and potential complications from our imaging capsule.

To date, we have performed clinical studies with a prior version of our imaging capsule and with several versions of non-imaging capsules. The clinical trial that was conducted using the prior version of our imaging capsule was conducted under a different protocol and used a different group of patients. Therefore, we will have a limited ability to identify potential problems and/or inefficiencies concerning our imaging capsule in advance of its use in patients and we cannot assure you that its actual clinical performances will be satisfactory, or that its use will not result in unanticipated complications. Furthermore, the results from our first clinical studies and the previous pre-clinical studies may not be indicative of the clinical results obtained when we examine our final imaging capsule on real screening population. If our imaging capsule does not function as expected over time, we could be subject to liability claims, our reputation may be harmed and our imaging capsule would not be widely adopted.

We expect to derive most of our revenues from sales of one product or product line. Our inability to successfully commercialize this product, or any subsequent decline in demand for this product, could severely harm our ability to generate revenues.

We are currently dependent on the successful commercialization of our imaging capsule to generate revenues. As a result, factors adversely affecting our ability to successfully commercialize, or the pricing of or demand for, this product could have a material adverse effect on our financial condition and results of operations. If we are unable to successfully commercialize or create market demand for our imaging capsule, we will have limited ability to generate revenues.

Furthermore, and consequently, we are vulnerable to fluctuations in demand for our imaging capsule. Such fluctuations in demand may be due to many factors, including, among others:

- market acceptance of a new product, including healthcare professionals' and patients' preferences;

- development of similarly cost-effective products by our competitors;

- development delays of our imaging capsule;

- technological innovations in CRC screening, treatment and prevention;

- adverse medical side effects suffered by patients using our imaging capsule, whether actually resulting from the use of our imaging capsule or not;

- changes in regulatory policies toward CRC screening or imaging technologies;

- changes in regulatory approval or clearance requirements for our product;
- third-party claims of intellectual property infringement;
- budget constraints and the availability of reimbursement or insurance coverage from third-party payors for our imaging capsule;
- increases in market acceptance of other technologies; and
- adverse responses from certain of our competitors to the offering of our imaging capsule.

If healthcare professionals do not recommend our product to their patients, our imaging capsule may not achieve market acceptance and we may not become profitable.

CRC screening candidates are generally referred by their healthcare professional to a specified device and screening technologies are purchased by prescription. If healthcare professionals, including physicians, do not recommend or prescribe our product to their patients, our imaging capsule may not achieve market acceptance and we may not become profitable. In addition, physicians have historically been slow to change their medical diagnostic and treatment practices because of perceived liability risks arising from the use of new products. Delayed adoption of our imaging capsule by healthcare professionals could lead to a delayed adoption by patients and third-party payors. Healthcare professionals may not recommend or prescribe our imaging capsule until certain conditions have been satisfied including, among others:

- there is sufficient long-term clinical evidence to convince them to alter their existing screening methods and device recommendations;
- there are recommendations from other prominent physicians, educators and/or associations that our imaging capsule is safe and effective;
- we obtain favorable data from clinical studies for our imaging capsule;
- reimbursement or insurance coverage from third-party payors is available; and
- they become familiar with the complexities of our imaging capsule.

We cannot predict when, if ever, healthcare professionals and patients may adopt the use of our imaging capsule. Even if favorable data is obtained from clinical studies for our imaging capsule, there can be no assurance that prominent physicians would endorse it or that future clinical studies will continue to produce favorable data regarding our imaging capsule. In addition, prolonged market exposure may also be a pre-requisite to reimbursement or insurance coverage from third-party payors. If our imaging capsule does not achieve an adequate level of acceptance by patients, healthcare professionals and third-party payors, we may not generate significant product revenues and we may not become profitable.

If we are unable to market and sell our imaging capsule, we may not become profitable.

We have not had any sales of our imaging capsule to date. There can be no assurance that we will be able to receive regulatory clearance for our imaging capsule in the foreseeable future or ever or that our imaging capsule will be accepted as comparable or superior to existing technologies for the visualization, imaging or screening of the colon. Our ability to market and sell our imaging capsule successfully depends on one or more of the following:

- the existence of clinical data sufficient to support the use of our imaging capsule for the visualization, imaging, or screening of the colon as compared to other colon visualization, imaging or screening methods (if clinical trials indicate that our imaging capsule is not as clinically effective as other current methods, or if our technology causes unexpected complications or other unforeseen negative effects, we may not obtain regulatory clearance or approval to market and sell our imaging capsule or physicians may be reluctant to use it);
- the availability of sufficient clinical data for physicians to use our imaging capsule in their practice and for private third-party payors to make an adequate reimbursement decision to provide coverage for our imaging capsule; and
- the availability of a reliable contrast agent for our imaging capsule that is accepted by physicians and patients.

If one or more of the above conditions is not satisfied, we may not be able to market and sell our imaging capsule or the demand for our imaging capsule may be lower than expected and sales of our imaging capsule may not contribute to our growth at the rate we expect or at all.

We expect to face competition from large, well-established manufacturers of traditional technologies for detecting gastrointestinal disorders, as well as from other manufacturers of optical capsule endoscopy systems.

Competition for our imaging capsule comes from traditional well-entrenched manufacturers of equipment for detecting gastrointestinal disorders and diseases, such as colonoscopy, sigmoidoscopy, optical capsule endoscopy and CTC. The principal manufacturers of equipment for optical colonoscopy, sigmoidoscopy and optical capsule endoscopy are Olympus, Richo Company Ltd., Hoya, Covidien plc and Fuji Film. The principal manufacturers of equipment for CTC are General Electric Healthcare Systems, Siemens Medical Solutions, Philips Medical Systems Ltd. and Toshiba Corporation. All of these companies have substantially greater financial resources than we do, and they have established reputations as well as worldwide distribution channels for providing medical instruments to physicians.

In addition, several companies are developing technologies based on molecular diagnostics (from blood and other bodily fluids), or MDx, tests that investigate the link between genes and the function of metabolic pathways, drug metabolism and disease development with a primary focus on the study of DNA, RNA and proteins. Genetic markers can be traced within stool samples in minute quantities. A U.S. based company, Exact Sciences, is developing a special collecting kit for stool samples and an analyzer to diagnose CRC based on these stool-based markers. The method of screening for colon cancer using stool DNA testing has been endorsed by the ACS, the U.S. Multi-Society Task Force on Colorectal Cancer and the American College of Radiology, but not by the U.S. Preventive Services Task Force.

Certain companies are developing or commercializing optics-based optical capsule endoscopy systems. The existing capsule technology requires intense bowel cleansing, even more so than is required for colonoscopy. Given Imaging, an Israeli-based company that was acquired by Covidien plc (NYSE: COV) in February 2014, has developed visualization capsules for the detection of disorders of the esophagus, small bowel and colon. It launched its PillCamColon capsule in Europe in 2007 and has limited sales. In early 2014, the FDA granted approval for optical capsule endoscopy for colon cancer screening only for patients after incomplete colonoscopy. However, this technology requires bowel cleansing to an even greater degree than that required for regular optical colonoscopy, which can result in dehydration and, in turn, can lead to cancellation of the procedure in certain cases. Other companies, including Olympus, Intromedic and RF System, are developing similar approaches for optical capsule endoscopy.

Procedures for bowel cleansing that are less onerous are constantly being developed, which could make our entry into the market more difficult. For instance, bowel cleansing initiated by the ingestion of pills rather than through drinking large amounts of distasteful liquids may be viewed as an improvement to the cleansing process, but other screening methods may be even more palatable to patients.

If we are unable to convince physicians to adopt our imaging capsule over the current technologies marketed by our competitors, our results of operations may suffer.

We are planning to rely on local distributors to market and distribute our imaging capsule.

We are planning to rely on distributors for the marketing and distribution of our imaging capsule. Our success in generating sales in countries or regions where we will engage local distributors will depend in part on the efforts of third parties over whom we have limited control. If we are unable to identify suitable local distributors in the countries where we intend to market and distribute our imaging capsule, our business, financial condition and results of operations could be negatively affected.

We have limited manufacturing capabilities and if we are unable to scale our manufacturing operations to meet anticipated market demand, our growth could be limited and our business, financial condition and results of operations could be materially adversely affected.

We currently have limited resources, facilities and experience in commercially manufacturing sufficient quantities of our imaging capsule, external receiver and software application to meet the demand we expect from our expanded commercialization efforts. We expect to face certain technical challenges as we increase manufacturing capacity, including, among others, logistics associated with the handling of radioactive materials, equipment design and automation, material procurement, lower than expected yields and increased scrap costs, as well as challenges related to maintaining quality control and assurance standards. Furthermore, we may encounter similar or unforeseen challenges initiating and later expanding production of any new products. If we are unable to scale our manufacturing capabilities to meet market demand, our growth could be limited and our business, financial condition and results of operations could be materially adversely affected.

In addition, we have received grants from Government of the State of Israel through the OCS (see “Risk Factors – Risks Related to Our Operations in Israel”), the terms of which require that products developed with OCS grants be manufactured in Israel and that the technology developed thereunder may not be transferred outside of Israel, unless prior approval is received from the OCS, which we may not receive. We are currently considering whether it would be possible to assemble the capsule without the X-ray source in Israel, and have the X-ray source subsequently inserted into our imaging capsule at a reactor or cyclotron site or at a distribution center outside Israel. Even following the full repayment of any OCS grants, we must nevertheless continue to comply with the requirements of the Encouragement of Industrial Research and Development Law 5744-1984, or the Research Law. The foregoing restrictions may impair our ability to outsource or transfer development or manufacturing activities with respect to any product or technology outside of Israel.

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

We currently depend on limited source suppliers for some of the components necessary for the production of our product. For example, for the current version of the imaging capsule used in clinical trials, we currently have one leading supplier for the motor that we are using to rotate the collimated X-ray source in our imaging capsule and we currently have one leading supplier for the X-ray detectors used in our imaging capsule. There are a limited number of manufacturers worldwide who are capable of manufacturing the motor and the specially designed X-ray detectors that we currently use in our imaging capsule. In addition, the application-specific integrated circuit, or ASIC, residing in our imaging capsule is currently manufactured for us by a single semiconductor fabrication plant, or FAB. There are many alternative FABs worldwide and the design of our current ASIC could be adapted in the event it became necessary to use an alternative FAB. Our current suppliers have been able to supply the required quantities of such components to date. However, if the supply of these components is disrupted or terminated or if our current suppliers are unable to supply required quantities of components, we may not be able to find alternative sources for these key components in a timely manner. Although we are planning to maintain strategic inventory of key components, the inventory may not be sufficient to satisfy the demand for our imaging system if such supply is interrupted or otherwise affected by catastrophic events such as a fire at our storage facility. As a result, we may be unable to meet the demand for our imaging system, 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. In addition, 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 imaging system in a timely manner or within budget. Furthermore, in the event that the manufacturer of a key component of our imaging system 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 imaging system in a timely manner or within budget.

The use of any of our imaging capsule, external receiver or software application could result in product liability or similar claims that could be expensive damage our reputation and harm our business.

Our business exposes us to an inherent risk of potential product liability or similar claims related to the manufacturing, marketing and sale of medical devices. The medical device industry has historically been litigious, and we face financial exposure to product liability or similar claims if the use of any of our imaging capsule, external receiver or software application were to cause or contribute to injury or death, including, without limitation, harm to the body caused by the procedure or inaccurate diagnoses from the procedure that could affect treatment options. There is also the possibility that defects in the design or manufacture of any of these products might necessitate a product recall. Although we plan to 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 business, financial condition and results of operations.

Our imaging capsule is a complex medical device that requires intensive training and care for data analysis.

Our imaging capsule is a complex medical device that requires intensive training and care for data analysis. Although our distributors will be required to ensure that our imaging capsule is only prescribed by trained clinicians, the

potential for misuse of our imaging capsule still exists due to its complexity. Such misuse could result in adverse medical consequences for patients that could damage our reputation, subject us to costly product liability litigation and otherwise have a material adverse effect on our business, financial condition and results of operations.

We depend on third parties to manage our clinical studies and trials and to perform related data collection and analysis and, as a result, we may face costs and delays that are beyond our control.

We rely on third parties, including clinical investigators and clinical sites, to manage our clinical trials and to perform data collection and analysis. Although we have and expect to continue to have contractual arrangements with these third parties, we may not be able to control the amount and timing of resources that these parties devote to our studies and trials or the quality of these resources. If these third parties fail to properly manage our studies and trials, we will be unable to complete them at all or in a satisfactory manner, which could prevent us from obtaining regulatory approvals for, or achieving market acceptance of, our product.

In addition, termination of relationships with third parties may result in delays, inability to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional clinical sites involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new clinical site commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We intend to sell our products in the United States, Europe and Japan and, if we are unable to manage our operations in these territories, our business, financial condition and results of operations could be materially adversely affected.

Our headquarters and all of our operations and employees are presently located in Israel, but we intend to market our products in the United States, Europe and Japan. Accordingly, we are subject to risks associated with international operations, and our international sales and operations will require significant management attention and financial resources. In addition, our international sales and operations will subject us to risks inherent in international business activities, many of which are beyond our control and include, among others:

- foreign certification, registration and other regulatory requirements;
- customs clearance and shipping delays;
- import and export controls;
- trade restrictions;
- multiple and possibly overlapping tax structures;
- difficulty forecasting the results of our international operations and managing our inventory due to our reliance on third-party distributors;
- differing laws and regulations, business and clinical practices, third-party payor reimbursement policies and patient preferences;
- differing standards of intellectual property protection among countries;
- difficulties in staffing and managing our international operations;
- difficulties in penetrating markets in which our competitors' products are more established;
- currency exchange rate fluctuations; and

- political and economic instability, war or acts of terrorism.

If we are unable to manage our international operations effectively, our business, financial condition and results of operations could be materially adversely affected.

We will require additional funding in order to complete the commercialization of our imaging capsule and the development and commercialization of any future products.

Our operations have consumed substantial amounts of cash. We expect that we will need to continue to spend substantial amounts in order to complete the development, clinical development, regulation and commercialization of our imaging capsule. Although we intend to use the proceeds of this offering and the concurrent Private Placement to finance these efforts, we will need to raise additional funds prior to commercialization of our product. Additional financing may not be available to us on a timely basis on terms acceptable to us, or at all. In addition, any additional financing may be dilutive to our shareholders or may require us to grant a lender a security interest in our assets.

Furthermore, if adequate additional financing on acceptable terms is not available, we may not be able to develop our imaging capsule at the rate or to the stage we desire and we may have to delay or abandon the commercialization of our imaging capsule. Alternatively, we may be required to prematurely license to third parties the rights to further develop or to commercialize our imaging capsule on terms that are not favorable to us. Any of these factors could materially adversely affect our business, financial condition and results of operations.

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, research and development team and scientific staff. In order to implement our business strategy, we will need to retain our key personnel with expertise in the areas of research and development, clinical testing, government regulation, manufacturing, finance, marketing and sales. 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.

Substantially all of our operations are currently conducted at a single location near Haifa, Israel, and any disruption at our facility could materially adversely affect our business, financial condition and results of operations.

Substantially all of our operations are conducted at a single location near Haifa, Israel. We take precautions to safeguard our facility, including obtaining insurance coverage and implementing health and safety protocols and off-site storage of computer data. However, a natural or other disaster, such as a fire, flood or an armed conflict involving Israel, as detailed further below, could damage or destroy our facility and our manufacturing equipment or inventory, cause substantial delays in our operations and otherwise cause us to incur additional unanticipated expenses. In addition, the insurance we maintain against fires, floods and other natural disasters may not be adequate to cover our losses in any particular case and it does not cover losses resulting from armed conflicts or terrorist attacks in Israel. Damage to our facility, our other property or to any of our suppliers, whether located in Israel or elsewhere, due to fire, a natural disaster or casualty event or an armed conflict, could materially adversely affect our business, financial condition and results of operations, with or without insurance.

We will incur significant increased costs as a result of operating as a public company in the United States, and our management will be required to devote substantial time to new compliance initiatives.

As a public company in the United States, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, as well as rules and regulations implemented by the U.S. Securities and Exchange Commission and the NASDAQ Stock Market, impose various requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial controls. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some

activities more time consuming and costly. We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs. These rules and regulations could make it more difficult and more expensive for us to obtain certain types of insurance including director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantial costs to maintain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We cannot predict or estimate the amount or timing of additional costs we may incur in order to comply with such requirements.

We will be required to develop and maintain proper and effective internal controls over financial reporting. We may not complete our analysis of our internal controls over financial reporting in a timely manner, or these internal controls may have one or more material weaknesses, which may adversely affect investor confidence in our company and, as a result, the value of our securities.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis will be a costly and time-consuming effort that will need to be evaluated frequently. Section 404 of the Sarbanes-Oxley Act requires the management of public companies to conduct an annual review and evaluation of their internal controls and to obtain an attestation report from their registered public accounting firm regarding the effectiveness of internal controls. We would be required to perform the annual review and evaluation of our internal controls no later than in connection with the second annual report on Form 20-F filed after the offering to which this prospectus relates. However, if we qualify as a smaller reporting company and/or emerging growth company, which we expect to, we will be exempt from the auditors' attestation requirement until such time as we no longer qualify as a smaller reporting company and/or emerging growth company. We would no longer qualify as a smaller reporting company if the market value of our public float exceeded $75 million as of the last day of our second fiscal quarter in any fiscal year following this offering. We would no longer qualify as an emerging growth company at such time as described in the risk factor immediately below.

We are in the early stages of the costly and challenging process of compiling the system and processing documentation necessary to evaluate and correct a material weakness in internal controls needed to comply with Section 404. The material weakness relates to our being a small company with a limited number of employees which limits our ability to assert the controls related to the segregation of duties. During the evaluation and testing process, if we identify one or more additional material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. If we are unable to assert that our internal control over financial reporting is effective, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our securities to decline.

While we currently qualify as an "emerging growth company" under the JOBS Act, we will cease to be an emerging growth company on or before the end of 2019, and at such time our costs and the demands placed upon our management will increase.

We will continue to be deemed an emerging growth company until the earliest of (i) the last day of the fiscal year in which our annual gross revenues exceed $1 billion (as indexed for inflation); (ii) the last day of the fiscal year in which the fifth anniversary of the date of the first sale of securities under this registration statement; (iii) the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt; or (iv) the date on which we are deemed to be a 'large accelerated filer,' as defined by the U.S. Securities and Exchange Commission, which would generally occur upon our attaining a public float of at least $700 million. Once we lose emerging growth company status, we expect the costs and demands placed upon our management to increase, as we will be required to comply with additional disclosure and accounting requirements, particularly if we also no longer qualify as a smaller reporting company.

Risks Related to Regulations

If we are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals, CE Certificates of Conformity, or equivalent third country approvals for our imaging capsule or future products or product enhancements, our ability to commercially distribute and market our products could suffer.

Our products are subject to rigorous regulation by FDA and numerous other federal, state and foreign governmental authorities and notified bodies. The process of obtaining regulatory clearances or approvals, CE Certificates of

Conformity, or equivalent third country approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals, CE Certificates of Conformity, or equivalent third country approvals on a timely basis, if at all. In particular, we expect to eventually generate a portion of our revenues from sales of our imaging capsule and future products in the United States, the European Union, or third countries. Before a new medical device, or a new use of, or claim for, an existing product can be marketed in the United States, it must first receive clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FDA approval of a premarket approval application, or PMA, unless an exemption applies. FDA will clear marketing of a low to moderate risk medical device through the 510(k) process if sufficiently similar predicate devices have previously been cleared via this pathway. In the 510(k) clearance process, FDA must only determine that the proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, with respect to intended use/indications for use, technological characteristics and principles of operation in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence.

High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require approval of a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on the data obtained in clinical trials. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to FDA's satisfaction the safety and efficacy of the device for its intended use.

In instances where a device is novel and there is no suitable predicate device, but that device is deemed to be of low to moderate risk, FDA can reclassify the device to class I or class II via de novo reclassification. This process involves the submission of a reclassification petition, and FDA accepting that "special controls" are adequate to ensure the product's performance and safety. FDA now allows "direct" de novo reclassification petitions, a mechanism by which a sponsor can directly submit a detailed de novo reclassification petition as the device's initial submission without having to first receive a not substantially equivalent, or NSE, decision on a 510(k) submission.

These processes can be expensive and lengthy. FDA's 510(k) clearance process usually takes from 6 to 9 months, but it can last longer. Direct de novo reclassification typically takes at least 9 to 12 months from filing to clearance. The PMA pathway is much more costly and uncertain than the 510(k) clearance process or de novo reclassification, and generally takes at least 12 to 18 months, or even longer, from the time the application is filed with FDA to ultimate approval.

We are not aware of any legally marketed predicate device upon which FDA could base a determination of substantial equivalence under a 510(k) clearance process. Our strategy therefore is to submit a direct de novo reclassification petition for our imaging capsule. To support this petition, our objective is to demonstrate that the device poses a low to moderate risk to patients. We cannot assure you that FDA will not demand that we obtain PMA approval of our imaging capsule.

FDA can delay, limit or deny clearance or approval of an application for many reasons, including, among others:

- we may not be able to demonstrate to FDA's satisfaction that our products are safe and effective for their intended use;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval;
- in the case of a PMA submission, that the manufacturing process or facilities we use may not meet applicable requirements; and
- changes in FDA's 510(k) clearance, de novo reclassification, or PMA approval processes and policies, or the adoption of new regulations may require additional data.

We may not obtain the necessary regulatory clearances, approvals, CE Certificates of Conformity or equivalent third country approvals to market our imaging capsule or future products in the United States or elsewhere. Any delay in, or failure to receive or maintain, clearance, approval or CE Certificates of Conformity for our imaging capsule or other products under development could prevent us from generating revenue from these products or achieving profitability.

There is no guarantee that the FDA will grant de novo reclassification or PMA approval of our imaging capsule and failure to obtain necessary 510(k) clearances or approvals for our future products would adversely affect our ability to grow our business.

Our imaging capsule and some of our future products will require FDA clearance of a 510(k), de novo reclassification, or may require FDA approval of a PMA. The FDA may not approve or clear our imaging capsule or our future products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance, de novo reclassification or premarket approval for our imaging capsule or any other future product, new intended uses or modifications to these products once they are cleared or approved for marketing.

Our strategy is to submit a direct de novo reclassification petition for our imaging capsule. A de novo reclassification generally applies where there is no predicate device and the FDA believes the device poses a low to moderate risk. De novo reclassifications can either be submitted in lieu of a 510(k) notice, such as in our case, or after a 510(k) notice has been filed and found NSE. If a 510(k) notice is found NSE, a de novo petition must be submitted within 30 days from the receipt of the NSE determination.

To support our direct de novo reclassification petition, our objective is to demonstrate that the device poses a low to moderate risk to patients. If the FDA determines that our imaging capsule is not a candidate for de novo reclassification, it will require approval of the device for market through the PMA process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use. By statute, the FDA has 180 days to review the "accepted application," although, generally, review of the application can take between one and three years. During this review period, the FDA may request additional information or clarification of information already provided or even request new data that may require us to conduct additional tests. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. The FDA's review of a PMA could significantly delay our plans to get to market. There is also no guarantee that the FDA would approve a PMA. Failure to receive clearance or approval for our imaging capsule or future products would have an adverse effect on our ability to expand our business.

If we or our future distributors do not obtain and maintain the necessary regulatory clearances or approvals, or CE Certificates of Conformity, or equivalent third country approvals in a specific country or region, we will not be able to market and sell our imaging capsule or future products in that country or region.

We intend to market our imaging capsule in a number of international markets. To be able to market and sell our imaging capsule 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 authorities or that we obtain CE Certificates of Conformity from a Notified Body. These regulations, including the requirements for approvals or CE Certificates of Conformity, and the time required for regulatory review, vary from country to country. Obtaining regulatory approvals or CE Certificates of Conformity is expensive and time-consuming, and we cannot be certain that we or our distributors will receive regulatory approvals or CE Certificates of Conformity for our imaging capsule or any future products in each country or region in which we plan to market such products. If we modify our imaging capsule or any future products, we or our distributors may need to apply for new regulatory approvals or our Notify Body may need to review the planned changes before we are permitted to sell them. We may not meet the quality and safety standards required to maintain the authorizations or CE Certificates of Conformity that we or our distributors have received. If we or our distributors are unable to

maintain our authorizations or CE Certificates of Conformity in a particular country or region, we will no longer be able to sell our imaging capsule or any future products in that country or region, and our ability to generate revenues will be materially and adversely affected.

Our imaging capsule may be considered a drug-device combination product because of the preparatory use of Iodine or barium sulfate to provide a coating for colonic imaging. We cannot be sure how the FDA or the competent regulatory authorities of foreign countries will regulate this product. The review of combination products is often more complex and more time consuming than the review of products under the jurisdiction of only one center within the FDA.

Our imaging capsule may be considered a combination product because of the preparatory use of barium sulfate or Iodine to provide a coating for colonic imaging. A combination product is the combination of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are combined or mixed and produced as a single entity; packaged together in a single package or as a unit; or a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication or effect. For a combination product, the FDA must determine which center or centers within the FDA will review the product and under what legal authority the product candidate will be reviewed. The combination product's primary mode of action is used to determine which center within the FDA has primary regulatory jurisdiction over the product. The other centers within the agency also may provide consulting or collaborative reviews of the product as necessary. We believe that we have put forth a reasonable argument to the FDA that our imaging capsule should be regulated as a device and or a combination product with a device primary mode of action. However, we cannot be sure as to whether the FDA will treat our imaging capsule as a device or a combination product. The review of combination products is often more complex and more time consuming than the review of a product under the jurisdiction of only one center within the FDA. In the case of the imaging capsule, should the FDA determine that the barium sulfate is not being used in accordance with its approved labeling, the Center for Drug Evaluation and Research may take a prominent role it its regulation. If the FDA does not approve or clear our imaging capsule, or any future products, in a timely fashion, or at all, our business and financial condition will be adversely affected.

Similar obstacles may be encountered in foreign countries should our imaging capsule be considered as a combination product.

If the indications for use or instructions for use for which the Iodine-based contrast agent or the barium sulfate- based contrast agent is approved are not sufficiently broad to support its use prior to the ingestion of our imaging capsules, the FDA or the competent regulatory authorities in the EU Member States and other foreign countries may consider that contrast agent is being used off-label.

Ingestion of our imaging capsule requires the preparatory use of Iodine or barium sulfate to provide a coating for colonic imaging. We cannot be sure that the indications for which Iodine-based contrast agent or the barium sulfate-based contrast agent are approved in the United States, the EU Member States or in other countries is sufficiently broad to cover such use. If the FDA or the competent regulatory authorities in the EU Member States and in other countries consider that Iodine and/or barium sulfate is not approved for the purpose for which it is used with the imaging capsules, we may be considered to promote the off-label use of the Iodine and/or barium sulfate. Because the off-label use of drugs or medicinal products is generally prohibited in the United States, the EU Member States and in other countries, we could face both related issues with the FDA and/or the competent authorities of the EU Member States and/or other countries. In these circumstances, the FDA and/or the competent regulatory authorities in the EU Member States and/or other countries may require us to obtain appropriate regulatory approvals for the Iodine-based contrast agent or the barium sulfate-based contrast agent prior to marketing our imaging capsules with such substances. Under such circumstances, should we fail to obtain approval of the contrast agent for use with our imaging capsule, in a timely fashion, or at all, our business and financial condition will be adversely affected.

If we are unable to successfully complete clinical trials with respect to our imaging capsule, we may be unable to receive regulatory approvals or clearances, CE Certificates of Conformity or equivalent third country approvals for

our imaging capsule and/or our ability to achieve market acceptance of our imaging capsule will be harmed.

The development of medical devices typically includes pre-clinical studies. Certain other devices require the submission of data generated from clinical trials, which can be long, expensive and uncertain processes, subject to delays and failure at any stage. The data obtained from the studies and trials may be inadequate to support regulatory clearances or approvals, or to obtain CE Certificates of Conformity or equivalent third country approval, or to allow market acceptance of the products being studied. Our imaging capsule technology is currently undergoing clinical development and clinical trials. To date, we have performed clinical studies with a prior version of our imaging capsule and with several versions of non-imaging capsules.

The development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required, and we may not adequately develop such protocols to support clearance, approval, or to obtain CE Certificates of Conformity or equivalent third country approval. The clinical trial that was conducted using the prior version of our imaging capsule, was conducted under a different protocol and used a group of patients different from those we intend to study in future clinical trials. Further, FDA, the competent regulatory authorities of other countries, or our Notified Body in the EU may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or they may change the data collection requirements or data analysis applicable to our clinical trials.

The commencement or completion of any of our clinical studies or trials may be delayed or halted, or be inadequate to support regulatory clearance, approval or product acceptance, or to obtain CE Certificates of Conformity or equivalent third country approval, for numerous reasons, including, among others:

- patients do not enroll in the clinical trial at the rate we expect;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate we expect;
- patients experience adverse side effects;
- patients die during a clinical trial, even though their death may be unrelated to our product;
- FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- institutional review boards, or IRBs, Ethics Committees and third-party clinical investigators may delay or reject our trial protocol and Informed Consent Form;
- third-party clinical investigators decline to participate in a study or trial or do not perform a study or trial on our anticipated schedule or consistent with the investigator agreements, study or trial protocol, good clinical practices or other FDA or IRBs, Ethics Committees, or any other applicable requirements;
- third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the study or trial protocol or investigational or statistical plans;
- regulatory inspections of our studies, trials or manufacturing facilities may require us to, among other things, undertake corrective action or suspend or terminate our studies or clinical trials;
- changes in governmental regulations or administrative actions;
- the interim or final results of the study or clinical trial are inconclusive or unfavorable as to safety or efficacy; and
- a regulatory agency or our Notified Body concludes that our trial design is or was inadequate to demonstrate safety and efficacy.

The results of pre-clinical and clinical studies do not necessarily predict future clinical trial results, and predecessor clinical trial results may not be repeated in subsequent clinical trials. Additionally, FDA, the competent regulatory authorities of EEU Member States, other third country regulatory entities, or our Notified Body may disagree with our

interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to demonstrate safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which could further delay the clearance, approval, or CE marking of our products. The data we collect from our non-clinical testing, our pre-clinical studies and other clinical trials may not be sufficient to support regulatory clearance, approval or to obtain CE Certificates of Conformity.

If the third parties on which we rely to conduct our clinical trials and clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval, CE Certificates of Conformity, or equivalent third country approval for, or commercialize, our imaging capsule or future products.

We do not have the ability to independently conduct our clinical trials for our imaging capsule and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain CE Certificates of Conformity, regulatory clearance, approval for, or successfully commercialize, our imaging capsule or future products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product claims or that the FDA, foreign authorities or our Notified Body will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that clinical trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our imaging capsule, or any future products, are safe and effective for the proposed indicated uses, which could cause us to abandon a product and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our imaging capsule, or any future products, and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

Even if our imaging capsule or future products are cleared or approved by regulatory authorities or if we obtain CE Certificates of Conformity from our Notified Body, modifications to our imaging capsule or future products may require new regulatory clearances or approvals, new CE Certificates of Conformity, or may require us to recall or cease marketing it until the necessary clearances, approvals or CE Certificates of Conformity are obtained.

Once marketed, modifications to our imaging capsule or future products may require new regulatory approvals, clearances, including 510(k) clearances or premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Any modification to a 510(k)-cleared device that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use, requires a new 510(k) clearance or, possibly, a PMA. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We may make modifications to our imaging capsule in the future that we believe do not or will not require additional clearances or approvals. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. Any recall or FDA requirement that we seek additional approvals or clearances could result in significant delays, fines, increased costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or efficacy, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a premarket approval application. Where we determine that modifications to our products require a new 510(k) clearance or premarket approval application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all.

Any modification to a PMA-approved device must either be approved in a PMA Supplement, or if the modification does not impact the device's safety or effectiveness, described in a 30-Day Notice or in the device's Annual Report. The FDA may not approve a modification described in a PMA Supplement, in which case the modified device cannot be marketed. The FDA can also disagree that a change described in a 30-Day Notice or Annual Report is appropriately described in either filing, and request that the company file a PMA Supplement and/or request that the company cease marketing the modified device until the PMA Supplement is approved.

Similar rules also apply in foreign jurisdictions. In the European Union, or EU, we must inform the Notified Body that carried out the conformity assessment of the medical devices we market or sell in the EU of any planned substantial changes to our quality system or changes to our devices which could affect compliance with the Essential Requirements laid down in Annex I to the Council Directive 93/42/EEC concerning medical devices ("Medical Devices Directive") or the devices' intended purpose. The Notified Body will then assess the changes and verify whether they affect the products' conformity with the Essential Requirements laid down in Annex I to the Medical Devices Directive or the conditions for the use of the device. If the assessment is favorable, the Notified Body will issue a new CE Certificate of Conformity or an addendum to the existing CE Certificate of Conformity attesting compliance with the Essential Requirements laid down in Annex I to the Medical Devices Directive.

If the Notified Body or relevant regulatory authorities disagree with our assessments and require modifications to an existing CE Certificate of Conformity, the preparation of a new CE Certificates of Conformity or new regulatory clearances or approvals for modifications, we may be required to recall and to stop marketing the modified devices.

Obtaining clearances and approvals, or new or amended CE Certificates of Conformity for device modifications can be a time consuming process, and delays in obtaining required future clearances, approvals, or CE Certificates of Conformity would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Even if our imaging capsule and future products are cleared or approved by regulatory authorities or if we obtain CE Certificates of Conformity from our Notified Body, if we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, our products could be subject to restrictions or withdrawal from the market.

The manufacturing processes, reporting requirements, post-approval clinical data and promotional activities associated with any product for which we obtain clearance or approval CE Certificates of Conformity, or equivalent third country approval will be subject to continuous regulatory review, oversight and periodic inspections by FDA other domestic and foreign regulatory authorities and our Notified Body. In particular, we and certain of our suppliers are required to comply with FDA's Quality System Regulations, or QSR. In the EU, we will also be subject to the quality system requirements laid down in the Annexes to the Medical Devices Directive. Such compliance can be facilitated by, among other things, a certificate of compliance with ISO 13485:2003. Through compliance with the ISO 13485:2003 standard, we will benefit from a presumption of conformity with the relevant quality system requirements laid down in the Annexes to Medical Devices Directive. These regulations and standards govern the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval, CE Certificates of Conformity, or equivalent third country approval. Regulatory authorities, such as FDA, and our Notified Body enforce the QSR and other regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations falling within the competence of FDA and other regulatory authorities or our Notified Body, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, corporate integrity agreements, consent decrees and civil penalties;

- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement or refunds;

- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances on PMA approvals that have already been granted;
- suspension or withdrawal of our CE Certificates of Conformity;
- refusal to grant export approval for our products; or
- criminal prosecution.

If any of these actions were to occur, it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

Even if regulatory clearance or approval of a product is granted, or if we obtain CE Certificates of Conformity, such clearance or approval, or CE Certificates of Conformity may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If FDA or the competent regulatory authorities of foreign countries determines that our promotional materials, labeling, training or other marketing or educational activities constitute the promotion of an unapproved use or the promotion of an intended purpose not covered by our CE mark, they could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse side effects or adverse side effects of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension or withdrawal of regulatory approvals or CE Certificates of Conformity, product seizures, injunctions or the imposition of civil or criminal penalties, all of which would adversely affect our business, financial condition and operating results and prospects.

If we fail to maintain necessary regulatory clearances or CE Certificates of Conformity for our imaging capsule and indications in our target foreign markets, if clearances or approvals, or CE Certificates of Conformity for future products and indications are delayed or not issued, or if there are regulatory changes in our existing or future target markets, our commercial operations could be harmed.

Our imaging capsule is a medical device that is subject to extensive regulations that are intended to assure its safety, effectiveness and compliance with applicable consumer laws. If we fail to obtain and maintain these regulatory approvals or clearances, or CE Certificates of Conformity, our ability to sell our imaging capsule and generate revenues will be materially harmed.

These laws and regulations relate to the design, development, testing, manufacturing, storage, labeling, packaging, content and language of the instructions for use of the device, sale, promotion, distribution, importing and exporting, shipping, post-sale surveillance and recall from our imaging capsule's markets, and all countries in which we intend to sell our imaging capsule apply some form of regulations of this kind. Most notably, we must comply with the Medical Devices Directive and are subject to extensive regulation in the United States by FDA and other federal, state and local authorities. In the EU, compliance with the requirements laid down in the Medical Devices Directive, including the Essential Requirements laid down its Annex I thereto, is a prerequisite to be able to affix the CE mark of conformity to our medical devices. Without such CE mark, our products cannot be marketed or sold in the EU. To demonstrate compliance with the Essential Requirements laid down in Annex I to the Medical Devices Directive we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Apart from low risk medical devices (Class I with no measuring function and which are not sterile), in relation to which the manufacturer can make an EC Declaration of Conformity based on self-assessment of the conformity of its products with the Essential Requirements laid down in Annex I to the Medical Devices Directive, a conformity assessment procedure requires the intervention a Notified Body. The Notified Body would typically audit and examine products' Technical File, which we must create, and the quality system for manufacture, design and final inspection of our devices before issuing a CE Certificate of Conformity demonstrating compliance with the relevant Essential Requirements laid down in Annex I to the Medical Devices Directive or the quality system requirements laid down in the other Annexes to the Directive. Following the issuance of this CE Certificate of Conformity, we can draw up an EC Declaration of Conformity and affix the CE mark to the products covered by this CE Certificate of Conformity and by the EC Declaration of Conformity Other countries outside the EU also accept the CE mark as a certification of quality, efficacy and safety of medical devices and an element of related authorization of the products in their territory.

We will be subject to annual audits by a Notified Body under the Medical Devices Directive. During this audit, the third-party assessor or Notified Body will examine the maintenance and implementation of our quality control system, device post-marketing vigilance system and any changes or modifications made to our products.

On September 26, 2012, the European Commission adopted a package of legislative proposals designed to replace the existing regulatory framework for medical devices in the EU. These proposals are intended to strengthen the medical devices rules in the EU. On October 22, 2013, the European Parliament voted in favor of an amended draft of the Regulation. The proposed text is currently being discussed by the Council of the European Union. These adopted or expected regulatory changes may adversely affect our business, financial condition and results of operations or restrict our operations.

Our imaging capsule may in the future be subject to product recalls that could harm our reputation, business and financial results.

FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Once marketed, recalls of any of our products, including our imaging capsule, would divert managerial and financial resources and have an adverse effect on our business, financial condition and results of operations. FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require us to

notify FDA. If FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, FDA could take enforcement action against us based on our failure to report the recalls when they were conducted.

If our imaging capsule or future products cause or contribute to a death or a serious injury, or malfunction in such a way that causes or contributes to a death or serious injury, we will be subject to medical device reporting regulations, which can result in corrective actions or enforcement actions from regulatory authorities.

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

In addition, we must also comply with the EU Medical Device Vigilance System (MEDDEV 2.12/1 rev.8), which is intended to protect the health and safety of patients, users and others by establishing reporting procedures and reducing the likelihood of reoccurrence of incidents related to the use of a medical device. Under this system, incidents (which are defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, may lead to or may have led to the death of a patient, or user or other persons or to a serious deterioration in such person's state of health) must be reported by manufacturers through a Manufacturer's Incident Reports to competent authorities within periods of time specified in the MEDDEV 2.12/1 rev. 8. Such incidents are evaluated and, where appropriate, information is disseminated between the competent authorities of the EU Member States. The MEDDEV 2.12/1 rev. 8 is also intended to facilitate a direct, early and harmonized establishment of Field Safety Corrective Actions, or FSCAs, across the EU Member States in which the device is being marketed. An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA may include device recall, modification, exchange, or destruction. FSCAs must be reported by the manufacturer or the manufacturer's European Authorized Representative, to its customers and/or the end users of the device through a Field Safety Notice. FSCAs must also be reported to the competent authorities of the EU Member States.

Our failure to comply with radiation safety or radio frequency regulations in a specific country or region could impair our ability to commercially distribute and market our imaging capsule in that country or region.

Our imaging capsule includes a tiny X-ray source and wireless radio frequency transmitter and receiver, and is therefore subject to equipment authorization requirements in a number of countries and regions. In the United States, the EU and Japan, authorities often require advance clearance of all radiation and radio frequency devices before they can be sold or marketed in these jurisdictions, subject to limited exceptions. Modifications to the approved system design and specifications may require new or further regulatory clearances or approvals before we are permitted to market and sell a modified system. If we are unable to obtain any required clearances or approvals from the authorities responsible for the radiation as well as the radio frequency regulations in these and other jurisdictions, the sale or use of our imaging capsule could be prevented in these countries. Any such action could negatively affect our business, financial condition and results of operations.

Our business is subject to complex environmental legislation that may increase our costs and our risk of noncompliance.

Our research and development and manufacturing processes involve the handling of potentially harmful radioactive and other hazardous materials. We are subject to local laws and regulations governing the use, shipping, handling, storage and disposal of these materials, and we incur expenses related to compliance with these laws and regulations. If we are found to have violated environmental, health and safety laws, 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. In the future, we could be subject to additional environmental requirements or existing environmental laws could become more stringent, which could lead to greater compliance costs and increasing risks and penalties associated with violations. For example, changes to, or restrictions on, permitting requirements or processes, hazardous or radioactive material storage or handling might require an unplanned capital investment or relocation. If we fail to comply with existing or new environmental laws or regulations, our business, financial condition and results of operations could be materially adversely affected.

If we are unable to achieve reimbursement and coverage from third-party payors for procedures using our imaging capsule, or if reimbursement is insufficient to create an economic benefit for purchasing or using our imaging capsule when compared to alternative procedures, demand for our products may not grow at the rate we expect.

The demand for our imaging capsule will depend significantly on the eligibility of the procedures performed using our imaging capsule 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, and we must obtain reimbursement approvals on a country-by-country and/or region-by-region basis. In general, the process of obtaining reimbursement and coverage approvals has been longer outside of the United States. We may not be able to obtain reimbursement approvals in a timely manner or at all and existing reimbursement and coverage policies may be revised from time to time 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 imaging capsule, if reimbursement is, or is perceived by our customers to be, insufficient to create an economic incentive for purchasing or using our imaging capsule, or if such reimbursement does not adequately compensate physicians and health care providers compared to the other procedures they offer, demand for our products may not grow at the rate we expect.

Federal and state privacy laws, and equivalent laws of third countries, may increase our 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, to which we refer 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 will 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 Act of 2009, or HITECH, 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" of some of our customers. 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 "business associates" to report any breach of unsecured, individually identifiable health information to their covered entity customers and imposes penalties for failing to do so.

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 U.S. state laws, which may be even more stringent than the HIPAA requirements, are not preempted by the federal requirements, and we are therefore required to comply with them to the extent they are applicable to our operations.

These and other possible changes to HIPAA or other U.S. federal or state laws or regulations, or comparable laws 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.

The protection of personal data, particularly patient data, is subject to strict laws and regulations in many countries. The collection and use of personal health data in the EU is governed by the provisions of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, commonly known as the Data Protection Directive. The Directive imposes a number of requirements including an obligation to seek the consent of individuals to whom the personal data relates, the information that must be provided to the individuals, notification of data processing obligations to the competent national data protection authorities of individual EU Member States and the security and confidentiality of the personal data. The Data Protection Directive also imposes strict rules on the transfer of personal data out of the EU to the US. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of the EU Member States may result in fines and other administrative penalties and harm our business. We may incur extensive costs in ensuring compliance with these laws and

regulations, particularly if we are considered to be a data controller within the meaning of the Data Protection Directive.

The adoption of healthcare reform and deficit reduction measures in the United States may adversely affect our business and financial results.

On March 23, 2010, President Obama signed into law major healthcare reform legislation under the Patient Protection and Affordable Care Act of 2010, or the PPACA, which was modified on March 30, 2010 by the enactment of the Health Care and Education Reconciliation Act of 2010. This law substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the device industry. The PPACA is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. Under the PPACA, it is expected that expanded healthcare coverage will be made available to millions of Americans. The increased costs to the U.S. government from the PPACA are expected to be funded through a combination of payment reductions for providers over time and several new taxes. The PPACA imposes, among other things, an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States beginning in 2013, resulting in an anticipated cost to the medical device industry of up to $20 billion over the next decade. We likely will be subject to the excise tax with respect to our imaging capsule if it is approved for sale in the United States. The PPACA also limits the rate of growth in Medicare payments to providers and authorizes certain voluntary demonstration projects beginning no later than 2013 around development of bundling payments for acute, inpatient hospital services, physician services, and post acute services for episodes of hospital care. In addition, the PPACA provides for the establishment of an Independent Payment Advisory Board, or IPAB, that, beginning in 2014, could recommend changes in Medicare payments to physicians and other providers that would take effect unless Congress passes an alternative measure to achieve the same amount of savings. The IPAB has not yet been created. The PPACA also increases fraud and abuse penalties and expands the scope and reach of the Federal Civil False Claims Act and government enforcement tools, which may adversely impact healthcare companies.

The U.S. Supreme Court heard a constitutional challenge to the PPACA and in June 2012 held that the PPACA is constitutional. However, states are allowed to opt out of the expansion of eligibility criteria for Medicaid under the PPACA and many states have chosen to do so, causing many uninsured patients to remain without coverage. In addition to the PPACA, the effect of which cannot presently be quantified given its recent enactment, various healthcare reform proposals have also emerged at the state level. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or the effect any future legislation or regulation will have on us. However, we anticipate that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the price that we receive for any approved product, and could adversely affect our business. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Insurers may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals, all of which may adversely affect our business, financial condition and results of operations, possibly materially.

In addition to health reform, other deficit reduction measures could affect reimbursement for our device and related procedures. For example, beginning April 1, 2013, Medicare payments for all items and services have been reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. These cuts will remain in effect until 2024 unless Congress enacts legislation to cancel or delay the cuts. These payment reductions, or similar efforts to reduce Medicare spending to control the federal deficit, could adversely affect our business by reducing reimbursement to the providers who purchase and use our devices and perform related procedures.

If we fail to comply with the U.S. federal Anti-Kickback Statute and similar state and third country laws, we could be subject to criminal and civil penalties and exclusion from federally funded healthcare programs including the Medicare and Medicaid programs and equivalent third country programs, which would have a material adverse effect on our business and results of operations.

A provision of the Social Security Act, commonly referred to as the federal Anti-Kickback Statute, prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration, directly or indirectly, in cash or in kind, to induce or reward the referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or services payable, in whole or in part, by Medicare, Medicaid or any other federal healthcare program. PPACA, among other things, clarified that a person or entity needs not to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it. Although there are a number of statutory exemptions and regulatory safe harbors to the federal Anti-Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exemption or safe harbor may be subject to scrutiny. The federal Anti-Kickback Statute is very broad in scope and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations. In addition, most of the states have adopted laws similar to the federal Anti-Kickback Statute, and some of these laws are even broader than the federal Anti-Kickback Statute in that their prohibitions may apply to items or services reimbursed under Medicaid and other state programs or, in several states, apply regardless of the source of payment. Violations of the federal Anti-Kickback Statute may result in substantial criminal, civil or administrative penalties, damages, fines and exclusion from participation in federal healthcare programs.

All of our financial relationships with healthcare providers, purchasers, formulary managers, and others who provide products or services to federal healthcare program beneficiaries are potentially governed by the federal Anti-Kickback Statute and similar state laws. We believe our operations are in compliance with the federal Anti-Kickback Statute and similar state laws. However, we cannot be certain that we will not be subject to investigations or litigation alleging violations of these laws, which could be time-consuming and costly to us and could divert management's attention from operating our business, which in turn could have a material adverse effect on our business. In addition, if our arrangements were found to violate the federal Anti-Kickback Statute or similar state laws, the consequences of such violations would likely have a material adverse effect on our business, results of operations and financial condition.

There are other federal and state laws that may affect our ability to operate, including the federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. PPACA amended the Social Security Act to provide that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Moreover, we may be subject to other federal false claim laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs. Moreover, there are analogous state laws. Violations of these laws can result in substantial criminal, civil or administrative penalties, damages, fines and exclusion from participation in federal healthcare programs.

Similar restrictions are imposed by the national legislation of many third countries in which our medical devices will be marketed. Moreover, the provisions of the Foreign Corrupt Practices Act of 1997 and other similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage. Recently, there has been a substantial increase in anti-bribery

law enforcement activity by U.S. regulators, with more aggressive and frequent investigations and enforcement by both the U.S. Securities and Exchange Commission and the Department of Justice. A determination that our operations or activities violated United States or foreign laws or regulations could result in imposition of substantial fines, interruption of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. In addition, lawsuits brought by private litigants may also follow as a consequence.

If the U.S. Nuclear Regulatory Commission, or NRC, or other nuclear regulatory commissions around the world, would take the position that an imaging capsule containing radioactive material cannot be passed in excreta into the sanitary sewer system without limitation, we may be subject to further regulations and patients may be required to retrieve our imaging capsule after use.

As our imaging capsule includes an ingestible capsule with a radioactive source, we must address NRC regulations in addition to FDA requirements as well as regulations of other nuclear regulatory commissions in jurisdictions in which we intend to commercialize our imaging capsule. Our imaging capsule is loaded with the X-ray source, sealed and then ingested by the patient. Although the NRC places conditions and limitations on the disposal of radioactive material in the sanitary sewer, such conditions and limitations do not apply to radioactive material contained in the excreta of individuals that are undergoing medical diagnosis or therapy with radioactive material. However, there is no assurance that the NRC or other regulatory commissions worldwide will take a similar position in relation to our imaging capsule and we may face limitations by the NRC or other nuclear regulatory commissions in jurisdictions in which we intend to commercialize our imaging capsule in relation to the disposal of our imaging capsule in the sanitary system, such as requiring patients to retrieve our imaging capsule after use, which could make our imaging capsule less attractive.

Our failure to comply with the necessary regulatory approval regarding the use of radioactive materials could significantly impair our ability to develop, manufacture and/or sell our imaging capsule.

The manufacture of our imaging capsule requires the use and storage of radioactive materials. In order to use such materials in the development and manufacture of our imaging capsule in Israel, we are required to obtain a permit from the Israeli Commissioner for Environmental Radiation, or the Commissioner, pursuant to the Israeli Pharmaceutical Regulations (Radioactive Elements and By-Products) – 1980. Should we fail to comply with the conditions of our currently existing permit, the Commissioner would have authority to cancel our permit. Should the Commissioner determine that our activities or facilities constitute a danger to the health and well-being of a person, the public or the environment, the cancellation of our permit could be immediate and without prior notice. Furthermore, we cannot guarantee the annual renewal of our permit and/or annual renewal subject to identical conditions, as the approval of an annual application and the conditions thereof are at the discretion of the Commissioner. Similar requirements and regulations may apply to the manufacture of our imaging capsule in other countries. Cancellation of or failure to renew our permit could have materially adverse consequences on our ability to manufacture and sell our products and therefore on our ability to continue our business and operations.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property rights, our competitive position could be harmed.

Our success and ability to compete depends in large part upon our ability to protect our intellectual property. Although we have patents issued in Israel, Europe, United States, Japan, China, India, Hong Kong, and Australia, we continue to file and prosecute in many of the same countries and additional countries such as Canada and Korea. We face several risks and uncertainties in connection with our intellectual property rights, including, among others:

- pending and future patent applications may not result in the issuance of patents or, if issued, may not be issued in a form that will be advantageous to us;
- our issued patents may be challenged, invalidated or legally circumvented by third parties;
- our patents may not be upheld as valid and enforceable or prevent the development of competitive products;

- the eligibility of certain inventions related to diagnostic medicine, more specifically diagnostic methods and processes, for patent protection in the United States has been limited recently which may affect our ability to enforce our issued patents in the United States or may make it difficult to obtain broad patent protection going forward in the United States;

- for a variety of reasons, we may decide not to file for patent protection on various improvements or additional features; and

- intellectual property protection and/or enforcement may be unavailable or limited in some countries where laws or law enforcement practices may not protect our proprietary rights to the same extent as the laws of the United States, the European Union, Canada or Israel.

Consequently, our competitors could develop, manufacture and sell products that directly compete with our products, which could decrease our sales and diminish our ability to compete. In addition, competitors could attempt to develop their own competitive technologies that fall outside of our intellectual property rights. If our intellectual property does not adequately protect us from our competitors' products and methods, our competitive position could be materially adversely affected.

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 imaging capsule.

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. We are presently unaware of any other parties' valid patents and proprietary rights which our evolving product designs would infringe. Searches typically performed to identify potentially infringed patents of third parties are often not 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 imaging capsule and the methods it employs may be covered by patents held by them. If our imaging capsule infringes a valid patent, we could be prevented from manufacturing or selling it 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 infringement. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate and could divert our management's attention from operating our business.

The steps we have taken to protect our intellectual property may not be adequate, which could have a material adverse effect on our ability to compete in the market.

In addition to patents, we rely on confidentiality, non-compete, non-disclosure and assignment of inventions provisions, as appropriate, with our employees, consultants and, to some extent, our distributors, to protect and otherwise seek to control access to, and distribution of, our proprietary information. These measures may not be adequate to protect our intellectual property from unauthorized disclosure, third-party infringement or misappropriation, for the following reasons:

- the agreements may be breached, may not provide the scope of protection we believe they provide or may be determined to be unenforceable;
- we may have inadequate remedies for any breach;
- proprietary information could be disclosed to our competitors; or
- others may independently develop substantially equivalent or superior proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies.

Specifically with respect to non-compete agreements, under current U.S. and Israeli law, we may be unable to enforce these agreements, in whole or in part, and it may be difficult for us to restrict our competitors from gaining the expertise that our former employees gained while working for us. For example, Israeli courts have recently required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or its intellectual property. 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. In addition, some states in the United States,

such as California, have laws which severely restrict the use of non-compete undertakings.

If, for any of the above reasons, our intellectual property is disclosed or misappropriated, it could harm our ability to protect our rights and could have a material adverse effect on our business, financial condition and results of operations.

Third-party claims of infringement or other claims against us could require us to redesign our imaging capsule, seek licenses, or engage in future costly intellectual property litigation, which could negatively affect our future business and financial performance.

Substantial litigation over intellectual property rights exists in the medical device industry in general and in the medical imaging sector in particular. We expect that we may be subject to third-party infringement claims as our revenues increase, the number of competitors grows and the functionality of products and technology in different industry segments converges. Third parties may currently have, or may eventually be issued, patents on which our current or future products or technologies may infringe.

In addition, litigation in which we are accused of infringement may cause negative publicity, adversely impact prospective customers, cause product shipment delays, prohibit us from manufacturing, marketing or selling our current or future products, require us to develop non-infringing technology, make substantial payments to third parties or enter into royalty or license agreements, which may not be available on acceptable terms, or at all. If a successful claim of infringement were made against us and we could not develop non-infringing technology or license the infringed or similar technology in a timely and cost-effective manner, our ability to generate significant revenues may be substantially harmed and we could be exposed to significant liability. A court could enter orders that temporarily, preliminarily or permanently enjoin us or our customers from making, using, selling, offering to sell or importing our current or future products, or could enter an order mandating that we undertake certain remedial activities. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our reputation, business, financial condition or results of operations.

We may also become involved in litigation in connection with our brand name rights. We do not know whether others will assert that our brand name infringes their trademark rights. In addition, names we choose for our products may be claimed to infringe names held by others. If we have to change the names we use, we may experience a loss in goodwill associated with our brand name, customer confusion and a loss of sales.

Third parties may challenge the validity of our issued patents or challenge patent applications in administrative proceedings before various patent offices which, if successful, could negatively affect our future business and financial performance.

Various patent offices, including in the United States and Europe, provide administrative proceedings by which a third party can challenge the validity of an issued patent or challenge an application that is being examined absent any threat of litigation. In some instances, including in the United States, the administrative proceedings provide a more efficient and favorable forum to challenge our patents which may lead to more opportunities for competitors to do so, particularly smaller competitors with limited resources. Moreover, the standards utilized in these administrative proceedings, at least in the United States, provide certain legal advantages versus challenging the validity of a patent in a district court. If a third party is successful in one of these administrative proceedings, the patent will no longer be enforceable in the corresponding jurisdiction. With this loss in patent rights, we will not be able to prevent third parties from offering identical or similar competing products which may result in lower profits and a less substantial market share.

We may need to initiate lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market.

We rely on patents to protect a portion of our intellectual property and our competitive position. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in the medical device industry are generally uncertain. In order to protect or enforce our patent rights, we may initiate

patent and related litigation against third parties, such as infringement suits or interference proceedings. Any lawsuits that we initiate could be expensive, take significant time and divert our management's attention from other business concerns and the outcome of litigation to enforce our intellectual property rights in patents, copyrights, trade secrets or trademarks is highly unpredictable. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. In addition, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, including attorney fees, if any, may not be commercially valuable. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations.

We may not be able to enforce covenants not to compete at all or, we may be unable to enforce them for the duration contemplated in our employment contracts and may, therefore, 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, all 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 all of our 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, an Israeli court may refuse to enforce our non-compete restrictions or reduce the contemplated period of non-competition such that we may be unable to prevent our competitors from benefiting from the expertise of our former employees.

Risks Related to Our Operations in Israel

Our principal offices, research and development facilities and some of our suppliers are located in Israel and, therefore, our business, financial condition and results of operation may be adversely affected by political, economic and military instability in Israel.

Our principal offices, research and development facilities are located in northern Israel. In addition, all of our employees and officers, and most of our directors, are residents of Israel. Accordingly, political, economic and military conditions in Israel may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. In addition, our operations may be adversely affected by the call-up of certain of our employees, including members of our senior management, to active military services in the case of such hostilities.

During the Second Lebanon War of 2006, between Israel and Hezbollah, a militant Islamic movement, rockets were fired from Lebanon into Israel, including into the Haifa area, where our facility is located, causing casualties and major disruption of economic activities in northern Israel. An escalation in tension and violence between Israel and the militant Hamas movement (which controls the Gaza Strip) and other Palestinian Arab groups, culminated with Israel's military campaign in Gaza in December 2008, in November 2012 and again in July and August 2014 in an endeavor to prevent continued rocket attacks against Israel's southern towns. It is unclear whether any negotiations that may occur between Israel and the Palestinian Authority will result in an agreement. In addition, Israel faces threats from more distant neighbors, in particular, Iran, an ally of Hezbollah and Hamas.

Popular uprisings in various countries in the Middle East and North Africa are affecting the political stability of those countries. Such instability may lead to deterioration in the political and trade relationships that exist between the State of Israel and these countries. Furthermore, several countries, principally in the Middle East, restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies if hostilities in the region continue or intensify. Such restrictions may seriously limit our ability to sell our products to customers in those countries. Parties with whom we may do business could decline to travel to Israel during periods of heightened unrest or tension. In addition, the political and security situation in Israel may result in parties with whom we may have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such

agreements. In addition, any hostilities involving Israel could have a material adverse effect on our facilities including our corporate office or on the facilities of our local suppliers, in which event all or a portion of our inventory may be damaged, and our ability to deliver products to customers could be materially adversely affected. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or significant downturns in the economic or financial condition of Israel, could adversely affect our operations and product development, cause our revenues to decrease and adversely affect our share price following this offering. Similarly, Israeli corporations are limited in conducting business with entities from several countries.

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

Our operations could also be disrupted by the obligations of personnel to perform military service. As of February 17, 2015, we had 36 employees and independent contractors, all of whom were based in Israel. Some of these employees may be called upon to perform up to 54 days in each three year period (and in the case of officers, up to 84 days in each three year period) of military reserve duty until they reach the age of 40 (and in some cases, depending on their specific military profession up to 45 or even 49 years of age) and, in certain emergency circumstances, may be called to immediate and unlimited active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists and it is possible that there will be similar large-scale military reserve duty call-ups in the future. Our operations could be disrupted by the absence of a significant number of employees related to military service, which could materially adversely affect our business and results of operations.

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

We have received grants from the Government of the State of Israel through the OCS for the financing of a portion of our research and development expenditures pursuant to the Research Law and related regulations. As of June 30, 2014, we had received funding from the OCS in the aggregate amount of $3.1 million. Since June 30, 2014, we have received additional funding from the OCS in the aggregate amount of $560,000 under an approved OCS grant in the total amount of $702,000 for a research and development program for the 12 month period commencing March 1, 2014. As of June 30, 2014, we had not paid any royalties to the OCS and had a contingent obligation to the OCS in the amount of $1.6 million. We may apply for additional OCS grants in the future. However, as the funds available for OCS grants out of the annual budget of the State of Israel have been reduced in the past and may be further reduced in the future, we cannot predict whether we will be entitled to any future grants, or the amounts of any such grants.

The terms of the Israeli government participation require that products developed with OCS grants be manufactured in Israel and that the technology developed thereunder may not be transferred outside of Israel, unless prior approval is received from the OCS, which we may not receive. In addition, payment of additional amounts would be required if manufacturing is moved outside of Israel, in which case the royalty repayment rate is increased and the royalty ceiling can reach up to three times the amount of the grants received, and if OCS developed know-how is transferred outside of Israel, the royalty ceiling can reach up to six times the amount of grants received (plus interest). We are currently considering whether it would be possible to assemble the capsule without the X-ray source in Israel, and have the X-ray source subsequently inserted into our imaging capsule at a reactor or cyclotron site or at a distribution center outside Israel. Even following the full repayment of any OCS grants, we must nevertheless continue to comply with the requirements of the Research Law. The foregoing restrictions and requirements for payment may impair our ability to sell our technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any product or technology outside of Israel. Furthermore, the consideration available to our shareholders in a transaction involving the transfer outside of Israel of technology or know-how developed with OCS funding (such as a merger or similar transaction) may be reduced by any amounts that we are required to pay to the OCS.

If we fail to comply with any of the conditions and restrictions imposed by the Research Law, or by the specific terms under which we received the grants, we may be required to refund any grants previously received together with interest and penalties, and, in certain circumstances, may be subject to criminal charges.

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

The rights and responsibilities of the holders of our ordinary shares are governed by our amended articles of association and by Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders in U.S.-based corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders, and to refrain from abusing its power in the company, including, among other things, in voting at a general meeting of shareholders on matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and related party transactions requiring shareholder approval. In addition, a shareholder who is aware that it possesses the power to determine the outcome of a shareholder vote or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company. There is limited case law available to assist us in understanding the nature of this duty or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U.S. corporations.

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

We are incorporated in Israel. All of our executive officers and the Israeli experts and all but two of our directors listed in this prospectus reside in Israel, and substantially all of our assets and most of the assets of these persons are located in Israel. Therefore, a judgment obtained against us, or any of these persons, including a judgment based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not be enforced by an Israeli court. It also may be difficult for you to effect service of process on these persons in the United States or to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws on the grounds that Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proven as a fact by expert witnesses, which can be a time consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above. As a result of the difficulty associated with enforcing a judgment against us in Israel, you may not be able to collect any damages awarded by either a U.S. or foreign court. See "Enforceability of Civil Liabilities" for additional information on your ability to enforce a civil claim against us and our executive officers or directors, or some of the experts named in this prospectus.

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

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to such types of transactions. For example, a tender offer for all of a company's issued and outstanding shares can only be completed if the acquirer receives positive responses from the holders of at least 95% of the issued share capital and the approval of a majority of the offerees that do not have a personal interest in the tender offer, unless at least 98% of the company's outstanding shares are tendered. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer (unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek appraisal rights), may, at any time within six months following the completion of the tender offer, petition an Israeli court to alter the consideration for the acquisition. In addition, a merger may not be consummated unless at least 50 days have passed from the date on which a proposal for approval

of the merger was filed by each party with the Israeli Registrar of Companies and at least 30 days have passed from the date on which the merger was approved by the shareholders of each party. See “Description of Share Capital and Securities Offered Hereby—Acquisitions under Israeli Law” for additional information.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of a number of conditions, including, in some cases, a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are subject to certain restrictions. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no disposition of the shares has occurred.

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

Under the Israeli Patents Law, 5727-1967, or the Patents Law, inventions conceived by an employee during the scope of his or her employment are regarded as "service inventions" and are owned by the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Patents Law also provides that if no such agreement between an employer and an employee exists, which prescribes whether, to what extent, and on what conditions the employee is entitled to remuneration for his or her service inventions, then such matters may, upon application by the employee, be decided by a government-appointed compensation and royalties committee established under the Patents Law, or the Committee. Recent conflicting decisions of the Committee and the Israeli Supreme Court have created uncertainty with respect to an employee's right to receive remuneration for service inventions. In an August 2012 decision, the Israeli Supreme Court held that an employee's contractual waiver of rights to compensation for service inventions does not necessarily preclude the employee's claim to such compensation, and as a result an employee who executed a waiver may still bring a claim for compensation for service inventions before the Committee. However, in a decision issued in May 2014, the Committee held that employees may waive their right to remuneration for service inventions. We understand that a petition was recently filed and is currently pending with the Israeli High Court of Justice claiming that the Committee did not have authority to render such decision. A significant portion of our intellectual property has been developed by our employees in the course of their employment. Although our employees have agreed to assign to us all rights to any intellectual property created in the scope of their employment and most of our current employees, including all those involved in the development of our intellectual property, have agreed to waive their economic rights with respect to service inventions, we cannot assure you that claims will not be brought against us by current or former employees demanding remuneration in consideration for assigned service inventions. If any such claims were filed, we could be required to pay remuneration to our current or former employees for such assigned service inventions, or be forced to litigate such claims, which could negatively affect our business.

Risks Related to the Company

For as long as we are an "emerging growth company," we will not be required to comply with certain reporting requirements that apply to other public companies. We cannot predict whether the reduced disclosure requirements applicable to emerging growth companies will make our securities less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may choose to take advantage of certain exemptions from reporting requirements applicable to other public companies that are not emerging growth companies. These include: (i) not being required to comply with the auditor attestation requirements for the assessment of our internal controls over financial reporting provided by Section 404 of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act; (ii) not being required to comply with any requirements adopted by the Public Company Accounting Oversight Board, or PCAOB, requiring mandatory audit firm rotation or a supplement to the auditor's report in which the auditor would be required to provide additional information about the audit and the financial statements of the issuer; (iii) not being required to comply with any new audit rules adopted by the PCAOB after April 5, 2012 unless the U.S. Securities and Exchange Commission determines otherwise, (iv) not being required to provide certain disclosure regarding executive compensation required of larger public companies; and (v) not being required to hold a non-binding advisory vote on executive compensation or seek shareholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years from the end of our current fiscal year, although, if the market value of our ordinary shares that is held by non-affiliates exceeds $700 million as of any June 30 before the end of that five-year period, we would cease to be an emerging growth company as of the following December 31. We cannot predict if investors will find our securities less attractive if we choose to rely on these exemptions. If some investors find our securities less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market

for our securities and the price for our securities may be more volatile. Further, as a result of these scaled regulatory requirements, our disclosure may be more limited than that of other public companies and you may not have the same protections afforded to security holders of such companies.

We will be a foreign private issuer and, as a result, we will not be subject to U.S. proxy rules and will be subject to the Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those applicable to a U.S. issuer.

Upon the completion of this offering, we will report under the Exchange Act as a foreign private issuer. Because we qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. We intend to furnish quarterly reports to the SEC on Form 6-K for so long as we are subject to the reporting requirements of Section 13(g) or 15(d) of the Exchange Act, although the information we furnish may not be the same as the information that is required in quarterly reports on Form 10-Q for U.S. domestic issuers. In addition, while U.S. domestic issuers that are not large accelerated filers or accelerated filers are required to file their annual reports on Form 10-K within 90 days after the end of each fiscal year, in the fiscal years ending on or after December 15, 2011, foreign private issuers will not be required to file their annual report on Form 20-F until 120 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. Although we intend to make interim reports available to our shareholders in a timely manner, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

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

As a foreign private issuer, we are permitted, and intend, to follow certain home country corporate governance practices instead of those otherwise required under the Listing Rules of the NASDAQ Stock Market for domestic U.S. issuers. For instance, we intend to follow home country practice in Israel with regard to, among other things, director nomination procedures, the approval of compensation of officers, and quorum requirements at general meetings of our shareholders. In addition, we intend to follow our home country law instead of the Listing Rules of the NASDAQ Stock Market that require us to obtain shareholder approval for certain dilutive events, such as the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or greater interest in the company, and certain acquisitions of the stock or assets of another company. Following our home country governance practices as opposed to the requirements that would otherwise apply to a United States company listed on NASDAQ may provide less protection to you than what is accorded to investors under the Listing Rules of the NASDAQ Stock Market applicable to domestic U.S. issuers.

Exchange rate fluctuations between the U.S. dollar and the NIS and the Euro and inflation may negatively affect our earnings and we may not be able to hedge our currency exchange risks successfully.

The dollar is our functional and reporting currency. However, a significant portion of our operating expenses, including personnel and facilities related expenses, are incurred in NIS. As a result, we are exposed to the risks that the NIS may appreciate relative to the U.S. dollar, or, if the NIS instead devalues relative to the U.S. dollar, that the inflation rate in Israel may exceed such rate of devaluation of the NIS, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected. The Israeli rate of inflation has not had a

material adverse effect on our financial condition during 2012 and 2013 and during the six months ended June 30, 2014. In addition, we expect to incur operating expenses denominated in Euros, and therefore, our operating results are also subject to fluctuations due to changes in the U.S. dollar/Euro exchange rate. Given our general lack of currency hedging arrangements to protect us from fluctuations in the exchange rates of the NIS, the Euro and other foreign currencies in relation to the U.S. dollar (and/or from inflation of such foreign currencies), we may be exposed to material adverse effects from such movements. We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the NIS against the U.S. dollar.

Our management team's lack of experience as officers of publicly-traded companies may hinder our ability to comply with the Sarbanes-Oxley Act.

It may be time-consuming, difficult and costly for us to develop and implement the internal controls and reporting procedures required by the Sarbanes-Oxley Act. We may need to hire additional financial reporting, internal controls and other finance staff or consultants in order to develop and implement appropriate internal controls and reporting procedures. If we are unable to comply with the Sarbanes-Oxley Act's internal controls requirements, we may not be able to obtain the independent auditor certifications that the Sarbanes-Oxley Act requires publicly-traded companies to obtain.

Risks Related to this Offering and Our Securities

The price of our securities may be volatile, and the market price of our securities after this offering and the concurrent Private Placement may drop below the price you pay.

The initial public offering price per unit may vary from the market price of our securities that prevails after the offering. If an active market for our securities develops and continues, the price of our securities nevertheless may be volatile. Market prices for securities of early-stage medical device companies have historically been particularly volatile. As a result of this volatility, you may not be able to sell your securities at or above the initial public offering price paid per unit. The factors that may cause the market price of our securities to fluctuate include, but are not limited to:

- progress, or lack of progress, in developing and commercializing our products;
- favorable or unfavorable decisions about our products or intellectual property from government regulators, insurance companies or other third-party payors;
- our ability to recruit and retain qualified regulatory and research and development personnel;
- changes in investors' and securities analysts' perception of the business risks and conditions of our business;
- changes in our relationship with key collaborators;
- changes in the market valuation or earnings of our competitors or companies viewed as similar to us;
- changes in key personnel;
- depth of the trading market in our securities;
- termination of the lock-up agreement or other restrictions on the ability of us or any of our existing shareholders to sell securities after this offering and the concurrent Private Placement;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the granting or exercise of employee stock options or other equity awards;
- realization of any of the risks described under this section entitled "Risk Factors;" and
- general market and economic conditions.

In addition, the equity markets have experienced significant price and volume fluctuations that have affected the market prices for the securities of newly public companies for a number of reasons, including reasons that may be unrelated to our business or operating performance. These broad market fluctuations may result in a material decline in the market price of our securities and you may not be able to sell your securities at prices you deem acceptable. In the past, following periods of volatility in the equity markets, securities class action lawsuits have been instituted against public companies. Such litigation, if instituted against us, could result in substantial cost and the diversion of management attention.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

If you purchase units in this offering, assuming no value is attributed to the Series A Warrants included in the units, the public offering price that you pay per ordinary share will be substantially higher than the net tangible book value per ordinary share immediately after this offering. Therefore, you will incur an immediate dilution of $4.81 (or 69%) in net tangible book value per ordinary share from the price you paid, based on the public offering price of $7.00 per unit. The exercise of outstanding warrants and options may result in further dilution of your investment. In addition, if we raise funds by issuing additional shares or convertible securities in the future, the newly issued shares may further dilute your ownership interest.

Future sales of our securities, or the perception that future sales may occur, may cause the market price of our securities to decline, even if our business is doing well.

Sales of substantial amounts of our securities in the public market after this offering and the concurrent Private Placement, or the perception that these sales may occur, could materially and adversely affect the price of our ordinary shares and could impair our ability to raise capital in the future, particularly through the sale of additional equity securities. The securities sold in this offering will be freely tradable, without restriction, in the public market, except for any securities sold to our affiliates.

In connection with this offering, we, our officers and directors and the holders of 1% or more of our ordinary shares have agreed prior to the commencement of this offering, subject to limited exceptions, not to sell or transfer any of our ordinary shares for 180 days after the date of this prospectus without the consent of Chardan Capital Markets, LLC. However, Chardan Capital Markets, LLC may release these shares from any restrictions at any time. We cannot predict what effect, if any, market sales of shares held by any shareholder or the availability of shares for future sale will have on the market price of our ordinary shares.

Approximately 248,888 ordinary shares may be sold in the public market by existing shareholders who are not affiliated after the date of this prospectus and an additional 7,602,978 ordinary shares may be sold in the public market by shareholders on or about 181 days after the date of this prospectus, subject to volume and other limitations imposed under the federal securities laws. See “Securities Eligible for Future Sale” for a more detailed description of the restrictions on selling our ordinary shares after this offering.

We are issuing Series A Warrants to purchase 1,000,000 ordinary shares in this offering (1,150,000 if the overallotment option is exercised in full) and Long Term Incentive Warrants to purchase 3,000,000 ordinary shares in the offering (3,450,000 if the overallotment is exercise in full). In addition, we are issuing a warrant to Chardan Capital Markets, LLC in this offering to purchase an additional 100,000 ordinary shares. As of February 17, 2015, we had outstanding options to purchase 1,297,514 ordinary shares (including the Neev Options and certain options granted to executive officers that will be exercised prior to the closing of this offering), outstanding warrants to purchase 948,000 preferred shares (all of which will convert into warrants to purchase ordinary shares immediately prior to the closing of this offering) and outstanding warrants to purchase an aggregate of 3,265,793 ordinary shares (including certain warrants which will be exercised prior to the closing of this offering) . We plan to register for offer and sale the ordinary shares that are reserved for issuance pursuant to outstanding options. Shares covered by such registration statements upon the exercise of stock options generally will be eligible for sale in the public market, except that affiliates will continue to be subject to volume limitations and other requirements of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. After this offering and the concurrent Private Placement, the holders of approximately 6,491,390 ordinary shares will be entitled to registration rights.

The market price of our ordinary shares may drop significantly when the restrictions on resale by our existing shareholders lapse and these shareholders are able to sell our ordinary shares into the market. In addition, a sale by the

company of additional ordinary shares or similar securities in order to raise capital might have a similar negative impact on the share price of our ordinary shares. A decline in the price of our ordinary shares might impede our ability to raise capital through the issuance of additional ordinary shares or other equity securities, and may cause you to lose part or all of your investment in our ordinary shares.

An active trading market may not develop for our securities, and you may not be able to sell your units, ordinary shares and Series A Warrants at or above the initial public offering price per unit or the Series A Warrant exercise price per share.

There is no established trading market for our securities, and the market for our securities may be highly volatile or may decline regardless of our operating performance. Prior to this offering, you could not buy or sell our securities publicly. An active public market for our securities may not develop or be sustained after this offering. Furthermore, the requirement that Long Term Incentive Warrant holders must hold the ordinary shares underlying units purchased in the offering for the applicable vesting periods in order to be able to exercise their Long Term Incentive Warrants may adversely impact the development of an active trading market for our ordinary shares. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market in our units, ordinary shares and Series A Warrants, or how liquid that market might become. If a market does not develop or is not sustained, it may be difficult for you to sell your securities at the time you wish to sell them, at a price that is attractive to you, or at all.

The initial public offering price per unit has been determined through negotiation between us and representatives of the underwriter, and may not be indicative of the market prices that prevail after this offering. You may not be able to sell your units, ordinary shares or warrants at or above the initial public offering price or warrant exercise price per share.

Due to the speculative nature of warrants, there is no guarantee that it will ever be profitable for holders of the Series A Warrants and Long Term Incentive Warrants to exercise such warrants.

The Series A Warrants and Long Term Incentive Warrants do not confer any rights of ordinary share ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire ordinary shares at a fixed price for a limited period of time. Specifically, commencing 45 days after the date of this prospectus, holders of the Series A Warrants may exercise their right to acquire the ordinary shares and pay an exercise price of $8.75 per share (which is equal to 125% of the public offering price of the units), prior to the expiration of the five-year term on , 2020, after which date any unexercised Series A Warrants will expire and have no further value. Subject to the satisfaction of the registration condition associated with the Long Term Incentive Warrants (described below), beginning on the first anniversary of the closing date of this offering, holders of the Long Term Incentive Warrants will be able to exercise one-third of the Long Term Incentive Warrants held by them to acquire ordinary shares at an exercise price of $8.05 per share (which is equal to 115% of the public offering price of the units). Subject to the satisfaction of the registration condition associated with the Long Term Incentive Warrants (described below), beginning on the second anniversary of the closing date of this offering, holders of the Long Term Incentive Warrants will be able to exercise the remaining two-thirds of the Long Term Incentive Warrants held by them to acquire ordinary shares at an exercise price of $8.05 per share (which is equal to 115% of the public offering price of the units). The Long Term Incentive Warrants will expire on , 2022. See “Description of Share Capital and Securities Offered Hereby.” Moreover, following this offering, the market value of the Series A Warrants is uncertain and there can be no assurance that the market value of the Series A Warrants will equal or exceed their public offering price. There can be no assurance that the market price of our ordinary shares will ever equal or exceed the exercise price of the Series A Warrants and Long Term Incentive Warrants, and, consequently, whether it will ever be profitable for holders of the Series A Warrants and Long Term Incentive Warrants to exercise such warrants.

Purchasers who fail to register the ordinary shares underlying the units purchased by them in this offering in their name as opposed to “street name” within 120 days of the closing of the offering, will forfeit their Long Term Incentive Warrants. In addition, if a Long Term Incentive Warrant holder transfers all or any portion of the ordinary shares underlying the units purchased by such holder in the offering during the one and two year vesting periods described elsewhere in this prospectus (other than by way of a “permitted transfer”), such holder will forfeit a pro rata portion of the unvested Long Term Incentive Warrants held by such holder.

We are issuing to each purchaser of a unit in this offering, one and one-half non-transferrable Long Term Incentive Warrants to purchase additional ordinary shares provided certain conditions are met. In addition to the vesting conditions described above, for a holder of Long Term Incentive Warrants to be able to exercise its Long Term Incentive Warrants, such holder must, within 120 days of the closing of the offering, register the ordinary shares underlying the units purchased by such holder in the offering in its name and not in “street name.” If the Long Term Incentive Warrant holder fails to timely register the ordinary shares underlying the units purchased by such holder in the offering, the unvested Long Term Incentive Warrants held by such holder will automatically expire. In addition, if the Long Term Incentive Warrant holder transfers all or any portion of the ordinary shares underlying the units purchased by such holder in the offering during the one and two year vesting periods described elsewhere in this prospectus, the holder will forfeit a pro rata portion of the Long Term Incentive Warrants held by such holder.

Registering the ordinary shares in a purchaser’s name rather than in “street name” could delay your ability to dispose of the ordinary shares and could cause partial or full loss of your investment in the event of a rapid decline in our share

price.

Our securities might be susceptible to financial market volatility and other financial and business-related risks that could cause the value of our securities to decline drastically within a short period of time. Registering the ordinary shares acquired by you in this offering may delay your ability to timely dispose of such ordinary shares, which could lead to a partial or full loss of your investment.

Our management will have broad discretion over the use of proceeds from this offering and the concurrent Private Placement and may not obtain a favorable return on the use of these proceeds.

Our management will have broad discretion in determining how to apply the net proceeds from this offering and the concurrent Private Placement and may spend the proceeds in a manner that our shareholders may not deem desirable. We currently intend to use the net proceeds that we will receive from this offering and the concurrent Private Placement to finance the continuation of our product development and clinical studies in Europe and in the United States. We cannot assure you that these uses or any other use of the net proceeds of this offering and the concurrent Private Placement will yield favorable returns or results.

Additional financing may result in dilution to our shareholders.

We may need to raise additional funds in the future to finance internal growth, to make acquisitions or for other reasons. Any required additional financing may not be available on terms acceptable to us, or at all. If we raise additional funds by issuing equity securities, you may experience significant dilution of your ownership interest and the newly issued securities may have rights senior to those of the holders of our ordinary shares. Alternatively, if we raise additional funds by obtaining loans from third parties, the terms of those financing arrangements may include negative covenants or other restrictions on our business that could impair our operational flexibility, and would also require us to fund additional interest expense. If additional financing is not available when required or is not available on acceptable terms, we may be unable to successfully commercialize our product or continue our research and development.

We have never declared or paid a dividend and currently do not intend to pay cash dividends in the foreseeable future. Any return on investment may be limited to the value of our securities.

We have never declared and do not anticipate paying cash dividends on our ordinary shares in the foreseeable future. Our board of directors has discretion to declare and pay dividends on our ordinary shares and will make any determination to do so based on a number of factors, such as our operating results, financial condition, current and anticipated cash needs and other business and economic factors that our board of directors may deem relevant. In addition, we are only permitted to pay dividends out of “profits” (as defined by the Israeli Companies Law), provided that there is no reasonable concern that the dividend distribution will prevent us from meeting our existing and foreseeable obligations, as they become due. If we do not pay dividends, our ordinary shares may be less valuable because a return on your investment will only occur if the trading price of our securities appreciates. Further, you should not rely on an investment in us if you require dividend income from your investments.

If securities or industry analysts do not publish research or reports about us or our business or publish unfavorable research about us or our business, the price of our securities and their trading volume could decline.

The trading market for our securities will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of us the trading price for our securities would be negatively affected. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our securities, the price of our securities would likely decline. If one or more of these analysts ceases to cover us or fails to publish regular reports on us, interest in the purchase of our securities could decrease, which could cause the price of our securities and their trading volume to decline.

Risks Related to Taxation

There is a risk that we could be treated as a domestic (U.S.) corporation for U.S. federal income tax purposes by reason of the transactions related to our acquisition of all of the business operations and substantially all of the assets of Check-Cap LLC on May 31, 2009 (hereinafter sometimes referred to as the "reorganization").

Section 7874(b) of the Internal Revenue Code of 1986, as amended, or the Code, generally provides that a foreign corporation (i.e., a corporation created or organization under the laws of a jurisdiction outside of the United States) would be treated as a domestic (U.S.) corporation for U.S. federal income tax purposes if, pursuant to a plan or a series of related transactions, (1) the foreign corporation acquires, directly or indirectly, substantially all of the assets of a domestic corporation (or substantially all of the properties constituting a trade or business of a domestic partnership), (2) after the acquisition, the former shareholders of the acquired corporation by reason of holding shares of the acquired corporation (or, in the case of an acquisition with respect to a domestic partnership, the former partners of the domestic partnership by reason of holding a capital or profits interest in the domestic partnership) own at least 80% of the stock (by vote or value) of the acquiring corporation, and (3) after the acquisition, the expanded affiliated group that includes the acquiring corporation does not have substantial business activities in the foreign country in which, or under the laws of which, the acquiring corporation is created or organized when compared to the total business activities of such expanded affiliated group. On the basis of an analysis by Deloitte Touche Tohmatsu, or Deloitte, of the relevant facts and circumstances and the relevant law (including the temporary regulations under Section 7874 applicable at the time of the reorganization), it was determined that the third condition described in the preceding sentence was not met with respect to the reorganization and, therefore, that the inversion tax rules of Section 7874(b) would not apply to treat us as a domestic corporation for U.S. federal income tax purposes. However, since this determination was made on the basis of all of the relevant facts and circumstances, and it is not clear which facts and circumstances the Internal Revenue Service, or the IRS, may consider more important than others, this conclusion is not free from doubt.

If Section 7874(b) were to apply to the reorganization (and we were to be treated as a domestic corporation for U.S. federal income tax purposes), then, among other things, (i) we would be subject to U.S. federal income tax on our worldwide taxable income (if and when we have taxable income); (ii) certain payments (e.g., interest and dividends) that we make (or have made) to our foreign investors may be (or may have been) subject to U.S. withholding taxes; (iii) we may be subject to significant penalties for the failure to file certain tax returns and reports, including reports with respect to our foreign bank accounts; and (iv) the U.S. unitholders of Check-Cap LLC would not have been subject to U.S. federal income tax on royalties that are deemed to be paid to them under Section 367(d) of the Code as a result of the reorganization. (As discussed under "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Contractual Obligations" and "– Application of Critical Accounting Policies and Estimates – Royalties provision – Reimbursement liability to Check-Cap LLC unitholders," as part of the reorganization, we committed to reimburse the unitholders of Check-Cap LLC for any tax burdens that may be imposed on them due to the reorganization, including royalties that are deemed to be paid to the U.S. unitholders under Section 367(d) of the Code.)

Prospective investors are urged to consult their own advisors on these issues. The balance of this discussion, including the discussion under "Taxation – U.S. Federal Income Taxation," assumes that we will be and have been treated as a foreign corporation for U.S. federal income tax purposes.

We may be eligible for tax benefits from government programs, which require us to meet certain conditions, including regarding the location of our property, plant and equipment and manufacturing in Israel. We can provide no assurance that we would continue to be eligible for such benefits and/or that any such benefits will not be terminated in the future.

Our manufacturing facilities in Israel may qualify as a "Benefited Enterprise" under the Israeli Law for Encouragement of Capital Investments, 1959, or the Investment Law, which would entitle us to receive certain tax benefits. In order to be eligible for such benefits, we would be required to meet certain conditions, including the making of a minimum capital investment in our productive assets and the carrying on of a required portion of our manufacturing in Israel. The amount of the benefit will be determined in accordance with various conditions, including the location of our property, plant and equipment and the location of certain of our sub-contractors. If we cease to meet the required conditions for eligibility, the tax benefits could be cancelled and we could be required to pay increased taxes or to refund the amounts of the benefits received with interest and penalties. We can provide no assurance as to the amount of future capital investment in our productive assets, our future manufacturing location and the future location of our property, plant and equipment and certain of our sub-contractors, and therefore, we cannot provide assurance that we will be eligible for such tax benefits or assurance as to the amount of such tax benefits. Even if we continue to meet the relevant requirements, the tax benefits that Benefited Enterprises receive may not be continued in the future at their current levels or at all. If these tax benefits were reduced or eliminated, the amount of taxes that we would be required to pay would likely increase, as all of our operations would consequently be subject to corporate tax at the standard rate, which could adversely affect our results of operations. See "Taxation— Israeli Tax Considerations and Government Programs —Law for the Encouragement of Capital Investments, 5719-1959" for additional information concerning these tax benefits.

There is a risk that we may be classified as a passive foreign investment company, or PFIC, which could result in adverse U.S. federal income tax consequences to U.S. investors.

In general, we will be treated as a PFIC for any taxable year in which either (1) at least 75% of our gross income (including our pro rata share of the gross income of our 25% or more-owned corporate subsidiaries) is passive income or (2) at least 50% of the average value of our assets (including our pro rata share of the assets of our 25% or more-owned corporate subsidiaries) is attributable to assets that produce, or are held for the production of, passive income. Passive income generally includes dividends, interest, rents, royalties, and gains from the disposition of passive assets. If we are determined to be a PFIC for any taxable year (or portion thereof) that is included in the holding period of a U.S. Holder (as defined in the section titled "Taxation—U.S. Federal Income Taxation—General") of our securities, the U.S. Holder may be subject to increased U.S. federal income tax liability upon a sale or other disposition of our securities or the receipt of certain excess distributions from us and may be subject to additional reporting requirements.

Our actual PFIC status for our current taxable year or any subsequent taxable year is uncertain and will not be determinable until after the end of such taxable year. Accordingly, there can be no assurance with respect to our status as a PFIC for our current taxable year or any subsequent taxable year.

U.S. investors are urged to consult their own tax advisors regarding the possible application of the PFIC rules. For more information, see "Taxation—U.S. Federal Income Taxation—U.S. Holders—Passive Foreign Investment Company Rules."

There is a risk that a holder of Long Term Incentive Warrants will recognize ordinary compensation income on the exercise of the Long Term Incentive Warrants, which may result in U.S. federal and Israeli income tax liability to such holder without the receipt of cash.

While not free from doubt, the Long Term Incentive Warrants may be treated for U.S. federal and Israeli income tax purposes as compensatory warrants (i.e., issued to compensate an original purchaser of units in this offering for holding the ordinary shares underlying the units for a certain period of time after the closing date of this offering). Based on this characterization, a holder may recognize ordinary compensation income for U.S. federal and Israeli income tax purposes on the exercise of the Long Term Incentive Warrants, as described under "Taxation - Israeli Tax Considerations and Government Programs - Taxation of our Shareholders - Taxation of Non-Israeli Shareholders upon Exercise of Long Term Incentive Warrants" and "Taxation - U.S. Federal Income Taxation - U.S. Holders - Exercise of Long Term Incentive Warrants" and "Non-U.S. Holders." Such compensation income may result in U.S. federal or Israeli income tax liability to such holder without the receipt of cash. Prospective investors are urged to consult their own tax advisors with respect to the U.S. federal and Israeli income tax consequences that may arise on the exercise of the Long Term Incentive Warrants.

## SPECIAL NOTE ON FORWARD-LOOKING STATEMENTS

This prospectus contains statements that may be deemed to be "forward-looking statements" within the meaning of the federal securities laws. These statements relate to anticipated future events, future results of operations and/or future financial performance. In some cases, you can identify forward-looking statements by their use of terminology such as "anticipate," "believe," "could," "estimate," "expect," "future," "intend," "may," "ought to," "plan," "possible," "potentially," "should," "will," "would," negatives of such terms or other similar terms. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The forward-looking statements in this prospectus include, without limitation, statements relating to:

- our goals and strategies;
- the timing and conduct of the clinical trials for our ingestible imaging capsule, including statements regarding the timing, progress and results of current and future preclinical studies and clinical trials, and our research and development programs;
- the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of our ingestible imaging capsule;
- our future business development, results of operations and financial condition;
- our ability to protect our intellectual property rights;
- our plans to develop, launch and commercialize our imaging capsule and any future products;
- the timing, cost or other aspects of the commercial launch of our imaging capsule;
- market acceptance of our product;
- our estimates regarding expenses, future revenues, capital requirements and our need for additional financing;
- our estimates regarding the market opportunity for our imaging capsule;
- the impact of government laws and regulations;
- our ability to recruit and retain qualified regulatory and research and development personnel;
- unforeseen changes in healthcare reimbursement for any of our approved product;
- difficulties in maintaining commercial scale manufacturing capacity and capability; our ability to generate growth;
- our failure to comply with regulatory guidelines;
- uncertainty in industry demand and patient wellness behavior;
- general economic conditions and market conditions in the medical device industry;

- future sales of large blocks or our securities, which may adversely impact our share price;
- depth of the trading market in our securities; and
- our intended use of proceeds of this offering and the concurrent Private Placement.

The preceding list is not intended to be an exhaustive list of all of our forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including those described in “Risk Factors.”

You should not unduly rely on any forward-looking statements. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that future results, levels of activity, performance and events and circumstances reflected in the forward-looking statements will be achieved or will occur. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus, to conform these statements to actual results or to changes in our expectations.

## USE OF PROCEEDS

We estimate that we will receive net proceeds from this offering of approximately $11.7 million, or $13.6 million if the underwriters exercise in full their option to purchase additional units (together with the accompanying Long Term Incentive Warrants), based on an assumed initial public offering price of $7.00, the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses. We will also expect to receive net proceeds of approximately $10.9 million from the sale of 1,714,286 units (together with the accompanying 2,571,429 Long Term Incentive Warrants) in the concurrent Private Placement after deducting commissions and estimated expenses payable by us. The information set forth below assumes concurrent consummation of the Private Placement and our receipt of net proceeds of approximately $10.9 million from the Private Placement.

A $1.00 increase (decrease) in the assumed initial public offering price of $7.00 would increase (decrease) the net proceeds that we receive from the offering by approximately $1.9 million, assuming that the number of units offered, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting and other discounts and commissions and estimated offering expenses. Similarly, each increase (decrease) of 100,000 units in the number of units offered by us would increase (decrease) the net proceeds to us from this offering by approximately $0.7 million, assuming that the assumed initial public offering price remains the same, and after deducting the underwriting and other discounts and commissions and estimated offering expenses.

We currently intend to use the net proceeds we receive from this offering and the concurrent Private Placement as follows:

- approximately $5.3 million on research and development;
- approximately $4.0 million on regulatory submissions for approvals of our product, including approximately $3.5 million on clinical trials in Europe and the United States;
- approximately $0.6 million to build our manufacturing capabilities for the clinical phase;
- approximately $1.1 million for the repayment of indebtedness incurred under the Bank Leumi Credit Facility; and
- the balance, if any, for working capital and other general corporate purposes.

The expected use of net proceeds of this offering and the concurrent Private Placement represents our current intentions based upon our present plans and business conditions. Investors are cautioned, however, that expenditures may vary substantially from these estimates. Investors will be relying on the judgment of our management, who will have broad discretion regarding the application of the proceeds of this offering and the concurrent Private Placement. The amounts and timing of our actual expenditures will depend upon numerous factors, including the amount of cash generated by our operations, the amount of competition and other operational factors. From time to time, we will evaluate these and other factors to determine if our allocation of resources, including the proceeds of this offering and the concurrent Private Placement, is being optimized.

Circumstances that may give rise to changes in our use of net proceeds from this offering and the concurrent Private Placement include:

- the timing of clinical studies and eventual FDA or other regulatory approvals of our imaging capsule;
-

the need or desire on our part to accelerate, increase or eliminate existing initiatives due to, among other things, changing market conditions and competitive developments; and

- the availability of other sources of cash including cash flow from operations and new bank debt financing arrangements, if any.

Pending any use as described above, we intend to invest the net proceeds to us from this offering and the concurrent Private Placement in bank deposits, U.S. government securities and Israeli government securities. We cannot predict whether the net proceeds from such investments will produce a favorable return.

## DIVIDEND POLICY

We have never declared or paid dividends on our ordinary shares and currently do not intend to pay cash dividends on our ordinary shares in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business.

Our ability to distribute dividends also may be limited by future contractual obligations and by Israeli law. The Israeli Companies Law restricts our ability to declare dividends. Unless otherwise approved by a court, we can distribute dividends only from "profits" (as defined by the Israeli Companies Law), and only if there is no reasonable concern that the dividend distribution will prevent us from meeting our existing and foreseeable obligations as they become due. Subject to the foregoing, payment of future dividends, if any, will be at the discretion of our board of directors and will depend on various factors, such as our financial condition, operating results, current and anticipated cash needs and other business and economic factors that our board of directors may deem relevant. See "Description of Share Capital and Securities Offered Hereby —Dividend and Liquidation Rights." In addition, the payment of dividends may be subject to Israeli withholding taxes. See "Taxation—Israeli Tax Considerations and Government Programs—Taxation of Our Shareholders—Taxation of Non-Israeli Shareholders on Receipt of Dividends." Furthermore, if we pay a dividend out of income attributed to our Benefited Enterprise that was generated during the tax exemption period, we may be subject to tax on the grossed-up amount of such distributed income at the corporate tax rate which would have been applied to our Benefited Enterprise's income had we not enjoyed the exemption. See "Taxation – Israeli Tax Considerations and Government Programs — Law for the Encouragement of Capital Investments, 5719-1959 — Tax Benefits Subsequent to the 2005 Amendment."

# CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2014:

- on an actual basis;
- on a pro forma basis to give effect to: (i) the conversion of all of our outstanding preferred shares on a 1:1 basis into an aggregate of 4,338,998 ordinary shares immediately prior to the completion of this offering; (ii) the issuance of 99,774 ordinary shares to Mr. Guy Neev upon the exercise of the Neev Options, which will occur, prior to the closing of this offering; (iii) the issuance of 171,715 ordinary shares under warrants that will be automatically exercised, for no consideration, upon the exercise of the Nee