Check-Cap Ltd
Form POS AM
December 18, 2015

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

Registration No. 333-201250

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

POST-AMENDMENT NO. 2
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)

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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. o

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. o

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. o

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. o

EXPLANATORY NOTE

This Post-Effective Amendment No. 2 on Form F-1 contains an updated prospectus relating to the offering and sale of (i) ordinary shares issuable upon exercise of the Series A Warrants that were issued to public investors in connection with the registrant's initial public offering; (ii) ordinary shares issuable upon exercise of the Long-Term Incentive Warrants that were issued to public investors in connection with the registrant's initial public offering; and (iii) ordinary shares issuable upon the exercise of a warrant issued to the representative of the underwriters in connection with the registrant's initial public offering, all of which were (together with certain other securities of the registrant) initially registered by the registrant, on the Registration Statement on Form F-1 (File No. 333-201250) (the "Original Registration Statement") declared effective by the Securities and Exchange Commission on February 18, 2015, as amended by Post-Effective Amendment No.1 to the Original Registration Statement declared effective by the Securities and Exchange Commission on June 30, 2015. All filing fees payable in connection with the registration of these securities were previously paid in connection with the filing of the Original 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.

PROSPECTUS SUBJECT TO COMPLETION DATED DECEMBER 18, 2015

Check-Cap Ltd.
3,677,376 Ordinary Shares

This prospectus relates to 3,677,376 of our ordinary shares, NIS 0.20 par value per share, (i) 1,125,000 of which are issuable upon the exercise of Series A Warrants originally issued in our initial public offering pursuant to a prospectus dated February 18, 2015, (ii) 2,452,376 of which are issuable upon the exercise of Long Term Incentive Warrants issued in our initial public offering pursuant to a prospectus dated February 18, 2015 and held by holders who completed the required registration process by August 23, 2015 (iii) 100,000 of which are issuable upon the exercise of a warrant issued to the representative of the underwriters in connection with our initial public offering pursuant to a prospectus dated February 18, 2015. In order to obtain the shares (i) the holders of the Series A Warrants must pay an exercise price of $7.50 per share (subject to adjustment as described herein), (ii) the holders of the Long Term Incentive Warrants must pay an exercise price of $6.90 per share (subject to adjustment as described herein) and satisfy the vesting conditions applicable to the Long Term Incentive Warrants, as more fully described herein and (iii) the holder of the representative's warrant must pay an exercise price of $7.50 per share (subject to adjustment as described herein). We will receive proceeds from the exercise of the Series A Warrants, the Long Term Incentive Warrants and the representative's warrant but not from the sale of the underlying ordinary shares.

Our ordinary shares are currently traded on the Nasdaq Capital Market under the symbol "CHEK." On December 17, 2015, the closing sale price of our ordinary shares was $1.95 per share.

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 7 of this prospectus.

Investing in our securities involves a high degree of risk. You should read carefully the "Risk Factors" beginning on page 13 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.

The date of this prospectus is December , 2015

TABLE OF CONTENTS

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 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 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.

We have not 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 13 and the financial statements and the accompanying notes to those financial statements beginning on page F-1 before making an investment decision. 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 3.769, the exchange rate published by the Bank of Israel on June 30, 2015, and U.S. dollar translation of Euro amounts presented in this prospectus are translated using the rate of $1.00 = Euro 0.8976, the exchange rates published by the Wall Street Journal on June 30, 2015.

Our Company

We are a clinical stage medical diagnostics company engaged in the development of an ingestible imaging capsule system that utilizes ultra low-dose X-rays for the imaging and detection of colonic polyps and 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 35% of Americans between the ages of 50 to 75 are not current with any form of CRC screening due in large part to the pain, discomfort and embarrassment related to current screening methods. Unlike other screening modalities that are designed to generate structural information of the internal colon for the detection of colonic polyps and CRC, such as optical colonoscopy, computed tomographic colonography, or CTC, and other capsule-based technologies, our system is designed to be ingested without any cathartic preparation of the colon, and to travel through the gastrointestinal tract naturally while the patient continues his or her normal daily routine. Furthermore, unlike existing CRC imaging modalities currently on the market, all of which require the patient to fast for several hours prior to administration, the procedure for the Check-Cap system is designed to enable patients to continue eating normally. Our imaging system is comprised of three main components: (1) ingestible scanning capsule; (2) Capsule Positioning System, or CPS, a recorder worn on the patient's back; and (3) a PC-based work station for data reconstruction and image processing. We believe that this solution will be attractive to both physicians and patients, with the potential to increase the number of people adhering to CRC screening guidelines.

Our system is being designed to create a reconstructed three-dimensional image of the interior of the colon and to enable detection of clinically significant polyps with a high degree of sensitivity. Colonic polyps are tissue growths that occur on the lining of the colon. Polyps in the colon are extremely common, and certain

types of polyps can become cancerous over time.

Our scanning capsule will be ingested 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 scanning capsule employs low-dose X-rays, which allow the system to image the interior lining of the colon even when surrounded by intestinal content. As such, we believe that patients using our system will not be required to undergo any prior bowel preparation. 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 scanning 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 scanning 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 scanning 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 data recorder and CPS, which is worn 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 system capsule, the patient may be advised 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 system 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 system will still be attractive to doctors and patients as 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 system, did not identify any material safety or feasibility issues. The study demonstrated the applicability of our system to the human colon, generating images taken in the colon without any prior bowel preparation. 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 scanning 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 system. The 10-case study was the first phase of a multi-center, prospective clinical feasibility study to establish the safety, functionality and preliminary efficacy of the Check-Cap 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 75 subjects. The study is being conducted at multiple centers in Israel and is planned to also be conducted 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. A preliminary analysis conducted on the first 49 capsules swallowed by participants enrolled in the multi-center, prospective clinical feasibility study showed 48 of 49 capsules swallowed and naturally eliminated without major or minor side effects after 73.2±45.4 hours. Image reconstructions allowed 3D views of the colonic wall and lumen with the typical contour of different segments (hepatic flexure, triangular shape of the transverse colon). Both pedunculated and sessile polyps were detected in several patients and validated later by colonoscopy.

Following the successful completion of the broader multi-center, prospective clinical feasibility study, we plan to submit during 2016 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 approvals, available capital, and engagement with strategic partners, we anticipate launching our system commercially in Europe during 2017.

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 2016, 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 system'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 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 system capsule in the United States, available capital, and engagement with strategic partners, we anticipate launching our system commercially in the United States during 2018.

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 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, 2015, we had a total comprehensive loss of $8.0 million. We incurred net losses of $3.7 million in 2012, $4.0 million in 2013 and $4.1 million in 2014. As of June 30, 2015, we had an accumulated deficit of $34.6 million and a total shareholders' equity of $9.1 million.

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 2015, in the United States approximately 132,700 people are expected to be diagnosed with CRC and approximately 49,700 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 the incidence of and mortality from the disease 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 examinations, 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-based 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 the U.S. Preventive Services Task Force, clinicians and insurers and the known clinical value of screening for CRC, a large portion of the population is 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 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 one-third 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 preparation 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 insufflate 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 (removal of polyps) 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 2007, 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 preparation to a greater degree than is required for an 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 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 clinically-significant pre-cancerous polyps.

Our Solution

We believe that our system 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 preparation, which would differentiate our system 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;

4

- 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 scanning 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 scanning capsule will make our system 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 system. 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 scanning 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 capsule is expelled from a patient's body, the CPS data will be transferred to the physician, who will then utilize our data viewer software application to analyze the data collected by our scanning 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 and then compile a report with the clinical findings and recommendations for further treatment (if required) or repeated test after several years.

Our system 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 scanning capsule longitudinally through the colon, successive images of portions of the colon are collected to enable the three-dimensional reconstruction of the colon. Our 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.

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 system in the European Union, followed by obtaining regulatory approvals for the use of our system initially in the United States and Japan. In Europe and Japan, we intend to offer our system as an imaging and screening tool for the general population. In the United States, we may first seek to obtain regulatory approvals for our system as an adjunct tool to FOBTs and FITs, and after we have conducted more extensive clinical studies, we would anticipate applying to the FDA for the use of our system 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 system;
- we need to increase our manufacturing capabilities; and
- we need to establish and expand our user 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.

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. On June 9, 2015, we formed our wholly-owned subsidiary Check-Cap US, Inc., a Delaware corporation.

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

Appointment of New Chief Executive Officer

At a meeting of our shareholders held on May 19, 2015, our shareholders approved the terms of the engagement of William (Bill) Densel as President of our U.S. Operations, effective as of such meeting. At a meeting of our shareholders held on August 13, 2015, our shareholders approved the terms of engagement of Mr. Densel as our Chief Executive Officer, effective as of such meeting, who serves in such capacity as an employee of our U.S. subsidiary, Check-Cap US, Inc., which was formed on June 9, 2015. Mr. Densel was elected by our Board of Directors to serve as a director to fill a vacancy as of August 13, 2015. Mr. Densel has served as the President and Chief Executive Officer of our U.S. subsidiary, Check-Cap US, Inc., since July 2015.

Guy Neev, our former Chief Executive Officer and a former member of our Board of Directors, resigned from such positions in August 2015 and has served as a consultant since such time.

The Offering

Issuer	Check-Cap Ltd.
Securities offered	3,677,376 ordinary shares (i) 1,125,000 of which are issuable at an exercise price of $7.50 per ordinary share upon the exercise of Series A Warrants originally issued in our initial public offering pursuant to a prospectus dated February 18, 2015; (ii) 2,452,376 of which are issuable at an exercise price of $6.90 per ordinary share upon the exercise of Long Term Incentive Warrants issued in our initial public offering pursuant to a prospectus dated February 18, 2015 and held by holders who completed the required registration process by August 23, 2015; and (iii) 100,000 of which are issuable at an exercise price of $7.50 per ordinary share upon the exercise of a warrant issued to the representative of the underwriters in connection with our initial public offering pursuant to a prospectus dated February 18, 2015.
Ordinary shares outstanding immediately prior to the offering	10,949,834 ordinary shares
Ordinary shares to be outstanding after the offering(1)	12,074,834, assuming the exercise of all of the Series A Warrants; 14,527,209 assuming the exercise of all of the Series A Warrants and the Long Term Incentive Warrants; and 14,627,210 assuming the exercise of all of the Series A Warrants, the Long Terms Incentive Warrants and the underwriter warrant.
Offering Proceeds	Assuming the exercise of all of the Series A Warrants for cash, we will receive gross proceeds of $15.9 million. Assuming the exercise of all of the Series A Warrants and the Long Term Incentive Warrants for cash, we will receive gross proceeds of $53.5 million. Assuming the exercise of all of the Series A Warrants, the Long Terms Incentive Warrants and the

	underwriter warrant for cash we will receive gross proceeds of $54.3 million. We intend to use the proceeds from the exercise of the Series A Warrants, the Long Term Incentive Warrants and the underwriter warrant for working capital, operating expenses and other general corporate purposes. See “Use of Proceeds” beginning on page 46 of this prospectus.
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 13 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.
Trading Symbol and Listing	Our ordinary shares are listed on the NASDAQ Capital Market under the symbol “CHEK.”

(1) The number of ordinary shares to be outstanding after this offering is based on 10,949,834 ordinary shares outstanding as of December 16, 2015, and excludes:

- 10,236,286 ordinary shares issuable upon the exercise of outstanding warrants with a weighted average exercise price of $5.46 per ordinary share;

- 2,791,959 ordinary shares issuable upon the exercise of outstanding options with a weighted average exercise price of $4.01 per ordinary share, granted under our option and equity incentive plans;

- 922,674 ordinary shares that are available for future option grants under our 2015 Equity Incentive Plan and 2015 United States Sub-Plan to the 2015 Equity Incentive Plan.

- The ordinary shares underlying the 1,000,000 Series A Warrants and 3,000,000 Long Term Incentive Warrants issued by us in the private placement consummated simultaneously with the consummation of our initial public offering on February 24, 2015 have not be registered for issuance pursuant to a registration statement and therefore, such warrants are exercisable on a cashless basis and not included in the ordinary shares to be outstanding after the offering.

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, 2013 and 2014, and the statements of financial position data as of December 31, 2013 and December 31, 2014 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, 2014 and 2015, and the statements of financial position data as of June 30, 2015 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, 2015 and our results of operations for the six months ended June 30, 2014 and 2015. The historical financial information for the year ended December 31, 2012 was derived from our audited financial statements not included in this prospectus. Selected financial data as of, and for the years ended, December 31, 2011 and 2010 have been omitted from this prospectus because of our status as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and as per related guidance provided by the SEC. 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 Month Ended June 30,	
	2014	2013	2012	2015	2014
	(US$ in thousands, except per share data)				
Operating expenses(1)				(Unaudited)	
Research and development expenses, net(2)	$3,108	$2,662	$2,692	$2,733	$1,640
General and administrative expenses	1,702	1,090	1,203	3,700	564
Other expenses (income)	--	(10)	13	-	-
Operating loss	4,810	3,742	3,908	6,433	2,204
Finance income	(788)	(63)	(416)	(202)	(60)
Finance expenses	54	316	229	1,813	85
Finance expenses (income), net	(734)	253	(187)	1,611	25
Loss and total comprehensive loss for the period	4,076	3,995	3,721	8,044	2,229
Loss per ordinary share of NIS 0.20 par value, basic and diluted(3)	2.77	3.66	3.49	0.77	1.97
Weighted average number of ordinary shares	2,181	1,627	1,627	10,503	1,627

outstanding – basic and diluted (in thousands)(3)	

Statements of Financial Position Data

	As of December 31,			As of June 30,
	2014	2013	2012	2015
	(US$ in thousands)			(Unaudited)
Cash and cash equivalents	$ 1,075	$ 4,975	$ 4,583	$ 19,083
Working Capital(4)	3,214	4,131	7,451	18,077
Total assets	7,785	5,375	8,496	19,709
Capital stock	28,788	23,676	23,619	43,675
Total shareholders' equity	$ 2,227	$ 1,191	$ 5,129	$ 9,070

(1) Includes share-based compensation expense in the total amount of $312,000, $53,000 and $31,000 for the years ended December 31, 2014, 2013 and 2012, respectively, and $2.7 million and $422,000 for the six months ended June 30, 2015 and 2014, respectively. For additional information, see "Management's Discussion and Analysis of Financial Condition and Results of Operations-- Liquidity and Capital Resources—Application of Critical Accounting Policies and Estimates-Share-based compensation."

(2) Research and development expenses, net is presented net of the differences between the amount of grants received from the Office of the Chief Scientist of the Ministry of Economy (formerly named the Ministry of Industry, Trade and Labor), or the OCS, and Israel-United States Binational Industrial Research and Development Foundation, or the BIRD Foundation, and the fair value of their financial liability. The effect of the participation by the OCS and BIRD totaled $0.4 million, $0.4 million and $0.2 million for the years ended December 31, 2014, 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.

(3) 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 were deemed to be outstanding: (i) 99,774 ordinary shares that were issuable to Mr. Guy Neev upon exercise of options, referred to as the Neev Options, which options were exercised immediately prior to the consummation of our initial public offering on February 24, 2015; (ii) 375,204 ordinary shares issuable under warrants that are 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 were exercised immediately prior to the consummation of our initial public offering upon the exercise by Mr. Guy Neev, our former Chief Executive Officer, of the Neev Options; (iii) 2,658,463 ordinary shares issuable upon the exercise of outstanding warrants with an exercise price of NIS 0.20, of which 569,355 warrants were exercised during the six-month ended June 30, 2015; and (iv) 193,847 ordinary shares issuable upon the exercise of outstanding options with an exercise price of NIS 0.20. For additional information, see Note 17 to our financial statements for the year ended December 31, 2014 included elsewhere in this prospectus.

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

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, $4.1 million in 2014 and $8.0 million in the six months ended June 30, 2015. As of June 30, 2015, our accumulated deficit was $34.6 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 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 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 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 system;
- we may not be aware of possible complications from the continued use of our system since we have limited clinical experience with respect to the actual use of our capsule;
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Other technological breakthroughs in CRC screening, treatment and prevention may reduce the demand for our screening 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 capsule, which may adversely affect patients' willingness to purchase our capsule;

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

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

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

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