Check-Cap Ltd
Form F-3/A
July 06, 2016

As filed with the Securities and Exchange Commission on July 6, 2016
Registration No. 333-211065

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

AMENDMENT NO. 1
To

FORM F-3
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:
Mitchell S. Nussbaum, Esq. Angela M. Dowd, Esq. Loeb & Loeb LLP 345 Park Avenue New York, New York 10154 (212) 407-4000 – Telephone (212) 407-4990 – Facsimile	Eran Yaniv, Adv. Sharon Rosen, Adv. Fischer Behar Chen Well Orion & Co. 3 Daniel Frisch Street Tel Aviv, 6473104, Israel +972 3 6944111 – Telephone +972 3 6091116 – Facsimile

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

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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, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please 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 number of the earlier effective registration statement for the same offering. o

If this Form is a registration statement pursuant to General Instruction I.C. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.C. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

CALCULATION OF REGISTRATION FEE

Title of each class of securities being registered by issuer	Amount to be registered(1)	Proposed maximum offering price per unit	Proposed maximum aggregate offering price(1)	Amount of registration fee	
Ordinary shares, par value NIS 0.20 per share(5)	(4)	(2) (4)	(3) (4)		
Warrants	(4)	(2) (4)	(3) (4)		
Subscription rights(6)	(4)	(2) (4)	(3) (4)		
Units(7)	(4)	(2) (4)	(3) (4)		
Total	(4)	(2) (4)	$50,000,000	$5,035	(11)

Securities being Registered for Resale

Ordinary shares, par value NIS 0.20 per share(8)	4,338,998	$ 2.895	$ 12,561,399.2	$ 1,264.94	
Ordinary shares, par value NIS 0.20 per share(9)	6,000,000	$ 2.895	$ 17,370,000	$ 1,749.16	
Ordinary shares, par value NIS 0.20 per share(10)	2,658,463	$ 2.895	$ 7,696,250.38	$ 775.1	
Total	12,997,461		$ 37,627,649.60	$ 3,789.20	(11)

1. There are being registered hereunder such indeterminate number of ordinary shares, such indeterminate number of warrants, such indeterminate number of subscription rights, and such indeterminate number of units as will have an aggregate initial offering price not to exceed $50,000,000, or if any securities are issued in any non-United States currency units, the equivalent thereof in non-United States currencies. This registration statement shall also cover any additional securities to be offered or issued from stock splits, stock dividends, recapitalizations or similar transactions.

2. The proposed maximum aggregate offering price for each class of securities will be determined from time to time by the Registrant in connection with the issuance by the Registrant of the securities registered hereunder and is not specified as to each class of securities pursuant to General Instruction II.C. of Form F-3 under the Securities Act of 1933, as amended (the “Securities Act”).

3. Estimated solely for the purposes of calculating the registration fee pursuant to Rule 457(o) of Regulation C under the Securities Act.

4. Not required to be included in accordance with General Instruction II.C. of Form F-3 under the Securities Act.

5. The ordinary shares being registered also include such indeterminate number of ordinary shares as may be issued upon exercise, conversion or exchange of other securities. Separate consideration may or may not be received for securities that are issuable on exercise, conversion or exchange of other securities.

6. Rights evidencing the right to purchase ordinary shares.

7. Units may consist of any combination of the securities registered hereunder.

8. We are registering for resale by certain of the Selling Shareholders named herein (i) 337,500 ordinary shares issued upon conversion of our Series A Preferred Shares, (ii) 338,472 ordinary shares issued upon conversion of our Series B Preferred Shares, (iii) 820,756 ordinary shares issued upon conversion of our Series C-1 Preferred Shares, (iv) 1,489,455 ordinary shares issued upon conversion of our Series C-2 Preferred Shares, (v) 1,227,275 ordinary shares issued upon conversion of our Series D-1 Preferred Shares and (vi) 125,540 ordinary shares issued upon conversion of our Series D-3 Preferred Shares.

9. We are registering for resale by certain of the Selling Shareholders named herein (i) 2,000,000 ordinary shares issued in a private placement transaction on February 24, 2015 (the "Private Placement"), (ii) 1,000,000 ordinary shares issuable upon the exercise of Series A Warrants issued in the Private Placement and (iii) 3,000,000 ordinary shares issuable upon the exercise of Long Term Incentive Warrants issued in the Private Placement.

10. We are registering for resale by certain of the Selling Shareholders named herein 2,658,463 ordinary shares issued or issuable upon the exercise of certain warrants issued on October 14, 2014 pursuant to the Credit Line Agreement dated August 20, 2014, as amended, by and among the Registrant and the lenders named therein.

11. Previously paid.

The Registrant is filing a combined prospectus in this registration statement pursuant to Rule 429 under the Securities Act in order to satisfy the requirements of the Securities Act and the rules and regulations thereunder for this offering and other offerings registered on an earlier registration statement. The combined prospectus in this registration statement relates to, and shall act, upon effectiveness, as Post-Effective Amendment No. 3 on Form F-3 to the registration statement on Form F-1(File No. 333-201250) (the "F-1 Registration Statement") containing an updated prospectus relating to (i) the offering and sale of ordinary shares issuable upon exercise of Series A Warrants and Long Term Incentive Warrants that were issued in the Registrant's initial public offering and (ii) the offering and sale of ordinary shares issuable in connection with the exercise of warrants issued to the representatives of the underwriters ("Underwriter Warrants") in connection with the Registrant's initial public offering, each of which were initially registered pursuant to the F-1 Registration Statement declared effective by the Securities and Exchange Commission on February 18, 2015, as amended by Post-Effective Amendment No. 1 thereto, declared effective by the Securities and Exchange Commission on June 30, 2015 and Post-Effective Amendment No. 2 thereto declared effective by the Securities and Exchange Commission on December 30, 2015. All filing fees payable in connection with the registration of the securities covered by such Post-Effective Amendment No. 3 were previously paid in connection with the filing of the original F-1 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 thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Explanatory Note

This registration statement, which is a new registration statement, also constitutes Post-Effective Amendment No. 3 on Form F-3 to the Registration Statement on Form F-1 (File No. 333-201250) (the "F-1 Registration Statement ") of Check-Cap Ltd. (the "Company " or "Check-Cap ") and is being filed pursuant to the undertakings in Item 9 of the F-1 Registration Statement to update and supplement the information contained in the F-1 Registration Statement, as originally declared effective by the Securities and Exchange Commission on February 18, 2015, and amended by Post-Effective Amendment No.1 thereto, declared effective by the Securities and Exchange Commission on June 30, 2015, and Post-Effective Amendment No. 2 thereto declared effective by the Securities and Exchange Commission on December 30, 2015.

This Registration Statement contains three prospectuses, as set forth below.

- Offering Prospectus. A prospectus to be used for the offering and sale, from time to time in one or more offerings by the registrant of any combination of ordinary shares, warrants, subscription rights, or units having a maximum aggregate offering price not exceeding $50,000,000.

- Warrant Prospectus. A prospectus relating to 3,297,531 ordinary shares consisting of (i) 1,125,000 ordinary shares which are issuable upon the exercise of Series A Warrants that were issued in our initial public offering, (ii) 2,072,531 ordinary shares which are issuable upon the exercise of the Long Term Incentive Warrants that were issued in our initial public offering, and (iii) 100,000 ordinary shares which are issuable upon the exercise of warrants issued to the representative of the underwriters in connection with our initial public offering, each pursuant to a prospectus dated February 18, 2015.

- Resale Prospectus. A prospectus to be used for the resale by the Selling Shareholders named herein of up to 12,997,461 ordinary shares, consisting of (i) 337,500 ordinary shares issued upon conversion of our Series A Preferred Shares, (ii) 338,472 ordinary shares issued upon conversion of our Series B Preferred Shares, (iii) 820,756 ordinary shares issued upon conversion of our Series C-1 Preferred Shares, (iv) 1,489,455 ordinary shares issued upon conversion of our Series C-2 Preferred Shares, (v) 1,227,275 ordinary shares issued upon conversion of our Series D-1 Preferred Shares, (vi) 125,540 ordinary shares issued upon conversion of our Series D-3 Preferred Shares, (vii) 2,000,000 ordinary shares issued in the Private Placement transaction (viii) 1,000,000 ordinary shares issuable upon the exercise of Series A Warrants issued in the Private Placement, (ix) 3,000,000 ordinary shares issuable upon the exercise of Long Term Incentive Warrants issued in the Private Placement and (x) 2,658,463 ordinary shares issued or issuable upon the exercise of certain warrants issued on October 14, 2014 pursuant to the Credit Line Agreement dated August 20, 2014, as amended, by and among the Registrant and the lenders named therein.

The Warrant Prospectus is substantively identical to the Offering Prospectus, except for the following principal points:

- the outside and inside covers are different;

- the section entitled "About this Prospectus" on page 1 of the Offering Prospectus is not included;

- the section entitled "The Offering" on page 20 is different;

- the section entitled "Use of Proceeds" on page 21 is different;

- the sections entitled "Ratio of Earnings to Fixed Charges" and "Capitalization and Indebtedness" on page 7 of the Offering Prospectus are not included;

· the sections entitled “Description of Ordinary Shares”, “Description of Warrants”, “Description of Subscription Rights” and “Description of Units”” beginning on page 7 of the Offering Prospectus are not included;

· the section entitled “The Securities We May Offer” on page 4 of the Offering Prospectus is not included;

- the section entitled “Plan of Distribution” beginning on page 10 of the Offering Prospectus is not included; and

- the section entitled “Expenses” on page 13 of the Offering Prospectus is not included.

The Resale Prospectus is substantively identical to the Offering Prospectus, except for the following principal points:

- the outside and inside covers are different;
- the section entitled “About this Prospectus” on page 1 of the Offering Prospectus is not included;
- the section entitled “The Offering” on page 25 is different;
- the section entitled “Use of Proceeds” on page 26 is different;
- sections entitled “Ratio of Earnings to Fixed Charges” and “Capitalization and Indebtedness” on page 7 of the Offering Prospectus are not included;
- the sections entitled “Description of Ordinary Shares ” , “Description of Warrants”, “Description of Subscription Rights” and “Description of Units” beginning on page 7 of the Offering Prospectus are not included;
- the section entitled “The Securities We May Offer” on page 4 of the Offering Prospectus is not included;
- a section entitled “ Selling Shareholders” is included; and
- the section entitled “Plan of Distribution” beginning on page 10 of the Offering Prospectus is different.

The Registrant has included in this Registration Statement a set of alternate pages for the Warrant Prospectus to reflect the foregoing differences and a set of alternate pages for the Resale Prospectus to reflect the foregoing differences.

The Offering Prospectus will exclude the alternate pages and will be used for the public offering by the Registrant. The Warrant Prospectus will be substantially identical to the Offering Prospectus except for the addition or substitution of the alternate pages and will be used for the exercise of the warrants to which it relates. The Resale Prospectus will be substantively identical to the Offering Prospectus except for the addition or substitution of the alternate pages and will be used for the resale offering by the Selling Shareholders.

The information in this prospectus is not complete and may be changed. We and the selling shareholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated July 6, 2016

PROSPECTUS

$50,000,000
CHECK-CAP LTD.
Ordinary Shares

Warrants
Subscription Rights
Units

We may offer ordinary shares, par value NIS 0.20 per share, par value NIS 0.20 per share, warrants, subscription rights and/or units from time to time. When we decide to sell securities, we will provide specific terms of the offered securities, including the offering prices of the securities, in a prospectus supplement. The securities offered by the Registrant pursuant to this prospectus will have an aggregate public offering price of up to $50,000,000.

The securities covered by this prospectus may be offered and sold from time to time in one or more offerings, which may be through one or more underwriters, dealers and agents, or directly to the purchasers. The names of any underwriters, dealers or agents, if any, will be included in a supplement to this prospectus.

This prospectus describes some of the general terms that may apply to these securities and the general manner in which they may be offered. The specific terms of any securities to be offered, and the specific manner in which they may be offered, will be described in one or more supplements to this prospectus. A prospectus supplement may also add, update or change information contained in this prospectus.

Our ordinary shares are traded on the NASDAQ Capital Market under the symbol “CHEK”.

The aggregate market value of our outstanding ordinary shares held by non-affiliates is approximately $25,728,332, which was calculated based on 9,600,124 ordinary shares held by non-affiliates as of July, 6, 2016, and a price per share of $2.68, the last reported sale price per share of our ordinary shares on the Nasdaq Capital Market on May 9, 2016. As of the date hereof, we have not offered any securities pursuant to General Instruction I.B.5 of Form F-3 during the prior 12 calendar month period that ends on and includes the date hereof.

Pursuant to General Instruction I.B.5 of Form F-3, as long as the aggregate market value of our ordinary shares held by non-affiliates remains below $75.0 million, we will not, during any 12 calendar month period, sell the securities in a public primary offering with a value exceeding more than one-third of the aggregate market value of our ordinary shares held by non-affiliates.

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.

Investing in our securities involves risks. You should consider carefully the risk factors referred to in this prospectus on page 5 and in the applicable supplement to this prospectus before investing in any securities that may be offered.

Neither the Securities and Exchange Commission nor any state or other securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Prospectus dated July , 2016

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (the "SEC") using a "shelf" registration process. Under this shelf registration process, we may offer from time to time securities having a maximum aggregate offering price of $50,000,000. Each time we offer securities, we will prepare and file with the SEC a prospectus supplement that describes the specific amounts, prices and terms of the securities we offer. The prospectus supplement also may add, update or change information contained in this prospectus or the documents incorporated herein by reference. You should read carefully both this prospectus and any prospectus supplement together with additional information described below under the caption "Where You Can Find More Information."

This prospectus does not contain all the information provided in the registration statement we filed with the SEC. For further information about us or our securities offered hereby, you should refer to that registration statement, which you can obtain from the SEC as described below under "Where You Can Find More Information."

You should rely only on the information contained or incorporated by reference in this prospectus or any prospectus supplement. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell securities, and it is not soliciting an offer to buy securities, in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or any prospectus supplement, as well as information we have previously filed with the SEC and incorporated by reference, is accurate as of the date of those documents only. Our business, financial condition, results of operations and prospects may have changed since those dates.

We may sell securities through underwriters or dealers, through agents, directly to purchasers or through any combination of these methods. We and our agents reserve the sole right to accept or reject in whole or in part any proposed purchase of securities. The prospectus supplement, which we will prepare and file with the SEC each time we offer securities, will set forth the names of any underwriters, agents or others involved in the sale of securities, and any applicable fee, commission or discount arrangements with them. See "Plan of Distribution."

PROSPECTUS SUMMARY

The following summary is qualified in its entirety by, and should be read in conjunction with, the more detailed information and financial statements incorporated by reference into this prospectus. In addition to this summary, we urge you to read the entire prospectus carefully, especially the risks discussed under "Risk Factors" on page 6 before making an investment decision.

Unless otherwise stated in this prospectus,

- references to "Check-Cap," the "Company," "we," "us" or "our" refer to Check-Cap Ltd., an Israeli company, together with Check-Cap US, Inc., its U.S. subsidiary;
- references to "dollars," "US$" or "$" refer to the legal currency of the United States; and
- the term "NIS" refers to New Israeli Shekels, the lawful currency of the State of Israel.

Overview

We are a clinical stage medical diagnostics company engaged in the development of an ingestible capsule system that utilizes ultra low-dose X-rays for the detection and imaging of colonic polyps and colorectal cancers, or CRC. While CRC is the second leading cause of death from cancer for both sexes combined in the United States and is largely preventable with early detection, according to 2013 National Health Interview Survey, only 58% of Americans between the ages of 50 to 75 reported being current with CRC screening recommendations. 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 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 undergoing CRC screening.

Our scanning capsule will be swallowed 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 ultra 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 position, motility, and the data it collects to an external data recorder and capsule positioning system or CPS, that will be worn by the patient. The external data recorder is being designed to enable the transfer of the data to our PC-based work station with viewer software application to allow

physicians to analyze the data collected by our scanning capsule. The CPS is being designed to provide the physician with accurate localization data aligned with a reconstructed image. 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.

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. In the event that polyps are identified through our system, 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 any less attractive to physicians 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 physicians and patients as a majority of patients who are screened will not require a subsequent polypectomy. Published data from a multi-center CT colonography screening study of 2,531 asymptomatic adults showed that if all patients with a lesion measuring 5mm or more on CT colonography were referred for colonoscopy, the colonoscopy-referral rate would have been 17%.

A clinical proof-of-concept study, which was based on a 10-case study conducted at Tel Aviv Sourasky 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 our 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 our system in patients eligible for CRC screening, by comparing results from the clinical feasibility study with those from non-invasive, low-sensitivity FOBTs and FITs, as well as from optical colonoscopies. The feasibility study is designed allow for recruitment of 100 subjects. The study is being conducted at multiple centers in Israel, with the potential to be conducted at a single site in the Netherlands. The clinical feasibility study will evaluate the image resolution generated by the capsule in an a human colon without cathartic preparation, 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 54 capsules swallowed by participants enrolled in the multi-center, prospective clinical feasibility study showed 53 of 54 capsules swallowed and naturally eliminated without major or minor side effects after 66 ±37 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.

To date, we have achieved key product development milestones, including the demonstrated ability of our system to reconstruct the human colon and to identify polyps, and design freeze of the current version of our system. Following the successful completion of the multi-center, prospective clinical feasibility study and design release and transfer to manufacturing phases, we plan to submit during the first half of 2017, 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 2018.

We plan to conduct a pre-submission meeting with the FDA, during 2016. Subject to this meeting, we plan subsequently to submit a request for the approval of an investigational device exemption, or IDE, for a pilot study in the United States. Subject to successful completion of the pilot study and receipt of required approvals, we plan to initiate during 2018, 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 performance. We anticipate that FDA approval for the pivotal study will be subject to our providing sufficient clinical data from previous clinical studies, which may include the multi-center, prospective clinical feasibility study and U.S. pilot study. However, there can be no assurance that the FDA will grant approval for the pilot and/or pivotal studies to be conducted in the United States.

We also intend to pursue clinical trials for regulatory approvals in Japan and China in parallel to the U.S. pivotal study, subject to available capital and engagement with strategic partners. Pivotal studies are expected, among other things, to compare polyps identified by our system with the polyps identified by traditional optical colonoscopy. These clinical findings may be analyzed in comparison with results obtained from FOBTs and FITs.

Following and subject to the successful completion of our pivotal trial, our current strategy is to submit a direct de novo reclassification petition, which we anticipate submitting in 2019, for initial FDA clearance for the marketing of our system in the United States. Direct de novo reclassification typically takes at least 9 to 12 months from filing to clearance. If the FDA determines that our system is not a candidate for de novo reclassification, it will require approval of the device for market through the PMA process. 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.

Timelines expectations are based on our current estimations and expectations, which may continue to be updated along with our progress, which is subject to the occurrence of various factors and future events, among others, the satisfactory completion of system's development process, testing, and integration, which may require more time than currently expected, as well as the success of our clinical trials and the completion of our required regulatory approvals, all of which are uncertain as of the date of this Prospectus.

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. We incurred net losses of $3.4 million in 2013, $610,000 in 2014 and $12.3 million in 2015. As of March 31, 2016, we had an accumulated deficit of $36.8 million and a total shareholders' equity of $10.3 million.

Check-Cap's principal executive offices at Check-Cap Building, Abba Hushi Avenue, P.O. Box 1271, Isfiya, 30090, Mount Carmel, Israel. Our telephone number is +972-4-8303400 and our website is located at www.check-cap.com (the information contained therein or linked thereto shall not be considered incorporated by reference in this annual report). Our U.S. agent is Puglisi & Associates, located at 850 Library Avenue, Suite 204, Newark, Delaware 19711.

The Securities We May Offer

We may use this prospectus to offer up to $50,000,000 of:

- ordinary shares;

- warrants;
- subscription rights; and
- units, which may consist of any combination of the above securities.

We may also offer securities of the types listed above that are convertible or exchangeable into one or more of the securities listed above.

RISK FACTORS

An investment in our securities involves risk. Before you invest in securities issued by us, you should carefully consider the risks involved. Accordingly, you should carefully consider:

- the information contained in or incorporated by reference into this prospectus;
- the information contained in or incorporated by reference into any prospectus supplement relating to specific offerings of securities;
- the risks described in our Annual Report on Form 20-F for our fiscal year ended December 31, 2015 on file with Securities and Exchange Commission (the "SEC"), which is incorporated by reference into this prospectus; and
- other risks and other information that may be contained in, or incorporated by reference from, other filings we make with the SEC, including in any prospectus supplement relating to specific offerings of securities.

The discussion of risks related to our business contained in or incorporated by reference into this prospectus or into any prospectus supplement comprises material risks of which we are aware. If any of the events or developments described actually occurs, our business, financial condition or results of operations would likely suffer.

CAUTIONARY NOTE REGARDING 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,” “target”, “future,” “intend,” “may,” “ought to,” “plan,” “possible,” “pote “project,” “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 Annual Report include, without limitation, statements relating to:

- our goals, targets and strategies;
- the timing and conduct of the clinical trials for our scanning system, 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 system;
- 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 system and any future products;
- the timing, cost or other aspects of the commercial launch of our system;
- market acceptance of our product;
- our estimates regarding expenses, future revenues, capital requirements and our need for additional financing and strategic partnerships;
- our estimates regarding the market opportunity for our system;
- the impact of government laws and regulations;
- our ability to recruit and retain qualified clinical, 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 expectations regarding the use of proceeds of our initial public 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.

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

Unless the applicable prospectus supplement states otherwise, the net proceeds from the sale of securities offered by the Company will be used for general corporate purposes, which may include additions to working capital, operating expenses, research and developments expenses, and other general corporate purposes. The precise amount, use and timing of the application of such proceeds will depend upon our funding requirements and the availability and cost of other capital. Additional information on the use of net proceeds from an offering of securities covered by this prospectus may be set forth in the prospectus supplement relating to the specific offering.

RATIO OF EARNINGS TO FIXED CHARGES

Not applicable to smaller reporting companies.

CAPITALIZATION AND INDEBTEDNESS

Our capitalization and indebtedness will be set forth in a prospectus supplement to this prospectus or in a report on Form 6-K subsequently furnished to the SEC and specifically incorporated herein by reference.

DESCRIPTION OF ORDINARY SHARES

A description of our ordinary shares can be found in our Registration Statement on Form F-1, as amended, under the Securities Act of 1933, as amended (the “Securities Act”), as originally filed with the SEC on December 23, 2014 (Registration No. 333-201250) under the heading “Description of Securities” and as incorporated into the Company’s Form 8-A, filed with the SEC on February 11, 2015, which description is incorporated by reference herein.

DESCRIPTION OF WARRANTS

The following summary of certain provisions of the warrants does not purport to be complete and is subject to, and qualified in its entirety by reference to, the provisions of the warrant agreement that will be filed with the SEC in connection with the offering of such warrants.

General

We may issue warrants to purchase ordinary shares. Warrants may be issued independently or together with any other securities and may be attached to, or separate from, such securities. Each series of warrants will be issued under a separate warrant agreement to be entered into between us and a warrant agent. The warrant agent will act solely as our agent and will not assume any obligation or relationship of agency for or with holders or beneficial owners of warrants. The terms of any warrants to be issued and a description of the material provisions of the applicable warrant agreement will be set forth in the applicable prospectus supplement.

The applicable prospectus supplement will describe the following terms of any warrants in respect of which this prospectus is being delivered:

- the title of such warrants;
- the aggregate number of such warrants;
- the price or prices at which such warrants will be issued and exercised;

- the currency or currencies in which the price of such warrants will be payable;
- the securities purchasable upon exercise of such warrants;
- the date on which the right to exercise such warrants shall commence and the date on which such right shall expire;
- if applicable, the minimum or maximum amount of such warrants which may be exercised at any one time;

- if applicable, the designation and terms of the securities with which such warrants are issued and the number of such warrants issued with each such security;
- if applicable, the date on and after which such warrants and the related securities will be separately transferable;
- information with respect to book-entry procedures, if any;
- any material United States federal and Israel income tax consequences;
- the anti-dilution provisions of the warrants, if any; and
- any other terms of such warrants, including terms, procedures and limitations relating to the exchange and exercise of such warrants.

Amendments and Supplements to Warrant Agreement

We and the warrant agent may amend or supplement the warrant agreement for a series of warrants without the consent of the holders of the warrants issued thereunder to effect changes that are not inconsistent with the provisions of the warrants and that do not materially and adversely affect the interests of the holders of the warrants.

DESCRIPTION OF SUBSCRIPTION RIGHTS

The following summary of certain provisions of the subscription rights does not purport to be complete and is subject to, and qualified in its entirety by reference to, the provisions of the certificate evidencing the subscription rights that will be filed with the SEC in connection with the offering of such subscription rights.

General

We may issue subscription rights to purchase ordinary shares. Subscription rights may be issued independently or together with any other offered security and may or may not be transferable by the person purchasing or receiving the subscription rights. In connection with any subscription rights offering to our shareholders, we may enter into a standby underwriting arrangement with one or more underwriters pursuant to which such underwriters will purchase any offered securities remaining unsubscribed for after such subscription rights offering. In connection with a subscription rights offering to our shareholders, we will distribute certificates evidencing the subscription rights and a prospectus supplement to our shareholders on the record date that we set for receiving subscription rights in such subscription rights offering.

The applicable prospectus supplement will describe the following terms of subscription rights in respect of which this prospectus is being delivered:

- the title of such subscription rights;
- the securities for which such subscription rights are exercisable;
- the exercise price for such subscription rights;
- the number of such subscription rights issued to each shareholder;
- the extent to which such subscription rights are transferable;

- if applicable, a discussion of the material United States federal and Israel income tax considerations applicable to the issuance or exercise of such subscription rights;

- the date on which the right to exercise such subscription rights shall commence, and the date on which such rights shall expire (subject to any extension);

- the extent to which such subscription rights include an over-subscription privilege with respect to unsubscribed securities;

    - if applicable, the material terms of any standby underwriting or other purchase arrangement that we may enter into in connection with the subscription rights offering; and

- any other terms of such subscription rights, including terms, procedures and limitations relating to the exchange and exercise of such subscription rights.

Exercise of Subscription Rights

Each subscription right will entitle the holder of the subscription right to purchase for cash such amount of ordinary shares at such exercise price as shall be set forth in, or be determinable as set forth in, the prospectus supplement relating to the subscription rights offered thereby. Subscription rights may be exercised at any time up to the close of business on the expiration date for such subscription rights set forth in the prospectus supplement. After the close of business on the expiration date, all unexercised subscription rights will become void.

Subscription rights may be exercised as set forth in the prospectus supplement relating to the subscription rights offered thereby. Upon receipt of payment and the subscription rights certificate properly completed and duly executed at the corporate trust office of the subscription rights agent or any other office indicated in the prospectus supplement, we will forward, as soon as practicable, the ordinary shares purchasable upon such exercise. We may determine to offer any unsubscribed offered securities directly to persons other than shareholders, to or through agents, underwriters or dealers or through a combination of such methods, including pursuant to standby underwriting arrangements, as set forth in the applicable prospectus supplement.

DESCRIPTION OF UNITS

As specified in the applicable prospectus supplement, we may issue units consisting of one or more ordinary shares, warrants or any combination of such securities.

PLAN OF DISTRIBUTION

We may offer and sell, from time to time, some or all of the securities covered by this prospectus up to an aggregate public offering price of $50,000,000.

Securities covered by this prospectus may be sold from time to time, in one or more transactions, at market prices prevailing at the time of sale, at prices related to market prices, at a fixed price or prices subject to change, at varying prices determined at the time of sale or at negotiated prices. The securities being offered by this prospectus may be sold:

- through agents;
- to or through one or more underwriters on a firm commitment or agency basis;
- through put or call option transactions relating to the securities;
- through broker-dealers (acting as agent or principal);
- directly to purchasers, through a specific bidding or auction process, on a negotiated basis or otherwise;
- through any other method permitted pursuant to applicable law; or
- through a combination of any such methods of sale.

At any time a particular offer of the securities covered by this prospectus is made, a revised prospectus or prospectus supplement, if required, will be distributed which will set forth the aggregate amount of securities covered by this prospectus being offered and the terms of the offering, including the name or names of any underwriters, dealers, brokers or agents, any discounts, commissions, concessions and other items constituting compensation and any discounts, commissions or concessions allowed or re-allowed or paid to dealers. Such prospectus supplement, and, if necessary, a post-effective amendment to the registration statement of which this prospectus is a part, will be filed with the SEC to reflect the disclosure of additional information with respect to the distribution of the securities covered by this prospectus. In order to comply with the securities laws of certain states, if applicable, the securities sold under this prospectus may only be sold through registered or licensed broker-dealers. In addition, in some states the securities may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from registration or qualification requirements is available and is complied with.

Any public offering price and any discounts or concessions allowed or re-allowed or paid to dealers may be changed from time to time.

The distribution of securities may be effected from time to time in one or more transactions, including block transactions and transactions on the NASDAQ Market Capital or any other organized market where the securities may be traded. The securities may be sold at a fixed price or prices, which may be changed, or at market prices prevailing at the time of sale, at prices relating to the prevailing market prices or at negotiated prices. The consideration may be cash or another form negotiated by the parties. Agents, underwriters or broker-dealers may be paid compensation for offering and selling the securities. That compensation may be in the form of discounts, concessions or commissions to be received from us or from the purchasers of the securities. Any dealers and agents participating in the distribution of the securities may be deemed to be underwriters, and compensation received by them on resale of the securities may be deemed to be underwriting discounts. If any such dealers or agents were deemed to be underwriters, they may be subject to statutory liabilities under the Securities Act.

Agents may from time to time solicit offers to purchase the securities. If required, we will name in the applicable prospectus supplement any agent involved in the offer or sale of the securities and set forth any compensation payable to the agent. Unless otherwise indicated in the prospectus supplement, any agent will be acting on a best efforts basis for the period of its appointment. Any agent selling the securities covered by this prospectus may be deemed to be an underwriter, as that term is defined in the Securities Act, of the securities.

If underwriters are used in a sale, securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale, or under delayed delivery contracts or other contractual commitments. Securities may be offered to the public either through underwriting syndicates represented by one or more managing underwriters or directly by one or more firms acting as underwriters. If an underwriter or underwriters are used in the sale of securities, an underwriting agreement will be executed with the underwriter or underwriters, as well as any other underwriter or underwriters, with respect to a particular underwritten offering of securities, and will set forth the terms of the transactions, including compensation of the underwriters and dealers and the public offering price, if applicable. The prospectus and prospectus supplement will be used by the underwriters to resell the securities.

If a dealer is used in the sale of the securities, we or an underwriter will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale. To the extent required, we will set forth in the prospectus supplement the name of the dealer and the terms of the transactions.

We may directly solicit offers to purchase the securities and may make sales of securities directly to institutional investors or others. These persons may be deemed to be underwriters within the meaning of the Securities Act with respect to any resale of the securities. To the extent required, the prospectus supplement will describe the terms of any such sales, including the terms of any bidding or auction process, if used.

Agents, underwriters and dealers may be entitled, under agreements which may be entered into, indemnification by us against specified liabilities, including liabilities incurred under the Securities Act, or to contribution by us and the Selling Shareholders to payments they may be required to make in respect of such liabilities. If required, the prospectus supplement will describe the terms and conditions of the indemnification or contribution. Some of the agents, underwriters or dealers, or their affiliates may be customers of, engage in transactions with or perform services for us, our subsidiaries or their affiliates.

Under the securities laws of some jurisdictions, the securities offered by this prospectus may be sold in those jurisdictions only through registered or licensed brokers or dealers.

Any person participating in the distribution of securities registered under the registration statement that includes this prospectus will be subject to applicable provisions of the Exchange Act, and the applicable SEC rules and regulations, including, among others, Regulation M, which may limit the timing of purchases and sales of any of our securities by that person. Furthermore, Regulation M may restrict the ability of any person engaged in the distribution of our securities to engage in market-making activities with respect to our securities. These restrictions may affect the marketability of our securities and the ability of any person or entity to engage in market-making activities with respect to our securities.

Certain persons participating in an offering may engage in over-allotment, stabilizing transactions, short-covering transactions and penalty bids that stabilize, maintain or otherwise affect the price of the offered securities. These activities may maintain the price of the offered securities at levels above those that might otherwise prevail in the open market, including by entering stabilizing bids, effecting syndicate covering transactions or imposing penalty bids, each of which is described below.

- A stabilizing bid means the placing of any bid, or the effecting of any purchase, for the purpose of pegging, fixing or maintaining the price of a security.

- A syndicate covering transaction means the placing of any bid on behalf of the underwriting syndicate or the effecting of any purchase to reduce a short position created in connection with the offering.

- A penalty bid means an arrangement that permits the managing underwriter to reclaim a selling concession from a syndicate member in connection with the offering when offered securities originally sold by the syndicate member are purchased in syndicate covering transactions.

These transactions may be effected on an exchange or automated quotation system, if the securities are listed on that exchange or admitted for trading on that automated quotation system, or in the over-the-counter market or otherwise.

If so indicated in the applicable prospectus supplement, we will authorize agents, underwriters or dealers to solicit offers from certain types of institutions to purchase offered securities from us at the public offering price set forth in such prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. Such contracts will be subject only to those conditions set forth in the prospectus supplement and the prospectus supplement will set forth the commission payable for solicitation of such contracts.

In addition, ordinary shares may be issued upon conversion of or in exchange for other securities.

Each series of offered securities, other than the ordinary shares which are listed on NASDAQ Capital Market, will be a new issue of securities and will have no established trading market. Any underwriters to whom offered securities are sold for public offering may make a market in such offered securities, but such underwriters will not be obligated to do so and may discontinue any market making at any time without notice. The offered securities may or may not be listed on a national securities exchange. No assurance can be given that there will be a market for the offered securities.

Any securities that qualify for sale pursuant to Rule 144 or Regulation S under the Securities Act may be sold under Rule 144 or Regulation S rather than pursuant to this prospectus.

To the extent that we make sales to or through one or more underwriters or agents in at-the-market offerings, we will do so pursuant to the terms of a distribution agreement between us and the underwriters or agents. If we engage in at-the-market sales pursuant to a distribution agreement, we will offer and sell our ordinary shares to or through one or more underwriters or agents, which may act on an agency basis or on a principal basis. During the term of any such agreement, we may sell ordinary shares on a daily basis in exchange transactions or otherwise as we agree with the underwriters or agents. The distribution agreement will provide that any ordinary shares sold will be sold at prices related to the then prevailing market prices for our ordinary shares. Therefore, exact figures regarding proceeds that will be raised or commissions to be paid cannot be determined at this time and will be described in a prospectus supplement. Pursuant to the terms of the distribution agreement, we also may agree to sell, and the relevant underwriters or agents may agree to solicit offers to purchase, blocks of our ordinary shares or other securities. The terms of each such distribution agreement will be set forth in more detail in a prospectus supplement to this prospectus.

In connection with offerings made through underwriters or agents, we may enter into agreements with such underwriters or agents pursuant to which we receive our outstanding securities in consideration for the securities being offered to the public for cash. In connection with these arrangements, the underwriters or agents may also sell securities covered by this prospectus to hedge their positions in these outstanding securities, including in short sale transactions. If so, the underwriters or agents may use the securities received from us under these arrangements to close out any related open borrowings of securities.

One or more firms, referred to as “remarketing firms,” may also offer or sell the securities, if the prospectus supplement so indicates, in connection with a remarketing arrangement upon their purchase. Remarketing firms will act as principals for their own accounts or as agents for us. These remarketing firms will offer or sell the securities in accordance with a redemption or repayment pursuant to the terms of the securities. The prospectus supplement will identify any remarketing firm and the terms of its agreement, if any, with us and will describe the remarketing firm’s compensation. Remarketing firms may be deemed to be underwriters in connection with the securities they remarket. Remarketing firms may be entitled under agreements that may be entered into with us to indemnification by us against certain civil liabilities, including liabilities under the Securities Act and may be customers of, engage in transactions with or perform services for us in the ordinary course of business.

We may enter into derivative transactions with third parties or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those

derivatives, such third parties (or affiliates of such third parties) may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, such third parties (or affiliates of such third parties) may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of shares, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of shares. The third parties (or affiliates of such third parties) in such sale transactions will be underwriters and, if not identified in this prospectus, will be identified in the applicable prospectus supplement (or a post-effective amendment).