Check-Cap Ltd
Form 20-F
March 09, 2017

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

FORM 20-F

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

RANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2016

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

for the transition period from _____ to _____

Commission file number 001-36848

Check-Cap Ltd.

(Exact name of the Registrant as specified in its charter)

Israel

(Jurisdiction of incorporation or organization)

Check-Cap Building
29 Abba Hushi Avenue
P.O. Box 1271
Isfiya, 3009000,
Israel

(Address of principal executive offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of Each Class

Ordinary Shares, par value NIS 0.20

Name of each exchange on which registered

NASDAQ Capital Market

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

As of December 31, 2016, the registrant had 15,205,075 ordinary shares outstanding, NIS 0.2 par value per share.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No T

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes No T

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes T No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes T No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer.

Large Accelerated filer Accelerated filerT Non-accelerated filer

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

T US GAAP International Financial Reporting Standards as issued by the International Accounting Standards Board Other

If “Other” has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No T

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of the securities under a plan confirmed by a court.

Yes No

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CERTAIN INFORMATION

We are a clinical stage medical diagnostics company engaged in the development of a capsule-based system that utilizes ultra-low-dose X-rays to generate structural information on the endoluminal surface of the colon that may be used for screening of the colon to detect polyps, masses 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 preventable with early screening and intervention, according to the National Health Interview Survey, in 2015, only 63% of Americans over the age of 50 reported being current with CRC screening recommendations. Unlike other screening modalities that are designed for direct visualization and imaging of the internal colon, such as optical colonoscopy, computed tomographic colonography, or CTC, and other capsule-based technologies, our C-Scan system is designed to function without any cathartic preparation of the colon and to transit the gastrointestinal tract by natural motility while the patient continues his or her normal daily routine. Furthermore, the C-Scan system does not require fasting prior to or during capsule transit. Our C-Scan system is comprised of three main components: (1) C-Scan Cap, an ingestible X-ray scanning capsule; (2) C-Scan Track, a biocompatible unit worn on the patient's back for capsule control, tracking and data recording; and (3) C-Scan View, a PC-based, standalone application used to process and display structural information of the colon. We believe that this solution will be attractive to both physicians and patients, with the potential to increase the number of people completing CRC screening.

Beginning with the fourth quarter of 2015, we have prepared our consolidated financial statements in accordance with generally accepted accounting principles in the United States of America, or U.S. GAAP. We recast the comparative amounts included in our 2015 financial statements to U.S. GAAP. Prior to the fourth quarter of 2015, we prepared our financial reports in accordance with International Financial Reporting Standards as issued by International Accounting Standard Board, or IFRS. We elected to use U.S. GAAP to increase the transparency and comparability of our financial reports and facilitate research and analysis by shareholders, analysts and other participants in the U.S. capital markets.

In this Annual Report on Form 20-F, or the Annual Report, unless the context indicates otherwise, references to "NIS" are to the legal currency of Israel, "U.S. dollars," "$" or "dollars" are to United States dollars, and the terms "we," "us," "our company," "our," and "Check-Cap" refer to Check-Cap Ltd. Unless otherwise indicated, U.S. dollar translation of NIS amounts presented in this Annual Report are translated using the rate of $1.00 = NIS 3.845, the exchange rate published by the Bank of Israel on December 31, 2016, and U.S. dollar translation of Euro amounts presented in this Annual Report are translated using the rate of $1.00 = Euro 0.9506, the exchange rates published by the Wall Street Journal on December 31, 2016.

We effected a 1-for-20 reverse stock split of our ordinary shares effective immediately prior to the consummation of our initial public offering on February 24, 2015, in accordance with the approval of our shareholders at a meeting held on January 15, 2015. All share numbers in this Annual Report are reflected on a post- reverse stock split basis.

USE OF TRADE NAMES AND TRADEMARKS

Throughout this Annual Report, we refer to various trademarks, service marks and trade names that we use in our business. The "CHECK-CAP" and "C-Scan" trademarks and design logos are the property of Check-Cap Ltd. Other trademarks and service marks appearing in this annual report are the property of their respective holders. We do not intend our use or display of other companies' tradenames, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by these other companies. Solely for convenience, trademarks and trade names referred to in this Annual Report appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names.

FORWARD-LOOKING STATEMENTS

This Annual Report contains statements that may be deemed to be "forward-looking statements" within the meaning of the federal securities laws. These statements relate to anticipated future events, future results of operations and/or future financial performance. In some cases, you can identify forward-looking statements by their use of terminology such as "anticipate," "believe," "could," "estimate," "expect," "future," "intend," "may," "ought to," "plan," "possible," "poten "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 C-Scan system, including statements regarding the timing, progress and results of current and future preclinical studies and clinical trials, and our research and development programs;
- timing or likelihood of regulatory filings, approvals and required licenses for our C-Scan system;
- our future business development, results of operations and financial condition;
- our ability to adequately protect our intellectual property rights and enforce such rights and to avoid violation of the intellectual property rights of others;
- our plans to develop, launch and commercialize our C-Scan system and any future products;
- the timing, cost or other aspects of the commercial launch of our C-Scan system;
- our estimates regarding expenses, future revenues, capital requirements and our need for additional financing and strategic partnerships;
- our estimates regarding the market opportunity, clinical utility, potential advantages, and market acceptance of our C-Scan system.
- the impact of government laws and regulations;
- our ability to recruit and retain qualified clinical, regulatory and research and development personnel;
- the availability of reimbursement or other forms of funding for our products from government and commercial payors;
- difficulties in maintaining commercial scale manufacturing capacity and capability and 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 of 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 as well as our August 2016 registered direct offering.

The preceding list is not intended to be an exhaustive list of all of our forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including those described in Item 3D “Key Information - Risk factors.”

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

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

A. Directors and Senior Management

Not required.

B. Advisers

Not required.

C. Auditors

Not required.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not required.

ITEM 3. KEY INFORMATION

A. Selected financial data

The following selected consolidated financial data should be read in conjunction with Item 5 “Operating and Financial Review and Prospects” and the consolidated Financial Statements and Notes thereto included elsewhere in this Annual Report.

The following table summarizes our historical consolidated financial data. We have derived the selected consolidated statements of operations data for the years ended December 31, 2016, 2015 and 2014 and the selected consolidated balance sheet data as of December 31, 2016 and 2015 from our audited consolidated financial statements included elsewhere in this Annual Report. We have derived the selected consolidated statements of operations data for the years ended December 31, 2013 and 2012 and the selected consolidated financial data as of December 31, 2014, 2013 and 2012 from our audited consolidated financial statements not included in this Annual Report. Our Consolidated Financial Statements have been prepared in accordance with U.S. GAAP.

Certain factors that affect the comparability of the information set forth in the following table are described in Item 5 “Operating and Financial Review and Prospects” and the Consolidated Financial Statements and related notes thereto included elsewhere in this Annual Report.

Consolidated Statements of Operations Data

	Year Ended December 31,				
	2016	2015	2014	2013	2012
	(US$ in thousands, except per share data)				
Operating expenses[1]					
Research and development expenses, net[2]	$5,491	$5,837	$2,832	$2,893	$2,377
General and administrative expenses	3,571	6,626	1,703	1,090	1,118
Other income (expenses)	-				