UNITED STATES

SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer Pursuant to Rule 13a-16 or 15d-16 under the Securities Exchange Act of 1934

For the month of: March 2015

Commission file number: 001-35932

<u>ALCOBRA LTD.</u> (Translation of registrant's name into English)

Amot Investment Building 2 Weizman St. 9th Floor <u>Tel Aviv 6423902 Israel</u> (Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F x Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(1):_____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(7):_____

Attached hereto and incorporated by reference herein is the registrant's press release issued on March 10, 2015.

The first three paragraphs in the press release herein are incorporated by reference into the Registration Statements on Form F-3 (File No. 333-197411) and Form S-8 (File No. 333-194875 and File No. 333-202394) of the Registrant, filed with the Securities and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

<u>Exhibit</u>

99.1 Press Release issued by Alcobra Ltd. on March 10, 2015.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

<u>Alcobra Ltd.</u> (Registrant)

By <u>/s/ Dr. Yaron Daniely</u> Name: Dr. Yaron Daniely Chief Executive Officer and President

Date: March 10, 2015



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Alcobra's MDX Meets Primary Endpoint in Phase II Safety and Tolerability Clinical Trial in Adolescents with ADHD

Tel Aviv, Israel – March 10, 2015 – Alcobra Ltd. (NasdaqGM: ADHD), an emerging pharmaceutical company focused on the development of new medications to help patients with cognitive disorders, including Attention Deficit Hyperactivity Disorder (ADHD) and Fragile X Syndrome, today announced that its Phase II safety and tolerability study of a single administration of MDX in adolescent patients with ADHD achieved its primary endpoint. In the study, MDX showed good tolerability and no safety concerns were identified. The profile of adverse events in the MDX treated group was not different from the placebo comparator group. There were no reported cases of discontinuation from the study due to adverse events.

A total of 83 patients enrolled in the Phase II trial, which was a multi-center, randomized, double-blind, placebo controlled, fixed dose study designed to evaluate the safety and tolerability of a single administration of MDX in adolescents (aged 13-17) with predominantly inattentive ADHD. Following a screening period, patients were exposed to either placebo or one of three MDX dose options determined by their weight and followed for several hours that day. Patients returned several days after this treatment visit for a safety follow-up visit.

Patients' baseline characteristics were similar between MDX and placebo groups. The most common side effects were headache (8% of patients in the MDX group and 12% in the placebo group), nausea (3% vs. 5%) and fatigue (3% vs. 5%). No clinically significant safety findings in laboratory values, vital sign measurements, ECG parameters, cardiovascular parameters or findings during clinical examination were observed. Analyses of secondary cognitive measures, after a single administration of MDX compared to placebo, did not produce statistically significant findings, yet resulted in an efficacy signal on the Test of Variables of Attention (TOVA) assessments Response Time and Errors of Omission.

"The successful completion of this safety study is an important milestone in the development of MDX and supports our ability to advance into efficacy trials of MDX for pediatric ADHD," said Dr. Yaron Daniely, President and Chief Executive Officer of Alcobra. "I would like to thank all the patients who participated in the trial and their parents, as well as our investigators who quickly and rigorously conducted this trial over the last few months".

The study is the first clinical trial using MDX in a pediatric ADHD population. For further information on this clinical trial, please visit www.ClinicalTrials.gov, Identifier: NCT02189772. A separate study evaluating MDX in adolescents and adults with Fragile X Syndrome is currently underway and actively enrolling patients. Results of the Fragile X Study are expected to be reported by the end of 2Q15.

About MDX

MDX (Metadoxine Extended Release (MG01CI)) is a proprietary investigational new drug candidate being developed by Alcobra for the potential treatment of ADHD and Fragile X Syndrome. MDX is not a stimulant and acts as a monoamine-independent modulator of GABA (gamma-aminobutyric acid) transmission. This novel mechanism of action does not directly affect dopamine or norepinephrine. In studies to date, metadoxine has shown no potential for abuse or addiction. MDX is currently in Phase III development for adults with ADHD and Phase II development for pediatric ADHD. A study of MDX is also ongoing in adolescents and adults with Fragile X Syndrome.

About Attention Deficit Hyperactivity Disorder (ADHD)

ADHD is a common and impairing neuropsychiatric condition. Once believed to only affect children, ADHD is now known to persist into adolescence and adulthood in a sizeable number of cases. Key symptoms of ADHD include inattention, hyperactivity and impulsivity.

According to the Centers for Disease Control and Prevention, about 9% of children in the U.S. meet criteria for ADHD with similar numbers reported in other countries. Although boys are more commonly diagnosed, ADHD is also common in girls who often go undiagnosed. Approximately 4-5% of adults worldwide are affected with ADHD, yet most adults with ADHD remain undiagnosed and untreated. There is no known cause of ADHD, however studies suggest that genetics may play a role.

About Alcobra Ltd.

Alcobra Ltd. is an emerging pharmaceutical company primarily focused on the development and commercialization of a proprietary drug candidate, MDX, to treat cognitive disorders including ADHD and Fragile X Syndrome. MDX has completed multiple Phase II studies in adults and adolescents with ADHD and has completed a Phase III study in adults with ADHD. The company is conducting a Phase II trial in adolescents and adults with Fragile X Syndrome. The company was founded in 2008 and is headquartered in Tel Aviv, Israel. For more information please visit the Company's website, <u>www.alcobra-pharma.com</u>, the content of which is not incorporated herein by reference.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and other Federal securities laws. Because such statements deal with future events and are based on Alcobra's current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Alcobra could differ materially from those described in or implied by the statements in this press release. For example, forward-looking statements include statements regarding advancement to initiate a Phase III study in pediatric ADHD, expected announcement of results of clinical trials. In addition, historic results of scientific research do not guarantee that the conclusions of future research would not suggest different conclusions or that historic results referred to in this press release would not be interpreted differently in light of additional research or otherwise. The forward-looking statements contained or implied in this press release are subject to other risks and uncertainties, including those discussed under the heading "Risk Factors" in Alcobra Ltd.'s Annual Report on Form 20-F for the fiscal year ended December 31, 2014 filed with the Securities and Exchange Commission (SEC) and in subsequent filings with the SEC. Except as otherwise required by law, Alcobra disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date hereof, whether as a result of new information, future events or circumstances or otherwise.