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: May 2014 (Report Number 2)

ALCOBRA LTD.

(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):
Indicate by check mark, whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.
Yes □ No ⊠
If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b):
Attached hereto and incorporated by reference herein is the registrant's press release issued on May 8, 2014.

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.

Alcobra Ltd. (Registrant)

By <u>/s/ Dr. Yaron Daniely</u> Name: Dr. Yaron Daniely

Chief Executive Officer and President

Date: May 8, 2014



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Alcobra Announces FDA Clearance of Protocol for Phase IIb Study of Metadoxine Extended Release (MDX) in the Treatment of Fragile X Syndrome

TEL AVIV, Israel, May 8, 2014 – Alcobra Ltd. (NasdaqGM: ADHD), an emerging biopharmaceutical company primarily focused on the development and commercialization of its proprietary drug candidate Metadoxine Extended Release (MDX), to treat cognitive dysfunctions, such as ADHD and Fragile X Syndrome, today announced that FDA has approved the protocol for the Company's planned Phase IIb clinical trial of MDX for the treatment of Fragile X Syndrome. The trial is expected to begin enrolling patients shortly.

The Phase IIb study will be a multi-center, randomized, placebo-controlled study, conducted primarily in the US, and is supported by positive data collected from multiple earlier pre-clinical studies. Results from these pre-clinical studies demonstrated significant improvement in behavioral and cognitive outcomes based on evaluations of memory, learning, and social interaction. In a validated mouse model of Fragile X Syndrome, metadoxine treatment was shown to result in improved levels of certain Fragile X-associated blood and brain biological markers that may have a role in learning and memory, while simultaneously reducing the number of immature brain connections and levels of abnormally increased protein. The FDA granted "Orphan Drug" designation to Metadoxine in the treatment of Fragile X Syndrome in December 2013.

"Given the lack of FDA approved therapies, there is a substantial unmet need for treatment options for Fragile X Syndrome," said Dr. Yaron Daniely, President and Chief Executive Officer of Alcobra. "We are pleased that the FDA has approved the protocol for our Phase IIb study, and we expect it to provide important insights into the potential role of MDX in this and related conditions."

About Fragile X Syndrome

Fragile X syndrome (FXS) is a genetic condition that causes intellectual disability, behavioral and learning challenges and various physical characteristics. Behavioral characteristics can include ADHD, autism and autistic behaviors, social anxiety, stereotypic movements, poor eye contact, sensory disorders and increased risk for aggression. Fragile X Syndrome is the leading known genetic cause of autism, accounting for about 2-5% of cases. Fragile X Syndrome represents an unmet medical need and a rare disease, as defined by the Orphan Drug Act. According to the U.S. Centers for Disease Control and Prevention (CDC), approximately one in 4,000 males and one in 8,000 females have Fragile X Syndrome. The FDA has not approved any drugs specifically for the treatment of Fragile X Syndrome or its symptoms.

About Alcobra Ltd.

Alcobra Ltd. is an emerging biopharmaceutical company primarily focused on the development and commercialization of a proprietary drug candidate, MDX (Metadoxine Extended Release (MG01CI)), to treat cognitive dysfunctions including Attention Deficit Hyperactivity Disorder (ADHD) and Fragile X Syndrome. MDX has completed Phase II studies to treat Attention Deficit Hyperactivity Disorder. The company was founded in 2008 and is headquartered in Tel Aviv, Israel. For more information please visit the Company's website, www.alcobra-pharma.com, the content of which is not incorporated herein by reference.

Forward Looking Statements – This press release may contain 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 our plan to initiate a Phase IIb MDX clinical trial for the treatment of Fragile X Syndrome, timing of commencement of such trials, the design and other aspects thereof, the potential of MDX to treat cognitive symptoms and the potential of such clinical trial to provide insight into the potential role of MDX in Fragile X Syndrome. In addition, historic results of scientific research and clinical and preclinical trials do not guarantee that the conclusions of future research or trials would not suggest different conclusions or that historic results referred to in this press release would be interpreted differently in light of additional research and clinical and preclinical trials results. 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 filed with the Securities and Exchange Commission ("SEC") on March 28, 2014, 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.