

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: December 2013 (Report Number 2)

ALCOBRA LTD.

(Translation of registrant's name into English)

Amot Investment Building  
2 Weizman St. 9<sup>th</sup> Floor  
Tel Aviv 6423902 Israel

(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  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 December 18, 2013.

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**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 /s/ Dr. Yaron Daniely  
Name: Dr. Yaron Daniely  
Chief Executive Officer and President

Date: December 18, 2013

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### **FDA Grants Orphan Drug Status to Metadoxine in Fragile X Syndrome**

**Tel Aviv, Israel – December 18, 2013 – Alcobra Ltd. (NasdaqCM: ADHD)** (the "Company"), an emerging biopharmaceutical company primarily focused on the development and commercialization of its proprietary drug candidate, MG01CI (Sustained-Release Metadoxine), to treat cognitive dysfunction, announced today that the U.S. Food & Drug Administration has granted "Orphan Drug" designation to Metadoxine in the treatment of Fragile X Syndrome. The Orphan Drug Act (ODA) provides for granting special status to a drug or biological product to treat a rare disease or condition upon request of a sponsor. Orphan designation qualifies the sponsor of the drug for various development incentives of the ODA, as well as an extended period of market exclusivity following approval.

"We are pleased that the FDA has granted Orphan Drug status to Metadoxine, the active ingredient in MG01CI, in Fragile X" said Dr. Yaron Daniely, President and Chief Executive Officer of Alcobra Ltd. "We recently achieved positive results from a preclinical study of Fragile X and believe this outcome supports investigation in clinical trials which we plan to initiate in 2014. We recently raised approximately \$38 million in a secondary offering, and we believe we now have enough cash to fund the Company through planned submissions of NDA and sNDA filings for MG01CI for adult ADHD, pediatric ADHD and Fragile X Syndrome."

In September this year, Alcobra announced positive findings from a pre-clinical study of Fragile X Syndrome. The study showed significant improvement in cognitive and social functioning following treatment with MG01CI in a valid animal model of Fragile X Syndrome (FMR1 knock-out mouse model). The study was funded in part by the FRAXA Research Foundation.

#### ***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 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. The FDA has not approved any drugs specifically for the treatment of Fragile X or its symptoms.

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**About Alcobra Ltd.**

Alcobra Ltd. is an emerging biopharmaceutical company primarily focused on the development and commercialization of a proprietary drug candidate, MG01CI, to treat cognitive dysfunctions including Attention Deficit Hyperactivity Disorder (ADHD) and Fragile X Syndrome. MG01CI 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](http://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 timing of initiation of clinical trials and the sufficiency of our financial resources to achieve certain milestones. 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 registration statement on Form F-1/A filed with the Securities and Exchange Commission ("SEC") on October 22, 2013, 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.*

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