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: September 2015

Commission file number: 001-35932

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):

Attached hereto and incorporated by reference herein is the Registrant's press release issued on September 21, 2015, announcing that the U.S. Food and Drug Administration has granted Fast Track designation to Metadoxine Extended Release for the treatment of Fragile X Syndrome.

The first paragraph of the press release attached to this Form 6-K of the Registrant is incorporated by reference into the Registration Statements on Form F-3 (File No. 333-197411) and Form S-8 (File No. 333-194875) 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and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

Exhibit No.

99.1

Press release issued by Alcobra Ltd. on September 21, 2015, announcing that the U.S. Food and Drug Administration has granted Fast Track designation to Metadoxine Extended Release for the treatment of Fragile X Syndrome.

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: September 21, 2015



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FDA Grants Fast Track Designation to Alcobra's MDX for Fragile X Syndrome

Tel Aviv, Israel – September 21, 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 the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to Metadoxine Extended Release (MDX) for the treatment of Fragile X Syndrome.

"We are pleased that the FDA has recognized the potential of MDX in Fragile X Syndrome and granted Fast Track designation for this indication," said Dr. Yaron Daniely, President and Chief Executive Officer of Alcobra. "We look forward to our upcoming meeting with the FDA to determine next steps in advancing the development program for MDX in this area of serious unmet medical need."

Fast Track designation is a process designed to facilitate the development and expedite the review of drugs that demonstrate the potential to address unmet medical needs in serious or life-threatening diseases or conditions. According to FDA, a disease or condition is considered serious based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe to a more serious condition.

Companies that receive Fast Track designation can have more frequent interactions with the FDA review team to facilitate product development. In addition, based on clinical data, the New Drug Applications (NDA) for these products could be eligible for priority and/or rolling review.

In 2013, the FDA granted orphan drug status to metadoxine for the treatment of Fragile X Syndrome. Currently, there are no FDA approved medications for Fragile X Syndrome.

About Fragile X Syndrome (FXS)

Fragile X Syndrome (FXS) is a genetic condition that causes intellectual disability, behavioral and learning challenges. FXS is the leading known genetic cause of autism, accounting for about 2-6% of cases. FXS represents an unmet medical need and a rare disease, as defined by the Orphan Drug Act. According to the National Institutes of Health (NIH), approximately one in 4,000 males and one in 8,000 females have FXS.

About MDX

MDX (Metadoxine Extended Release) is a proprietary investigational new drug candidate being developed by Alcobra for the potential treatment of ADHD and FXS. MDX is not a stimulant and acts as a monoamine-independent modulator of GABA (gamma-aminobutyric acid) transmission. In pre-clinical studies to date, metadoxine has shown no potential for abuse or addiction. MDX is currently in Phase III development for adults with ADHD, Phase II development for pediatric ADHD, and Phase II development for FXS.

About Alcobra

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 FXS. 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 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 the potential of MDX to treat Fragile X Syndrome, timing and subject matter of meetings with the FDA, whether we will have more frequent interactions with the FDA review team to facilitate product development, whether MDX will be eligible for priority review and/or rolling review of an NDA or that we will be able to benefit from the incentives granted to orphan drugs. 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. Also, while we have received Fast Track Designation for MDX for the treatment of FXS, we cannot guarantee that we will be able to maintain such designation due to reasons within our outside of our control. 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 circum