

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: July 2016

Commission file number: 001-35932

ALCOBRA LTD.
(Translation of registrant's name into English)

Azrieli Triangle Building
132 Derech Menachem Begin 39th Floor
Tel Aviv 6701101 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): _____

Attached hereto and incorporated by reference herein is the Registrant's press release issued on July 19, 2016, announcing that the European Commission has granted Orphan Drug designation to Metadoxine for the treatment of Fragile X Syndrome within the European Union.

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. 333-209960) and Form S-8 (File No. 333-194875, 333-202394 and 333-209947) 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and Exchange Commission, to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.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 July 19, 2016, announcing that the European Commission has granted Orphan Drug designation to Metadoxine for the treatment of Fragile X Syndrome within the European Union.

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. Tomer Berkovitz
Name: Dr. Tomer Berkovitz
Chief Financial Officer and Chief Operating Officer

Date: July 19, 2016



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Alcobra Granted European Orphan Drug Designation for Metadoxine in Fragile X Syndrome

Tel Aviv, Israel – July 19, 2016 – 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 European Commission (EC) has granted Orphan Drug designation to Metadoxine for the treatment of Fragile X Syndrome within the European Union.

EC Orphan Drug designation is granted to drugs that are intended for the treatment of life threatening or chronically debilitating rare diseases where no satisfactory therapeutic options exist. The designation provides sponsors with development and commercial incentives, including 10 years of market exclusivity, prioritized consultation by the European Medicines Agency on the development of the drug, including clinical studies, and certain exemptions from, or reductions in, regulatory fees.

In 2013, the U.S. Food and Drug Administration (FDA) granted orphan drug status in the United States to Metadoxine for the treatment of Fragile X Syndrome, and in 2015, the FDA granted Fast Track designation to our proprietary Metadoxine Extended Release (MDX) for Fragile X Syndrome. 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. Currently, there are no approved medications in the United States or Europe for Fragile X Syndrome.

About Fragile X Syndrome

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 U.S. Orphan Drug Act. According to the U.S. National Institutes of Health, 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 Fragile X Syndrome. 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 Fragile X Syndrome.

About Alcobra

Alcobra Ltd. is an emerging pharmaceutical company primarily focused on the development and commercialization of MDX (Metadoxine Extended Release), a proprietary drug candidate, to treat cognitive disorders including ADHD and Fragile X Syndrome. 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 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. 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, 2015, 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.

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