

Evoke Pharma Inc
Form 8-K
December 02, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 2, 2014

EVOKE PHARMA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

001-36075
(Commission

File Number)

20-8447886
(IRS Employer

Identification No.)

505 Lomas Santa Fe Drive, Suite 270

Solana Beach, California
(Address of Principal Executive Offices)

92075
(Zip Code)

Registrant's telephone number, including area code: (858) 345-1494

(Former Name or Former Address, if Changed Since Last Report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- .. Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- .. Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- .. Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- .. Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On December 2, 2014, Evoke Pharma, Inc. (the Company) announced results from an electrocardiogram study that assessed the potential of metoclopramide nasal spray (EVK-001) to increase the cardiac QT and corrected QT (QTc) interval across a range of plasma concentrations. The study was conducted to satisfy a safety requirement by the U.S. Food and Drug Administration (FDA) in support of the submission of a New Drug Application for EVK-001, an investigational medication for relief of symptoms associated with acute and recurrent diabetic gastroparesis in women. The study met the pre-specified primary endpoint, demonstrating that EVK-001, at therapeutic and supratherapeutic doses, did not prolong the QT/QTc interval in healthy subjects.

The QT interval represents the amount of time the heart 's electrical system takes to repolarize, or recharge, after each beat. Prolongation of the QT interval may increase the risk for cardiac arrhythmias. A TQT study is a specialized clinical trial designed to assess whether an investigational medication has the potential to prolong the QT interval.

This randomized, double-blind, double-dummy, four-way crossover TQT study, designed in accordance with the FDA 's published guidance on clinical evaluation of QT/QTc interval, compared the effects of EVK-001 on the QT/QTc interval when administered at therapeutic and supratherapeutic doses in 48 healthy female and male volunteers. Moxifloxacin, an antibiotic known to prolong the QT/QTc interval, was used as the positive control.

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 hereunto duly authorized.

EVOKE PHARMA, INC.

Date: December 2, 2014

By: /s/ Matthew J. D Onofrio
Name: Matthew J. D Onofrio
Title: Executive Vice President,
Chief Business Officer and Secretary