



Edgar Filing: Evoke Pharma Inc - Form 8-K

(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 1.01 Entry into a Material Definitive Agreement.

On April 17, 2017, Evoke Pharma, Inc. (the “Company”) entered into an agreement to work in partnership with Spaulding Clinical Research for its planned comparative exposure pharmacokinetic (PK) trial for its lead product candidate, Gimoti™, a patented nasal delivery formulation of metoclopramide for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in adult women. The pivotal PK trial conducted in healthy volunteers is designed to establish bioequivalence with the listed drug, Reglan® Tablets, and may serve as a basis for the 505(b)(2) new drug application (NDA) planned for submission to the Food and Drug Administration (FDA).

This PK trial follows recent communications with FDA regarding the final clinical development steps for the NDA submission. The Company held a face-to-face pre-NDA meeting with FDA in December 2016 to propose and discuss this PK trial and recently confirmed the final protocol design during a Type A Meeting with FDA last month. The Company engaged Spaulding to execute this trial and is now in the latter planning stages to initiate the trial.

The foregoing description of the agreement does not purport to be complete and is qualified in its entirety by the agreement, a copy of which the Company intends to file with its Quarterly Report on Form 10-Q for the period ending June 30, 2017, requesting confidential treatment for certain portions.

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.

Date: April 18, 2017 EVOKE PHARMA, INC.

By: /s/ Matthew J. D'Onofrio

Name: Matthew J. D'Onofrio

Title: Executive Vice President

Chief Business Officer and Secretary