Horizon Pharma plc
Form 8-K
December 08, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 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 8, 2016

Horizon Pharma Public Limited Company

(Exact name of registrant as specified in its charter)

Ireland	**001-35238**	**Not Applicable**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(IRS Employer Identification No.)**

Connaught House, 1st Floor, 1 Burlington Road, Dublin 4, D04 C5Y6, Ireland

(Address of principal executive offices)

Registrant s telephone number, including area code: 011-353-1-772-2100

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:

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 8, 2016, Horizon Pharma announced that the Phase 3 trial, STEADFAST (*S*afety, *T*olerability and *E*fficacy of *A*CTIMMUNE *D*ose Escalation in *F*riedreich s *A*taxia *st*udy), evaluating ACTIMMUNE® (interferon gamma-1b) for the treatment of Friedreich s ataxia (FA) did not meet its primary endpoint of a statistically significant change from baseline in the modified Friedreich s Ataxia Rating Scale (FARS-mNeuro) at 26 weeks versus treatment with placebo. In addition, the secondary endpoints did not meet statistical significance. No new safety findings were identified on initial review of data other than those already noted in the ACTIMMUNE prescribing information for approved indications. The Company, in conjunction with the independent Data Safety Monitoring Board, the principal investigator and the Friedreich s Ataxia Research Alliance (FARA) Collaborative Clinical Research Network (CCRN) in FA, has determined that, based on the trial results, the FA development program will be discontinued, including the 26-week extension study and the long-term safety study.

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: December 8, 2016

HORIZON PHARMA PUBLIC LIMITED COMPANY

By: /s/ Paul W. Hoelscher
Paul W. Hoelscher
Executive Vice President, Chief Financial Officer