CONCERT PHARMACEUTICALS, INC.
Form 8-K
March 12, 2015

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): March 12, 2015

Concert Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36310**	**20-4839882**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

99 Hayden Avenue, Suite 500

Lexington, Massachusetts **02421**
(Address of Principal Executive Offices) **(Zip Code)**
Registrant s telephone number, including area code: (781) 860-0045

(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

Deuterium-Modified Ivacaftor

On March 12, 2015, Concert Pharmaceuticals, Inc. (the Company) announced that it had initiated its Phase 1 clinical program for deuterium-modified ivacaftor, a novel, potentially disease-modifying treatment for cystic fibrosis. Ivacaftor is commercially available under the name Kalydeco®. The first Phase 1 trial will be a crossover study to compare two proprietary deuterium-modified compounds in order to select one for further clinical evaluation. The Phase 1 program also encompasses single- and multiple-ascending doses to further evaluate the safety and pharmacokinetics of the selected candidate.

The Phase 1 program is expected to enroll approximately 45 healthy volunteers. Dosing has been initiated in the first Phase 1 trial which is designed to assess single doses of two deuterium-modified compounds, each of which has demonstrated greater metabolic stability relative to Kalydeco in preclinical testing. Based on the results of this initial crossover study, Concert will select one compound for advancement into the single ascending dose portion of the Phase 1 program, which will assess single ascending doses of the selected compound compared to a single dose of Kalydeco. The final phase of the Phase 1 program will assess multiple ascending doses of the selected compound compared to placebo and is expected to begin in the second half of 2015. The Company expects to report top-line data upon completion of the multiple dose Phase 1 program.

CTP-354

As previously disclosed, the Company intends to conduct additional non-clinical studies to further evaluate CTP-354 and assess its development profile before advancing the compound into Phase 2 clinical testing. In March 2015, the Company received a partial clinical hold letter from the Food and Drug Administration (FDA) regarding this program. The partial clinical hold relates to the adverse effects previously observed by the Company in a non-clinical study. The FDA stated in its letter that, while the available nonclinical data support clinical trials of up to 28 days duration at doses that do not result in plasma exposure that exceeds a specified level, any additional clinical studies testing CTP-354 exceeding those parameters may not be initiated without prior agreement with the FDA. The Company believes the specified amount would allow dosing of 6 mg per day.

Cautionary Statement Regarding Forward-Looking Statements

Any statements in this Form 8-K about future expectations, plans and prospects, including statements about the success of any non-clinical studies or clinical trials for CTP-354, the Company s expectations for clinical development of the Company s therapeutic candidates or ability to commercialize any products and other statements containing the words anticipate, believe, continue, could, estimate, expect, intend, may, plan, potential, predict target, would, and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation of future clinical trials; whether preliminary results from a clinical trial will be predictive of the final results of that trial or whether results of early clinical trials will be indicative of the results of later clinical trials; expectations for regulatory approvals; failure to protect and enforce the Company s intellectual property and other proprietary rights and the risks and uncertainties relating to intellectual property claims; availability of funding sufficient for the Company s foreseeable and unforeseeable operating expenses and capital expenditure requirements and other factors discussed in the Risk Factors section of the Company s most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission and in other filings that the Company makes with the Securities and Exchange Commission. In addition, any forward-looking statements included in this Form 8-K represent the Company s views only as of the date of this Form 8-K and should not be relied upon as representing its views as of any subsequent date. The Company specifically disclaims any obligation to update any forward-looking statements included in this Form 8-K.

Kalydeco is a registered trademark of Vertex Pharmaceuticals Incorporated.

SIGNATURE

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.

CONCERT PHARMACEUTICALS, INC.

Date: March 12, 2015

/s/ Ryan Daws
Ryan Daws
Chief Financial Officer