# 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): May 18, 2016

# SYNDAX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware (state or other jurisdiction of incorporation) 001-37708 (Commission File Number) 32-0162505 (I.R.S. Employer Identification No.)

400 Totten Pond Road, Suite 110 Waltham, Massachusetts (Address of principal executive offices)

02451 (Zip Code)

Registrant's telephone number, including area code: (781) 419-1400

(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)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

### Item 8.01. Other Events.

On May 18, 2016, Syndax Pharmaceuticals, Inc. (the "Company") issued a press release announcing that clinical data from the National Cancer Institute's Cancer Therapy Evaluation Program will be presented at the 52nd Annual Meeting of the American Society of Clinical Oncology (ASCO), which is being held in Chicago, Illinois. Additionally, the Company announced that preliminary results from ENCORE-601, a Phase 1b/2, open-label trial evaluating entinostat in combination with *Keytruda*<sup>®</sup> (pembrolizumab) in non-small cell lung cancer and melanoma patients, are available as a published abstract only at abstract.asco.org.

The full text of the press release regarding the announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

99.1 Press Release, dated May 18, 2016.

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.

## SYNDAX PHARMACEUTICALS, INC.

By: /s/ Briggs W. Morrison, M.D.

Briggs W. Morrison, M.D. Chief Executive Officer

Dated: May 19, 2016

# EXHIBIT INDEX

## Exhibit No. Description 99.1

Press Release, dated May 18, 2016.



# ENTINOSTAT DATA TO BE HIGHLIGHTED AT THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO) 2016 ANNUAL MEETING

WALTHAM, Mass., May 18, 2016 (GLOBE NEWSWIRE) – Syndax Pharmaceuticals, Inc. (Nasdaq:SNDX), a clinical stage biopharmaceutical company focused on developing entinostat in multiple cancer indications, today announced that clinical data from the National Cancer Institute's Cancer Therapy Evaluation Program (NCI-CTEP) will be presented at the 52<sup>nd</sup> Annual Meeting of the American Society of Clinical Oncology (ASCO), which is being held from June 3 to June 7, 2016 in Chicago, Illinois.

Preliminary results from ENCORE-601, a Phase 1b/2, open-label trial evaluating entinostat in combination with *Keytruda*<sup>®</sup> (pembrolizumab) in non-small cell lung cancer and melanoma patients are available as a published abstract only at abstract.asco.org. Clinical results highlight entinostat's potential use in combination approaches to treat various cancers.

Details of the two investigator-sponsored poster presentations and the one company-sponsored abstract are as follows:

1) Title: Open-label phase Ib study of entinostat (E), and lapatinib (L) alone, and in combination with trastuzumab (T) in patients (pts) with HER2+ metastatic (mHER2+) breast cancer after progression on trastuzumab (NCI-CTEP #8871)

Poster Session: Breast Cancer – HER2/ER Location: Hall A Poster Board: 97 Date and Time: Sunday, June 5, 8:00 AM – 11:30 AM, Central time Abstract Number: 609 Presenter: Bora Lim, MD Anderson Cancer Center

2) Title: Immunomodulation by HDAC inhibition: Results from a phase II study with entinostat and high-dose interleukin 2 in metastatic renal cell carcinoma patients (NCI-CTEP #7870).

**Poster Session**: Genitourinary (nonprostate) cancer **Location**: Hall A

Poster Board: 182 Date and Time: Monday, June 6, 1:00 PM – 4:30 PM, Central time Abstract Number: 4560 Presenter: Roberto Pili, Indiana University

**3) Title**: Preliminary results of ENCORE 601, a phase 1b/2, open-label study of entinostat (ENT) in combination with pembrolizumab (PEMBRO) in patients with non-small cell lung cancer (NSCLC).

Publication Only Abstract Number: e20659 Lead Author: Melissa Johnson, Sarah Cannon Research Institute

### About Syndax Pharmaceuticals, Inc.

Syndax is a clinical stage biopharmaceutical company developing entinostat as a combination therapy in multiple cancer indications. Entinostat, which was granted Breakthrough Therapy designation by the U.S. Food and Drug Administration following positive results from our Phase 2b clinical trial, ENCORE 301, is currently being evaluated in a Phase 3 clinical trial for advanced hormone receptor positive breast cancer. Concurrently, Syndax is developing entinostat with a focus on tumors that have shown sensitivity to immunotherapy, including lung cancer, melanoma, ovarian cancer and triple-negative breast cancer (TNBC). Entinostat is an oral, small molecule drug candidate that has direct effects on both cancer cells and immune regulatory cells, potentially enhancing the body's immune response to tumors. Entinostat is being evaluated as a combination therapeutic in Phase 1b/2 clinical trials with Merck & Co., Inc. for non-small cell lung cancer and melanoma, with Genentech, Inc. for TNBC, with Pfizer Inc. and Merck KGaA, Darmstadt, Germany for ovarian cancer. For more information on Syndax please visit <u>www.syndax.com</u>.

#### Syndax's Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend," "believe" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Syndax's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, the reporting of clinical data for Syndax's product candidate and its potential use to treat various cancers. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, failure of Syndax's collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes. Other factors that may cause Syndax's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Syndax's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein. Except as required by law, Syndax assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

#### **Investor and Media Contacts**

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