# 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): **September 24, 2018** 

### SYNDAX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

001-37708

(Commission File Number)

**Delaware** (state or other jurisdiction of incorporation)

32-0162505

(I.R.S. Employer Identification No.)

	Building D, Floor 3 35 Gatehouse Drive Waltham, Massachusetts (Address of principal executive offices)	<b>02451</b> (Zip Code)
Registrant's telephone number, including area code: (781) 419-1400		
	(Former name or former address, is	changed since last report)
	the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy Instruction A.2. below):	the filing obligation of the registrant under any of the following provisions (see
	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 25	30.425)
	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	e Act (17 CFR 240.14d-2(b))
	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange	e Act (17 CFR 240.13e-4(c))
	by check mark whether the registrant is an emerging growth company as defined in b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).	as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or
Emergir	ng growth company $oxdim 2$	
	nerging growth company, indicate by check mark if the registrant has elected not to using standards provided pursuant to Section 13(a) of the Exchange Act. ☑	e the extended transition period for complying with any new or revised financial

## Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensation Arrangements of Certain Officers.

On September 25, 2018, Henry Chen and Luke Evnin, Ph.D. each notified Syndax Pharmaceuticals, Inc. (the "*Company*") of his respective decision to resign from the Board of Directors of the Company (the "*Board*") effective September 25, 2018. Mr. Chen and Dr. Evnin's resignations from the Board are not due to any disagreements with the Company on any matter relating to the Company's operations, policies or practices. Following Dr. Evnin's resignation, the Board appointed Keith A. Katkin as chair of the Compensation Committee.

On September 25, 2018, the Board unanimously voted to appoint Jennifer Jarrett and William Meury to the Board, each effective on September 25, 2018, and appointed Ms. Jarrett as a member of the Nominating and Corporate Governance Committee and Mr. Meury as a member of the Audit Committee. Ms. Jarrett and Mr. Meury's appointments fill vacancies on the Board resulting from the resignations of Mr. Chen and Dr. Evnin. The Board designated each of Ms. Jarrett and Mr. Meury as Class II members to serve until the 2021 annual meeting of the Company's stockholders, or until her or his successor has been duly elected and qualified, or until her or his earlier death, resignation or removal.

There were no arrangements or understandings between either Ms. Jarrett or Mr. Meury and any other persons pursuant to which each was selected as a director, and there are no related person transactions within the meaning of Item 404(a) of Regulation S-K promulgated by the U.S. Securities and Exchange Commission (the "SEC") between either Ms. Jarrett and the Company or Mr. Meury and the Company required to be disclosed herein.

Pursuant to the Company's Non-Employee Director Compensation Policy (the "*Policy*"), each of Ms. Jarrett and Mr. Meury will receive annual cash compensation in the amount \$40,000 for their Board service, and, in the case of Ms. Jarrett, \$4,000 for her Nominating and Corporate Governance Committee service, and, in the case of Mr. Meury, \$8,500 for his Audit Committee service. All amounts will be paid in quarterly installments. The Company will also reimburse each of Ms. Jarrett and Mr. Meury for their travel expenses incurred in connection with attendance at Board and Committee meetings. On September 25, 2018, the Board also granted each of Ms. Jarrett and Mr. Meury an initial one-time option to purchase 35,000 shares of the Company's common stock (each, an "*Option*"). Subject to each of Ms. Jarrett and Mr. Meury's continued service on the Board, each Option will vest as follows: 1/36 of the shares subject to each Option will vest monthly over a three-year period. In accordance with the Policy, as may be amended from time to time, each of Ms. Jarrett and Mr. Meury will also be eligible to receive an annual option award to purchase shares of the Company's common stock, subject to their continued service on the Board.

In connection with Ms. Jarrett and Mr. Meury's appointments to the Board, each entered into the Company's standard form of Indemnification Agreement, a copy of which was filed as Exhibit 10.21 to the Registration Statement on Form S-1 (File No. 333-208861) filed with the SEC on January 4, 2016. A copy of the Company's press release is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

#### Item 8.01. Other Events.

On September 24, 2018, the Company issued a press release updating its guidance regarding the Phase 3 registration trial of entinostat plus exemestane in advanced hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+, HER2-) breast cancer, E2112. A copy of the press release is attached as Exhibit 99.2 hereto and is incorporated herein by reference.

# (d) Exhibit Exhibit No. Description 99.1 Press Release, dated September 25, 2018. 99.2 Press Release, dated September 24, 2018.

Item 9.01.

Financial Statements and Exhibits.

#### **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: September 26, 2018



#### **Syndax Announces Changes to its Board of Directors**

- Jennifer Jarrett and William Meury appointed to Board of Directors -
  - Luke Evnin, Ph.D., and Henry Chen resign as active members –

WALTHAM, Mass., September 25, 2018 (PRNEWSWIRE) -- Syndax Pharmaceuticals, Inc. ("Syndax," the "Company" or "we") (Nasdaq:SNDX), a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today announced the appointment of Jennifer Jarrett and William Meury to its Board of Directors, effective today. Ms. Jarrett and Mr. Meury will succeed Luke Evnin, Ph.D. and Henry Chen, who resigned as active members of the Syndax Board of Directors, effective today.

"It is a pleasure to welcome Jennifer and Bill, both highly accomplished leaders in the biopharmaceutical industry, to our Board of Directors," said Dennis Podlesak, Chairman of Syndax. "Jennifer brings to the Board a wealth of financial and operational expertise, with a proven track record of creating and building value for numerous publicly traded biotech companies. Bill's extensive experience successfully launching and commercializing healthcare products will be invaluable as we move closer to the potential commercialization of entinostat. I look forward to their contributions and insights as Syndax continues its efforts to advance its innovative pipeline of cancer therapies and evolve into a commercial organization."

Mr. Podlesak added, "On behalf of the entire Board, I would like to thank Luke and Henry for their dedication and commitment to Syndax over the years. We wish them both the best of luck in all of their future endeavors."

Ms. Jarrett currently serves as Chief Operating Officer and Chief Financial Officer of Arcus Biosciences, a publicly traded biotechnology company developing next generation cancer immunotherapies. Prior to Arcus, Ms. Jarrett was Chief Financial Officer of Medivation up until the company's sale to Pfizer in 2016. Before Medivation, Ms. Jarrett spent 20 years in investment banking, most recently at Citigroup where she was responsible for the firm's West Coast life sciences investment banking practice. Prior to Citigroup, Ms. Jarrett worked in the investment banking divisions of Credit Suisse, Donaldson, Lufkin & Jenrette, Merrill Lynch and Kidder Peabody. Ms. Jarrett currently serves on the Board of Directors of Arena Pharmaceuticals and Audentes Therapeutics. She holds an M.B.A. from the Stanford Graduate School of Business and earned her bachelor's degree in Economics from Dartmouth College.

Mr. Meury currently serves as the Chief Commercial Officer of Allergan, plc, a global, publicly traded pharmaceutical company. He began his tenure at Allergan in 2014 as Executive Vice President, Commercial, North American Brands, and subsequently held the role of President, Branded Pharma. Prior to joining Allergan, Mr. Meury served as Executive Vice President, Sales and Marketing at Forest Laboratories, Inc. prior to its acquisition by Allergan, then known as Actavis. He joined Forest in 1993 and held multiple roles of increasing responsibility in Marketing, New Products, Business Development, and Sales. Before joining Forest, Mr. Meury worked in public accounting for Reznick Fedder & Silverman and in financial reporting for MCI Communications. He is currently on the Board of Directors of several organizations, including The Jed Foundation and the International Council of Ophthalmology Foundation. Mr. Meury earned his bachelor's degree in Economics from the University of Maryland.



#### About Syndax Pharmaceuticals, Inc.

Syndax Pharmaceuticals is a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. The Company is developing its lead product candidate, entinostat, a once-weekly, oral, small molecule, class I HDAC inhibitor, in combination with exemestane and several approved PD-1/PD-L1 antagonists. The Company's pipeline also includes SNDX-6352, a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor, as well as a portfolio of potent and selective inhibitors targeting the binding interaction of Menin with MLLr. For more information, please visit <a href="https://www.syndax.com">www.syndax.com</a> or follow the Company on <a href="https://www.syndax.com">Twitter</a> and <a href="https://www.syndax.com">LinkedIn</a>.

#### 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 forwardlooking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about the progress, timing, clinical development and scope of clinical trials and the reporting of clinical data for Syndax's product candidates, and the potential use of our product candidates to treat various cancer indications. 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.

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## Syndax Announces Updated Results from Phase 2 ENCORE 601 Trial of Entinostat in Combination with KEYTRUDA® (pembrolizumab) in Non-Small Cell Lung Cancer

- Updated biomarker analyses continue to support prior observation of enhanced clinical benefit in subpopulation of patients with elevated baseline levels of peripheral classical blood monocytes; 5.3 month PFS and 21% ORR observed in subpopulation –
- Company provides update on timeline for E2112 Phase 3 registration trial of entinostat plus exemestane in HR+, HER2- breast cancer –

WALTHAM, Mass., September 24, 2018 (PRNEWSWIRE) -- Syndax Pharmaceuticals, Inc. ("Syndax," the "Company" or "we") (Nasdaq:SNDX), a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today announced updated results from the ongoing ENCORE 601 cohort enrolling non-small cell lung cancer (NSCLC) patients previously treated with both chemotherapy and PD-(L)1 therapy. The oral presentation titled, "Efficacy/Safety of Entinostat (ENT) and Pembrolizumab (PEMBRO) in NSCLC Patients Previously Treated with Anti-PD-(L)1 Therapy", was presented by Matthew D. Hellman, M.D., study investigator and medical oncologist at Memorial Sloan Kettering Cancer Center, at the International Association for the Study of Lung Cancer (IASLC) 19th World Conference on Lung Cancer (WCLC) in Toronto, Canada. A copy of the presentation is available via the Syndax website at http://www.syndax.com/science/publications/.

"The observation of durable responses seen with the entinostat-pembrolizumab combination in NSCLC patients previously treated with both chemotherapy and PD-(L)1 therapy is an important result, and we look forward to more fully characterizing patient selection tools to identify those who are most likely to respond," said Peter Ordentlich, Ph.D., Syndax co-founder and Chief Scientific Officer. "The exploratory finding that baseline peripheral classical monocytes may predict clinical benefit to the combination provides an opportunity to potentially correlate a readily measurable circulating biomarker with the state of the tumor microenvironment and supports the use of this approach for patient selection in future studies."

The Company previously presented a subset of data from the first 57 patients in the Phase 2 ENCORE 601 NSCLC cohort, which enrolled patients whose disease had progressed after prior chemotherapy and anti-PD-(L)1 treatment, at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting this past June. The updated data set presented today includes data from all 76 patients who enrolled in this cohort prior to the close of enrollment in December 2017, and highlights the durability of the observed responses independent of prior treatment history or PD-(L)1 status. At the time of data cut-off, there were 7 confirmed partial responses (PRs) among the overall population of 72 efficacy-evaluable patients, for a 10% objective response rate (ORR) (95% CI: 4-19%), a median duration of response of 5.3 months, and a median progression free survival (PFS) of 2.8 months. The results did not meet the prespecified ORR endpoint. Six of the 7 responders had low or negative PD-(L)1 expression at study entry. At the time of data cut-off, 6 patients remain on study. Updated data continue to demonstrate a manageable toxicity profile for the entinostat-pembrolizumab combination, with treatment emergent adverse events observed consistent with those previously reported.



Exploratory analysis of baseline biomarkers in the fully enrolled cohort supports the previous observation from the first 57 patients that elevated pre-treatment baseline levels of peripheral classical blood monocytes (CD14+CD16-HLA-DRhi) are associated with enhanced clinical benefit to the entinostat-pembrolizumab combination. Baseline peripheral classical monocyte data were available for 65 of the 72 NSCLC patients evaluable for efficacy and were divided into a group of high baseline monocytes ("monocyte high" n = 19) and low baseline monocytes ("monocyte low" n = 46). The monocyte high subset showed an improved median PFS (5.3 months vs 2.7 months), and an enhanced ORR (21% vs 7%), with 5 of 19 (26%) patients remaining on study compared to only 1 of 46 (2%) in the monocyte low group.

"We continue to remain encouraged by the consistent observation of enhanced clinical benefit in the subgroup of patients who failed prior PD-1 treatment and had high baseline levels of classical peripheral monocytes, a population for whom novel therapies are needed," said Briggs Morrison, M.D., Chief Executive Officer of Syndax. "We recognize the importance of identifying patients more likely to respond to treatment and believe that our updated classical monocyte dataset strengthens the rationale for further validation of this patient selection biomarker. We look forward to communicating our plans for entinostat in this indication in the fourth quarter."

#### E2112 Update

Syndax also announced today that ECOG-ACRIN Cancer Research Group has informed the Company that enrollment in the ongoing E2112 Phase 3 registration trial of entinostat plus exemestane in advanced hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+, HER2-) breast cancer is now scheduled to close in late October. The Company will release the results of the PFS analysis following its review, and anticipates communicating this in the fourth quarter. The trial remains ongoing, with interim overall survival (OS) analyses scheduled to occur every May and November until either the appropriate number of events are achieved or definitive interim results are obtained.

#### **About Entinostat**

Entinostat is a selective, oral, once-weekly inhibitor of class 1 HDACs, currently being evaluated in a pivotal Phase 3 clinical trial (E2112) in combination with exemestane for advanced hormone receptor positive, human epidermal growth factor receptor 2 negative breast cancer, an indication for which it has been granted Breakthrough Therapy Designation by the FDA. Entinostat has also been shown to block the function of immune suppressive cells in the tumor microenvironment, and is being evaluated in combination with several approved PD-1/PD-L1 antagonists, including in ongoing Phase 2 clinical trials combining entinostat with KEYTRUDA® from Merck & Co., Inc. for non-small cell lung cancer, melanoma and colorectal cancer (ENCORE 601); with TECENTRIQ® from Genentech, Inc. for triple negative breast cancer as well as advanced hormone receptor positive, human epidermal growth factor receptor 2 negative breast cancer (ENCORE 602); and with BAVENCIO® from Pfizer Inc. and Merck KGaA, Darmstadt, Germany, for ovarian cancer (ENCORE 603).

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