
**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):
November 10, 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)
 - 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))
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Item 2.02. Results of Operations and Financial Condition.

On November 10, 2016, Syndax Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 2016. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information provided in this Form 8-K, including Exhibit 99.1 hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 10, 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: November 10, 2016

EXHIBIT INDEX

**Exhibit
No.**

Description

99.1 Press Release, dated November 10, 2016.



Syndax Pharmaceuticals Reports Third Quarter 2016 Financial Results and Provides Business Update

Execution on clinical timelines and advancement of oncology programs continues with initiation of:

- Phase 2 cohorts of ENCORE 601 in NSCLC and melanoma
- Phase 1 clinical trial of SNDX-6352

WALTHAM, Mass., Nov. 10, 2016 (GLOBE NEWSWIRE) — Syndax Pharmaceuticals, Inc. (“Syndax,” the “Company” or “we”) (Nasdaq:SNDX), a clinical stage biopharmaceutical company focused on developing entinostat and SNDX-6352 in multiple cancer indications, today reported its financial results for the third quarter ended September 30, 2016. In addition, the Company provided a pipeline update as well as a review of upcoming milestones. As of September 30, 2016, Syndax had \$115.6 million in cash, cash equivalents and short-term investments.

“We continue to advance our innovative pipeline and anticipate having five clinical trials in six cancer indications up and running by the end of the year,” said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. “We believe the continued execution of our strategy will bring us closer to achieving our mission and realizing a future in which people with cancer live longer and better than ever before.”

“According to ECOG, the accelerated pace of patient accrual in E2112, the Phase 3 registration clinical trial of entinostat in advanced HR+, HER2- breast cancer, now puts us on track to complete enrollment and should allow for the analysis of the progression-free survival results in the second half of 2017,” said Dr. Michael L. Meyers, Chief Medical Officer of Syndax.

Pipeline Updates

- E2112 is now 60% enrolled as patient accrual has continued at an accelerated pace. This Phase 3 registration clinical trial of entinostat plus Aromasin® (exemestane tablets) in advanced HR+, HER2- breast cancer is being conducted in collaboration with Eastern Cooperative Oncology Group-American College of Radiology Imaging Network Cancer Research Group (“ECOG”) and the National Cancer Institute under a special protocol assessment (“SPA”) with the U.S. Food and Drug Administration (“FDA”). Entinostat was granted Breakthrough Therapy designation by the FDA for this indication following positive results from the Company’s Phase 2b clinical trial, ENCORE 301.
- The Company initiated enrollment of the three cohorts in the first stage of the Phase 2 component of ENCORE 601 in patients with non-small cell lung cancer (“NSCLC”) and melanoma. Previously, Syndax announced the completion of enrollment for the dose confirmation stage of ENCORE 601, an open-label,

Phase 1b/2 clinical trial evaluating the combination of entinostat plus Merck's anti-PD-1 blocking therapy, KEYTRUDA® (pembrolizumab), in patients with NSCLC.

- The Phase 1b portion of ENCORE 602, a Phase 1b/2 clinical trial evaluating the combination of entinostat plus Genentech's PD-L1 inhibitor, Tecentriq™ (atezolizumab), in patients with triple negative breast cancer ("TNBC") continues to enroll on schedule. The trial's open label Phase 1b portion is designed to assess the safety of a 5 mg dose.
- Syndax commenced enrollment in the Phase 1 single ascending dose clinical trial of SNDX-6352 in healthy volunteers to determine the safety and pharmacokinetics of the anti-CSF-1R monoclonal antibody.
- In collaboration with Pfizer Inc. and Merck KGaA, Darmstadt, Germany, Syndax began prescreening patients for enrollment in the Phase 1b portion of ENCORE 603, a Phase 1b/2 clinical trial evaluating entinostat in combination with an investigational monoclonal antibody targeting PDL-1, avelumab, in patients with ovarian cancer.

Upcoming Milestones

- According to ECOG, based upon current enrollment trends, Syndax expects that E2112, a Phase 3 registrational clinical trial of entinostat in HR+, HER2- breast cancer, will be fully enrolled and an analysis of progression-free survival will likely be available in the second half of 2017.
- Syndax anticipates making a go/no go decision to progress into the second stage for each arm of ENCORE 601 in the Phase 2 trial in patients with advanced metastatic or recurrent NSCLC or melanoma by the end of the first quarter of 2017.
- In collaboration with Pfizer Inc. and Merck KGaA, Darmstadt, Germany, Syndax anticipates commencing enrollment in the Phase 1b portion of ENCORE 603 study in patients with ovarian cancer by the end of the fourth quarter of 2016.
- The Company anticipates safety data from the Phase 1b dose determination portion of ENCORE 602 in patients with TNBC and the Phase 1b safety portion of ENCORE 603 in patients with ovarian cancer in the first half of 2017.

Syndax Expects to Participate in the Following Upcoming Conferences

- Syndax plans to present safety, biomarker and initial efficacy data from the completed Phase 1b portions of the ENCORE 601 trial in patients with NSCLC and preclinical data for SNDX-6352 in two separate posters at the Society for Immunotherapy of Cancer Annual Meeting in National Harbor, MD on Friday, November 11, 2016.

- Syndax management will participate in the ROTH Innovations in Oncology Corporate Access Day in New York on November 17, 2016.
- Syndax management will participate in the Oppenheimer 2016 Life Sciences Summit in New York on November 29, 2016.
- Syndax management will present at the 28th Annual Piper Jaffray Healthcare Conference being held in New York on November 29 and 30, 2016.
- Syndax will present a poster describing the ENCORE 602 Phase 1b/2 trial in the Trials in Progress track at the San Antonio Breast Cancer Symposium on December 6 through 10, 2016.
- Syndax management will participate in the Citi 2016 Global Healthcare Conference being held in New York on December 7 and 8, 2016.
- Syndax management will participate in the Guggenheim Securities 4th Annual Boston Healthcare Conference in Boston on December 13, 2016.

Third Quarter 2016 Financial Results

As of September 30, 2016, Syndax had cash, cash equivalents and short-term investments of \$115.6 million and 18,189,880 shares issued and outstanding.

Third quarter 2016 research and development expenses increased to \$12.3 million from \$3.0 million for the comparable period in the prior year primarily due to increased patient accrual costs in E2112, higher expenses associated with the Phase 2 expansion of ENCORE 601, and the commencement of ENCORE 602 as well as the upfront payment related to expanding the pipeline with SNDX-6352.

General and administrative expenses totaled \$3.3 million during the third quarter of 2016, similar to the \$3.2 million expense level for the comparable prior year period.

For the three months ended September 30, 2016, Syndax reported a net loss attributable to common stockholders of \$15.0 million or \$0.84 per share compared to \$56.7 million or \$790.85 per share for the comparable prior year period. The net loss for the three months ended September 30, 2016 included non-cash stock-based compensation expense of \$0.8 million related to the issuance of stock option awards to employees.



Conference Call and Webcast

In connection with the earnings release, Syndax's management team will host a conference call and live audio webcast at 4:30 p.m. ET today, Thursday, November 10, 2016.

The live audio webcast and accompanying slides may be accessed through the Events & Presentations page in the Investors section of the Company's website at www.syndax.com. Alternatively, the conference call may be accessed through the following:

Conference ID: 96707118

Domestic Dial-in Number: 1-855-251-6663

International Dial-in Number: 281-542-4259

Live webcast: <http://edge.media-server.com/m/p/3py8kcmc>

For those unable to participate in the conference call or webcast, a replay will be available for 30 days on the Investors section of the Company's website, www.syndax.com.

About Syndax Pharmaceuticals, Inc.

Syndax is a clinical stage biopharmaceutical company focused on developing an innovative pipeline of combination therapies in multiple cancer indications. Our lead product candidate, entinostat, which was granted Breakthrough Therapy designation by the FDA following positive results from our Phase 2b clinical trial, ENCORE 301, is currently being evaluated in a Phase 3 registration clinical trial for advanced hormone receptor positive, human epidermal growth factor receptor 2 negative breast cancer. Syndax is developing entinostat, which has direct effects on both cancer cells and immune regulatory cells, and SNDX-6352, an anti-CSF-1R monoclonal antibody, to potentially enhance the body's immune response on tumors that have shown sensitivity to immunotherapy. 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, and with Pfizer Inc. and Merck KGaA, Darmstadt, Germany, for ovarian cancer. SNDX-6352 is being evaluated in a single ascending dose Phase 1 clinical trial and is expected to be developed to treat a variety of cancers. For more information on Syndax, please visit www.syndax.com.

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, 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 SNDX-6352 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, without limitation, the factors contained under the caption "Risk Factors" in Syndax's quarterly reports on Form 10-Q. 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.



SYNDAX PHARMACEUTICALS, INC.
(unaudited)
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	September 30, 2016	December 31, 2015
Cash, cash equivalents, and short-term investments	\$ 115,567	\$ 86,489
Total assets	\$ 117,729	\$ 89,903
Total liabilities	\$ 23,895	\$ 23,205
Total stockholders' equity (deficit)	\$ 93,834	\$ (252,415)
Common stock outstanding	18,189,880	100,124
Common stock and common stock equivalents*	21,055,803	15,856,356

* Common stock and common stock equivalents:

	September 30, 2016	December 31, 2015
Common stock	18,189,880	100,124
Convertible preferred stock	—	12,872,551
Options to purchase common stock	2,508,083	2,606,195
Common stock warrants	357,840	277,486
	<u>21,055,803</u>	<u>15,856,356</u>



SYNDAX PHARMACEUTICALS, INC.
(unaudited)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
License fee revenue	\$ 305	\$ 305	\$ 915	\$ 322
Operating expenses:				
Research and development	12,274	2,968	23,191	6,962
General and administrative	3,269	3,195	10,349	9,194
Total operating expenses	<u>15,543</u>	<u>6,163</u>	<u>33,540</u>	<u>16,156</u>
Loss from operations	(15,238)	(5,858)	(32,625)	(15,834)
Other income (expense), net	269	(1,873)	(1,032)	(3,022)
Net loss	<u>\$ (14,969)</u>	<u>\$ (7,731)</u>	<u>\$ (33,657)</u>	<u>\$ (18,856)</u>
Net loss attributable to common stockholders	<u>\$ (14,969)</u>	<u>\$ (56,656)</u>	<u>\$ (36,255)</u>	<u>\$ (95,066)</u>
Net loss per share attributable to common stockholders - basic and diluted	<u>\$ (0.84)</u>	<u>\$ (790.85)</u>	<u>\$ (2.70)</u>	<u>\$ (1,500.34)</u>
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders - basic and diluted	<u>17,899,481</u>	<u>71,639</u>	<u>13,419,919</u>	<u>63,363</u>

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