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 7, 2017

SYNDAX PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

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

Building D, Floor 3 **35 Gatehouse Drive** **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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☑

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☑

Item 2.02. Results of Operations and Financial Condition.

On November 7, 2017, Syndax Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2017. 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 into any of the Company's filings 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.

Exhibit No.	Description
99.1	Press Release, dated November 7, 2017.

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 7, 2017

Syndax Pharmaceuticals Reports Third Quarter 2017 Financial Results and Provides Clinical and Business Update

- Pipeline Expanded with Addition of Potential Best-in-Class Menin-MLL-r inhibitors -

- Enrollment in First Stage of Colorectal and Second Stage of PD-(L)1 Refractory NSCLC Cohorts of ENCORE 601 Complete -

- Company to Host Conference Call Today at 4:30 p.m. ET -

WALTHAM, Mass., Nov. 7, 2017 (PRNEWSWIRE) — Syndax Pharmaceuticals, Inc. ("Syndax," the "Company" or "we") (Nasdaq: SNDX), a clinical stage biopharmaceutical company developing entinostat and SNDX-6352 in multiple cancer indications, today reported its financial results for the third quarter ended September 30, 2017. In addition, the Company provided a clinical and business update. As of September 30, 2017, Syndax had $120.6 million in cash, cash equivalents and short-term investments.

The Company continues to expand its pipeline, and recently announced that it has entered into an exclusive worldwide license agreement with Vitae Pharmaceuticals, Inc., a subsidiary of Allergan plc, for a portfolio of preclinical, orally-available small molecule inhibitors of the interaction of Menin with the Mixed Lineage Leukemia ("MLL") protein. Syndax plans to initially study these compounds for the treatment of a genetically-defined subset of acute leukemias with chromosomal rearrangements in the MLL gene ("MLL-r").

All four cohorts of ENCORE 601, an open-label, Simon two-stage design, Phase 1b/2 clinical trial evaluating the combination of entinostat, the Company's class I selective HDAC inhibitor, plus Merck's anti-PD-1 (programmed death receptor-1) blocking therapy, KEYTRUDA®, continue to proceed on schedule. Enrollment in the first stage of the cohort of patients with microsatellite stable colorectal cancer (MSS-CRC) is complete, and a decision on whether to continue to the second stage is expected in the first quarter of 2018. Enrollment in the second stage of the PD-(L)1 refractory non-small cell lung cancer (NSCLC) cohort is complete, and Syndax expects to share updated data from this cohort in the first half of 2018.

"As we near the end of 2017, the momentum we've built throughout the year continues to yield meaningful progress and growth for our pipeline of potential best-in-class candidates," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "The recent expansion of our pipeline represents what we believe will be a long-term value enhancing transaction for the Company, while also potentially changing the treatment paradigm for acute leukemic patients harboring MLL translocations, where there exists a high unmet need. For entinostat, the ENCORE 601 program remains on track and we look forward to presenting data from both NSCLC cohorts, as well as biomarker data from the melanoma cohort, at the upcoming SITC Annual Meeting. We are also developing a global registration plan for entinostat in combination with a PD-1 inhibitor for patients with PD-1 refractory melanoma. We anticipate sharing details of our plan in the first half of 2018, in parallel with the full Phase 2 data from the melanoma cohort of ENCORE 601.

Pipeline Updates

- The Phase 3 registration trial of entinostat plus exemestane in advanced HR+, HER2- breast cancer, E2112, is 83% enrolled as of the end of October. ECOG-ACRIN Cancer Research Group, the trial sponsor, has notified the Company that the Data Safety Monitoring Committee (DSMC) completed the final progression free survival analysis and the first interim analysis for overall survival. The results of this analysis are held confidentially by the ECOG-ACRIN study statistician and the DSMC. No communication regarding this analysis will be released until completion of enrollment, which ECOG-ACRIN expects will occur in the first half of 2018.
- The ENCORE 601 cohort enrolling NSCLC patients naïve to PD-(L)1 therapy has satisfied the pre-specified efficacy criteria for advancement to the second stage, with ^{3} 4 responses out of 17.
- Enrollment in the second stage of the ENCORE 601 cohort enrolling patients with PD-(L)1 refractory NSCLC is complete. Data from this cohort is expected to be available in the first half of 2018.
- Following a meeting with the U.S. Food and Drug Administration (FDA) in June, the Company is continuing to meet with individual regulatory agencies in Europe to align on a global registration plan for entinostat in combination with a PD-1 inhibitor for patients with PD-(L)1 refractory melanoma. The Company anticipates being in a position to outline a regulatory plan for this indication around the time that full Phase 2 data from the melanoma cohort of ENCORE 601 are available in the first half of 2018.
- An oral presentation highlighting the data from stage one of both the ENCORE 601 NSCLC cohorts, as well as a poster presentation covering the biomarker data from the ENCORE 601 melanoma cohort, will be presented at the upcoming Society of Immunotherapy of Cancer (SITC) Annual Meeting. The Company anticipates sharing full Phase 2 trial data from both the PD-(L)1 refractory NSCLC and melanoma cohorts at a medical congress in the first half of 2018. Details on both SITC presentations are available here.
- Enrollment in the first stage of the cohort enrolling patients with microsatellite stable (MSS)--CRC is complete, and a decision on whether to advance to the second stage is expected in the first half of 2018. At least 2 confirmed objective responses are required to proceed to the second stage.
- Enrollment continues in the ENCORE 602 and ENCORE 603 trials, both of which are aimed at exploring the ability of entinostat to enhance the efficacy of checkpoint (PD-L1) inhibitor therapies. ENCORE 602, the Phase 1b/2 clinical trial evaluating the combination of entinostat plus Genentech's PD-L1 inhibitor, TECENTRIQ®, in patients with triple negative breast cancer, is now expected to complete enrollment in the Phase 2 portion in the first half of 2018, with results anticipated in the second half of the year. ENCORE 603, the Phase 1b/2 clinical trial evaluating entinostat in combination with Pfizer/Merck KGaA's BAVENCIO® in patients with ovarian cancer, continues to enroll patients into the Phase 2 portion and is on track to complete enrollment in the first half of 2018, with results anticipated in the first half of 2019.

- Dosing of patients with solid tumors in the Phase 1 multiple ascending dose (MAD) clinical trial of SNDX-6352, the Company's anti-CSF-1R monoclonal antibody, has commenced. A poster highlighting the safety, pharmacokinetic and pharmacodynamic data from the single ascending dose (SAD) trial of SNDX-6352 in healthy volunteers will be presented at the upcoming SITC Annual Meeting. Details on the presentation are available here.
- The Company entered into an exclusive worldwide license agreement with Vitae Pharmaceuticals, Inc., a subsidiary of Allergan plc, for a portfolio of preclinical, orally-available small molecule inhibitors of the interaction of Menin with the MLL protein. These compounds have potential application in the treatment of a genetically-defined subset of acute leukemias with chromosomal rearrangements in the MLL gene ("MLL-r"). The Company expects to initiate clinical trials in 2019.

Third Quarter 2017 Financial Results

As of September 30, 2017, Syndax had cash, cash equivalents and short-term investments of $120.6 million and 22.3 million shares issued and outstanding. In October 2017, the Company reported the sale of 2.0 million common shares in a registered direct offering with net proceeds of $24.8 million.

Third quarter 2017 research and development expenses decreased to $12.2 million from $12.3 million for the comparable period in the prior year. The decrease was primarily due to increased clinical trial activities of $3.9 million and increased employee compensation expense of $0.9 million, offset by a $5.0 million upfront payment in 2016 related to the in-license of SNDX-6352 from UCB. The increase in clinical trial activities was primarily due to additional cohorts added to ENCORE 601, increased activities in ENCORE 602 and ENCORE 603, costs related to SNDX-6352, Phase 1 clinical pharmacology trials and CMC activities. The increase in employee compensation costs was primarily due to increased headcount.

General and administrative expenses totaled $3.6 million during the third quarter of 2017 compared with $3.3 million in the comparable period in the prior year. The increase in general and administrative expenses was primarily due to an increase in non-cash stock-based compensation of $0.4 million and an increase in salary expense of $0.2 million due to increased headcount, offset by decreased legal fees of $0.3 million.

For the three months ended September 30, 2017, Syndax reported a net loss attributable to common stockholders of $15.1 million, or $0.68 per share, compared to $15.0 million, or $0.84 per share, for the comparable prior year period.

Financial Guidance

Today the Company provided operating expense guidance for the fourth quarter and full year 2017. For the fourth quarter and full year 2017, research and development expenses are expected to be $15 to $18 million and $47 to $50 million, respectively, and total operating expenses are expected to be $19 to $22 million and $63 to $66 million, respectively. Research and development expenses for the fourth quarter includes $5.0 million paid to Allergan in connection with the Menin-MLL license. This expense will be offset on a cash basis with a $5.0 million development milestone earned in the fourth quarter under our agreement with KHK.

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, Tuesday, November 7, 2017.

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: 4569859
Domestic Dial-in Number: 1-855-251-6663
International Dial-in Number: 281-542-4259
Live webcast: https://edge.media-server.com/m6/p/dq9yr3ta

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 developing an innovative pipeline of cancer therapies. 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 clinical trial in combination with exemestane for advanced hormone receptor positive, human epidermal growth factor receptor 2 negative breast cancer. Given its potential ability to block the function of immune suppressive cells in the tumor microenvironment, entinostat is also being evaluated in combination with approved PD-1 antagonists. Ongoing Phase 1b/2 clinical trials combine entinostat with KEYTRUDA from Merck & Co., Inc. for non-small cell lung cancer, melanoma and colorectal cancer; with TECENTRIQ® from Genentech, Inc. for triple negative breast cancer; and with BAVENCIO® from Pfizer Inc. and Merck KGaA, Darmstadt, Germany, for ovarian cancer. Our second clinical stage product candidate, SNDX-6352, is a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor and may also block the function of immune suppressive cells in the tumor microenvironment. SNDX-6352 is being evaluated in a Phase 1 clinical trial and is expected to be developed to treat a variety of cancers.

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 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.

SYNDAX PHARMACEUTICALS, INC.

(unaudited)

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)	September 30, 2017	December 31, 2016
ASSETS		
Cash, cash equivalents, and short-term investments	$ 120,594	$ 105,330
Other assets	3,899	3,683
Total assets	$ 124,493	$ 109,013
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	$ 14,207	$ 10,366
Deferred revenue, less current portion	13,305	14,220
Other liabilities	267	288
Total liabilities	27,779	24,874
Total stockholders' equity	96,714	84,139
Total liabilities and stockholders' equity	$ 124,493	$ 109,013

SYNDAX PHARMACEUTICALS, INC.

(unaudited)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
License fee revenue	$ 305	$ 305	$ 915	$ 915
Operating expenses:				
Research and development	12,188	12,274	31,603	23,191
General and administrative	3,563	3,269	11,777	10,349
Total operating expenses	15,751	15,543	43,380	33,540
Loss from operations	(15,446)	(15,238)	(42,465)	(32,625)
Other income (expense), net	358	269	766	(1,032)
Net loss	$ (15,088)	$ (14,969)	$ (41,699)	$ (33,657)
Net loss attributable to common stockholders	$ (15,088)	$ (14,969)	$ (41,699)	$ (36,255)
Net loss per share attributable to common stockholders — basic and diluted	$ (0.68)	$ (0.84)	$ (2.08)	$ (2.70)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders — basic and diluted	22,239,996	17,899,481	20,004,409	13,419,919

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