
**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 8, 2018

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.)

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 May 8, 2018, Syndax Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the first quarter ended March 31, 2018. 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated May 8, 2018.

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 8, 2018



Syndax Pharmaceuticals Reports First Quarter 2018 Financial Results and Provides Clinical and Business Update

– PFS results from pivotal Phase 3 E2112 trial of entinostat plus exemestane in HR+, HER2- breast cancer expected in 3Q18 –

– ENCORE 601 data from PD-(L)1 refractory NSCLC and melanoma cohorts and first stage MSS-CRC cohort to be presented at ASCO –

– Company to host conference call today at 4:30 p.m. ET –

WALTHAM, Mass., May 8, 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 reported its financial results for the first quarter ended March 31, 2018. In addition, the Company provided a clinical and business update. As of March 31, 2018, Syndax had \$113.2 million in cash, cash equivalents and short-term investments.

“Syndax is off to a strong start in 2018 and we believe this momentum will carry us through the balance of what we expect will be a milestone-rich and potentially transformative year. This includes the progression free survival readout from our ongoing pivotal Phase 3 E2112 trial, for which results are expected in the third quarter,” said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. “We also look forward to sharing additional data from multiple cohorts of the ENCORE 601 program, including biomarker analyses, later this quarter at the ASCO Annual Meeting. The ENCORE program represents a key pillar of our clinical strategy and is supported by an extensive correlative science program designed to identify biomarkers that could predict which patients will respond to our combination therapies.”

Pipeline Updates

- 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, is 92% enrolled as of the end of April. 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 (PFS) analysis and the first interim analysis for overall survival in November 2017. Earlier this quarter, the DSMC also notified Syndax that it conducted a subsequent interim overall survival analysis. The trial is proceeding as planned, and Syndax continues to anticipate that enrollment will be complete in the third quarter of 2018, at which time the result of the PFS analysis will be released to the Company.
 - Enrollment in the PD-(L)1 refractory melanoma ENCORE 601 cohort is now complete. The Company will present Phase 2 data from all evaluable patients at the American Society of Clinical Oncology (ASCO) Meeting in June. Later this quarter, the Company plans to communicate a registration strategy for entinostat in this indication.
 - Enrollment in the PD-(L)1 refractory non-small cell lung cancer (NSCLC) ENCORE 601 cohort is now complete. Phase 2 data from all evaluable patients in this cohort will be presented at ASCO next month, including updated results from the Company’s biomarker analyses.
 - Initial enrollment in the first stage of the ENCORE 601 cohort of patients with microsatellite stable colorectal cancer (MSS-CRC) completed in the third quarter of 2017. The Company expects to share preliminary data from this cohort at ASCO. The ENCORE 601 trial is being conducted in collaboration with Merck, through a subsidiary. The two companies recently agreed to expand this cohort, and expect to continue enrolling patients to the first stage later this quarter. A decision on whether to continue to the second stage of this cohort is expected in the first half of 2019.
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- Enrollment of the Phase 2 portion of ENCORE 602, the Phase 1b/2 clinical trial evaluating the combination of entinostat plus Genentech's PD-(L)1 inhibitor atezolizumab (TECENTRIQ®) in patients with triple negative breast cancer, remains on track to complete later this quarter. Topline results are now anticipated in the first half of 2019.
- Enrollment is now complete in the Phase 2 portion of ENCORE 603, the Phase 1b/2 clinical trial evaluating entinostat in combination with Pfizer/Merck KGaA's BAVENCIO® in patients with ovarian cancer. Topline results are expected 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 is ongoing. The Company anticipates presenting data from this trial and disclosing a Phase 2 strategy in the second half of 2018. In February, the Company entered into a clinical collaboration with AstraZeneca to evaluate the efficacy and safety of SNDX-6352 in combination with durvalumab (IMFINZI®), AstraZeneca's human monoclonal antibody directed against PD-(L)1, in multiple solid tumors. Initial work focusing on establishing the safety of this combination is expected to begin this quarter.
- Development of the Company's portfolio of Menin-Mixed Lineage Leukemia (MLL) inhibitors, in-licensed from Vitae Pharmaceuticals, Inc., a subsidiary of Allergan plc, is ongoing. Data from this program were recently presented in both oral and poster presentations at the 2018 American Association for Cancer Research (AACR) Annual Meeting. The Company expects to initiate clinical trials for this program in the first half of 2019.

First Quarter 2018 Financial Results

As of March 31, 2018, Syndax had cash, cash equivalents and short-term investments of \$113.2 million and 24,697,944 shares issued and outstanding.

First quarter 2018 research and development expenses increased to \$15.3 million from \$9.6 million for the comparable period in the prior year. The increases were primarily due to an increase in development activities of \$2.8 million, legal and professional fees of \$1.7 million and increased employee compensation expense of \$1.3 million. The increase in development activities was primarily due to increases in spending related to the increased CMC costs for SNDX-6352, and development of the Menin program, partially offset by completion of the Phase 1 clinical pharmacology trials and decrease in E2112 costs. The increase in employee compensation costs was primarily due to increased headcount.

General and administrative expenses totaled \$4.8 million during the first quarter of 2018, compared to \$3.9 million for the comparable period in the prior year. The increase in general and administrative expenses was primarily due to an increase in professional fees of \$0.7 million as well as an increase in legal fees of \$0.2 million. The increase in professional fees was primarily due to pre-commercialization activities. The increase in legal fees was primarily due to an increase in patent-related legal expenses.



For the three months ended March 31, 2018, Syndax reported a net loss attributable to common stockholders of \$19.4 million or \$0.79 per share compared to \$13.0 million or \$0.71 per share for the comparable prior year period.

Financial Guidance

Today the Company provided operating expense guidance for the second quarter and full year 2018. For the second quarter and full year 2018, research and development expenses are expected to be \$15 to \$18 million and \$62 to \$70 million, respectively, and total operating expenses are expected to be \$20 to \$23 million and \$82 to \$90 million, respectively.

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, May 8, 2018.

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: 7087078
Domestic Dial-in Number: 1-855-251-6663
International Dial-in Number: 281-542-4259
Live webcast: <https://edge.media-server.com/m6/p/f5ppmzsd>

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 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 www.syndax.com or follow the Company on [Twitter](#) and [LinkedIn](#).



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, the potential use of our product candidates to treat various cancer indications, and Syndax's first quarter and full-year 2018 net cash used in research and development and total operating activities. 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)	<u>March 31,</u>	<u>December 31,</u>
	2018	2017
Cash, cash equivalents, short-term and long-term investments	\$ 113,223	\$ 133,220
Total assets	\$ 119,957	\$ 137,186
Total liabilities	\$ 33,007	\$ 32,867
Total stockholders' equity (deficit)	\$ 86,950	\$ 104,319
Common stock outstanding	24,697,944	24,390,033
Common stock and common stock equivalents*	28,904,776	28,139,705
*Common stock and common stock equivalents:		
Common stock	24,697,944	24,390,033
Options to purchase common stock	4,206,832	3,391,832
Common stock warrants	-	357,840
	<u>28,904,776</u>	<u>28,139,705</u>



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

(In thousands, except share and per share data)	Three Months Ended March 31,	
	2018	2017
License fee revenue	\$ 379	\$ 305
Operating expenses:		
Research and development	15,339	9,552
General and administrative	4,791	3,930
Total operating expenses	20,130	13,482
Loss from operations	(19,751)	(13,177)
Other income, net	353	206
Net loss	\$ (19,398)	\$ (12,971)
Net loss attributable to common stockholders	\$ (19,398)	\$ (12,971)
Net loss per share attributable to common stockholders--basic and diluted	\$ (0.79)	\$ (0.71)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	24,478,269	18,231,602



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