
**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):
August 9, 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 August 9, 2016, Syndax Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 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 August 9, 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: August 9, 2016

EXHIBIT INDEX

**Exhibit
No.**

Description

99.1 Press Release, dated August 9, 2016.



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

Expanded pipeline with potentially best-in-class, IND-ready anti-CSF-1R antibody

Progressing to Phase 2 of ENCORE 601 in NSCLC and Melanoma

Initiated ENCORE 602 for TNBC in collaboration with Genentech in June 2016

Waltham, Massachusetts – August 9, 2016 (GLOBE NEWSWIRE): Syndax Pharmaceuticals (“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 second quarter ended June 30, 2016 and provided a pipeline update as well as a review of upcoming milestones. As of June 30, 2016, Syndax had \$125.5 million in cash, cash equivalents and short-term investments.

“Syndax is building momentum in the execution of our business strategy. The in-license of SNDX-6352 expands our immuno-oncology portfolio and further leverages our strong balance sheet and experienced leadership team,” said Briggs Morrison, M.D., Chief Executive Officer of Syndax. “By year end 2016, we expect to have four clinical trials evaluating combination therapies in six cancer indications, ranging from a late-stage Phase 3 study in breast cancer to Phase 1 clinical studies in immuno-oncology. As we continue to build and advance our pipeline, we are guided by our mission to realize a future in which people with cancer live longer and better than ever, which we believe will create value for all of our stakeholders.”

“We continue to advance entinostat’s development in multiple indications as we began dosing patients in ENCORE 602 in June 2016 and have completed the safety evaluation of the dose confirmation stage of ENCORE 601,” said Dr. Michael L. Meyers, Chief Medical Officer of Syndax. “We look forward to communicating scientific results in the fourth quarter of 2016 and to dosing our first subjects with SNDX-6352 later this year.”

Pipeline Updates

- Enrollment for E2112, our registrational Phase 3 clinical trial of entinostat plus Aromasin® (exemestane tablets) in advanced HR+, HER2- breast cancer has exceeded 50% and continues at an accelerated pace. The E2112 clinical trial 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 with the U.S. Food and Drug Administration (“FDA”). Entinostat was granted Breakthrough Therapy designation by the FDA for HR+ breast cancer following positive results from our Phase 2b clinical trial, ENCORE 301.
- Syndax completed 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 advanced metastatic or recurrent non-small cell lung cancer (“NSCLC”) or melanoma. Based upon a review of the safety data with our study investigators, we made the decision to proceed to the Phase 2 portion of the clinical trial. An abstract has been submitted for presentation at the Society for Immunotherapy of Cancer Annual Meeting in November, which includes safety, biomarker and initial efficacy data from the completed Phase 1b portion of ENCORE 601 clinical trial in patients with NSCLC.
- In June 2016, we dosed our first patient in 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”). We continue to dose patients and assess the safety of the 5 mg dose in the trial’s open label Phase 1b portion. An abstract describing the trial has been submitted for presentation in the Trials in Progress track at the San Antonio Breast Cancer Symposium in December 2016.

Key Recent Achievements

- On July 1, 2016, Syndax expanded its immuno-oncology pipeline by entering into an exclusive worldwide license agreement with UCB Biopharma Sprl for an anti-CSF-1R monoclonal antibody, UCB 6352, which Syndax refers to as SNDX-6352. Syndax expects to begin clinical trials during the fourth quarter of 2016. We believe that CSF-1R antibodies have the potential to be used to treat a wide variety of cancer indications in combination with other oncology agents, including immune checkpoint inhibitors, radiation, chemotherapy, and entinostat. SNDX-

6352 diversifies our approach to reversing immunosuppression in the tumor microenvironment, and we believe there is significant opportunity for its rapid and creative development.

- On July 27, 2016, Syndax announced the members of its Scientific Advisory Board (“SAB”). The SAB will serve as a strategic network of scientific and clinical experts to Syndax as it progresses the development of entinostat in multiple cancer indications and initiates clinical development of SNDX-6352. The SAB will also be an integral part of the Company’s strategy as it continues to assess opportunities to expand its pipeline.

Upcoming Milestones

- Syndax expects to start the three Phase 2 cohorts of ENCORE 601, including patients with NSCLC or Melanoma, in the third quarter of 2016.
- Syndax anticipates commencing ENCORE 603 in ovarian cancer in collaboration with Pfizer Inc. and Merck KGaA, Darmstadt, Germany, in the fourth quarter of 2016.
- Syndax expects to begin the Phase 1 single ascending dose clinical trial with SNDX-6352 in healthy volunteers to determine safety and pharmacokinetics during the fourth quarter of 2016.

Syndax Expects To Make Presentations at the Following Upcoming Conferences

- Syndax management expects to participate in a panel discussion and host one-on-ones at Citi’s 11th Annual Biotech Conference at The Mandarin Oriental in Boston on September 8.
- Syndax management expects to make a presentation and host one-on-ones at the Morgan Stanley Global Healthcare Conference at the Grand Hyatt in New York on September 12.
- Syndax management expects to make a presentation and host one-on-ones at the Rodman & Renshaw 18th Annual Global Investment Conference at the Lotte New York Palace Hotel in New York on September 13.

- Syndax management expects to make a presentation at the Discovery on Target Conference at the Westin Boston Waterfront Hotel in Boston on September 19.
- Syndax management expects to make a presentation and host one-on-ones at the Ladenburg Thalmann 2nd Annual Global Investment Conference at the Sofitel New York on September 27.

Second Quarter 2016 Financial Results

As of June 30, 2016, Syndax had cash, cash equivalents and short-term investments of \$125.5 million, and 17,782,150 shares issued and outstanding.

Second quarter 2016 research and development expenses increased \$3.8 million, or 170%, to \$6.1 million from \$2.3 million for the comparable period in the prior year primarily due to increased patient accrual costs in E2112, higher expenses associated with the expansion of ENCORE 601, and the commencement of ENCORE 602.

General and administrative expenses totaled \$2.8 million during the second quarter of 2016, and were below the \$3.3 million expense level for the comparable prior year period primarily due to 2015 restructuring costs, which were partially offset by increased costs in 2016 related to operating as a public company.

For the three months ended June 30, 2016, Syndax reported a net loss attributable to common stockholders of \$8.4 million, or \$0.47 per share, compared to a net loss attributable to common stockholders of \$26.3 million, or \$440.52 per share, for the comparable period in the prior year. The net loss for the three months ended June 30, 2016, included non-cash stock-based compensation expense of \$0.8 million related to the issuance of stock option awards to employees and non-employees.

Conference Call and Webcast

In connection with the earnings release, Syndax will host a conference call and live audio webcast at 8:00 a.m. ET on Tuesday, August 9, 2016 to discuss the financial results and give an update on the Company's progress.

Conference Call Information:

Date: Tuesday, August 9, 2016

Time: 8:00 a.m. ET

Conference ID: 52330666
Domestic Dial-in Number: 1-855-251-6663
International Dial-in Number: 1-281-542-4259
Live webcast: <http://edge.media-server.com/m/p/n5qtg36c>

For those unable to participate in the conference call or live webcast, a live audio webcast of the call will also be available on the Investor section of the Company's website, www.syndax.com, where a webcast replay will also be available for two weeks following the live event.

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 clinical trial for advanced hormone receptor positive 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 expected to begin clinical trials during the fourth quarter of 2016 and 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, the ability of the SAB to contribute to the success of Syndax and its programs 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 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 PHARMACEUTICALS, INC.
(unaudited)
CONDENSED CONSOLIDATED BALANCE SHEETS DATA

(In thousands)	<u>June 30, 2016</u>	<u>December 31, 2015</u>
Cash, cash equivalents, and short-term investments	\$ 125,457	\$ 86,489
Total assets	\$ 127,856	\$ 89,903
Total liabilities	\$ 21,615	\$ 23,205
Total stockholders' equity (deficit)	\$ 106,241	\$ (252,415)
Common stock outstanding	17,782,150	100,124
Common stock and common stock equivalents*	20,855,418	15,856,356

* Common stock and common stock equivalents:

	<u>June 30, 2016</u>	<u>December 31, 2015</u>
Common stock	17,782,150	100,124
Convertible preferred stock	—	12,872,551
Options to purchase common stock	2,715,428	2,606,195
Common stock warrants	357,840	277,486
	<u>20,855,418</u>	<u>15,856,356</u>

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

(In thousands, except share and per share data)	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
License fee revenue	\$ 305	\$ 17	\$ 610	\$ 17
Operating expenses:				
Research and development	6,131	2,271	10,917	3,994
General and administrative	2,808	3,288	7,080	5,999
Total operating expenses	8,939	5,559	17,997	9,993
Loss from operations	(8,634)	(5,542)	(17,387)	(9,976)
Other income (expense), net	276	(672)	(1,301)	(1,149)
Net loss	\$ (8,358)	\$ (6,214)	\$ (18,688)	\$ (11,125)
Net loss attributable to common stockholders	\$ (8,358)	\$ (26,338)	\$ (21,286)	\$ (38,410)
Net loss per share attributable to common stockholders - basic and diluted	\$ (0.47)	\$ (440.52)	\$ (1.91)	\$ (649.30)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders - basic and diluted	<u>17,769,514</u>	<u>59,788</u>	<u>11,155,525</u>	<u>59,156</u>

Investor and Media Contacts

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