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 7, 2019

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))

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	SNDX	The Nasdaq Stock Market, LLC

Indicate by check mark whether the registrant is an emerging growth company 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 August 7, 2019, Syndax Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2019. 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 August 7, 2019

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 7, 2019

Syndax Pharmaceuticals Reports Second Quarter 2019 Financial Results and Provides Clinical and Business Update

– IND cleared for SNDX-5613, highly selective menin inhibitor for treatment of MLL-rearranged and NPM1-mutant acute leukemias –

– Final interim OS analysis for E2112 expected in 4Q19 –

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

WALTHAM, Mass., August 7, 2019 (PRNEWSWIRE) – Syndax Pharmaceuticals, Inc. (Nasdaq: SNDX), a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies, today reported its financial results for the second quarter ended June 30, 2019. In addition, the Company provided a clinical and business update. As of June 30, 2019, Syndax had $80.5 million in cash, cash equivalents and short-term investments.

“The FDA’s recent clearance of our IND application for SNDX-5613, a potent, highly selective, oral Menin inhibitor, marks an important milestone not only for Syndax, but also for patients suffering with acute leukemias,” said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. “The Menin-MLL interaction has been strongly implicated in the development of MLL-r and NPM1 mutant leukemias. We look forward to initiating the clinical program and anticipate establishing a safe dose that provides appropriate target coverage in patients.”

Dr. Morrison added, “We look forward to the near-term completion of E2112, the Phase 3 registration trial of entinostat plus exemestane in HR+, HER2- breast cancer, which we anticipate will occur either in the fourth quarter of 2019 or the first half of 2020. A positive survival benefit at either assessment will enable us to file an NDA with the FDA and take us one step closer to improving outcomes for patients with this difficult to treat disease."

Pipeline Updates

Entinostat

In May 2019, Syndax announced that the E2112 trial passed its fourth interim overall survival (OS) analysis and will continue as planned until either an OS benefit is observed, or the final target number of events occur. E2112 is Syndax’s NCI-sponsored, ECOG-ACRIN led Phase 3 registration trial of entinostat, a Class I selective HDAC inhibitor, plus exemestane in advanced hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+, HER2-) breast cancer.

The Company continues to anticipate the final E2112 interim OS analysis in 4Q19. If necessary, the final OS assessment, which will be triggered when the trial reaches a total of 410 death events, is expected to be conducted in 2Q20. A positive OS assessment at any point would enable the Company to file for full regulatory approval. The E2112 trial design was informed by the Phase 2b ENCORE 301 trial, the results of which led to entinostat's Breakthrough Therapy designation in HR+, HER2- breast cancer, in which patients receiving the entinostat/exemestane combination demonstrated a strong OS benefit.

SNDX-5613

In July 2019, Syndax announced that the U.S. Food and Drug Administration (FDA) cleared the Company's Investigational New Drug (IND) application to begin a Phase 1/2 trial for SNDX-5613, a highly selective Menin inhibitor. The Company will refer to the clinical development of SNDX-5613 as the AUGMENT Program. The Phase 1/2 open-label trial will assess orally administered SNDX-5613 in adults with relapsed/refractory (R/R) acute leukemias. The Phase 1 dose escalation portion of the study will evaluate the safety, tolerability and pharmacokinetics of SNDX-5613, and will seek to establish a recommended Phase 2 dose. The Phase 2 portion will evaluate efficacy, as defined by Complete Response rate (per International Working Group response criteria), across three expansion cohorts: MLL-rearranged (MLL-r) acute lymphoblastic leukemia (ALL), MLL-r acute myeloid leukemia (AML), and NPM1 mutant AML. The Company expects to report initial clinical data from the trial in 2020.

SNDX-6352

Enrollment continues in the Phase 1 dose escalation trial of SNDX-6352, Syndax's anti-CSF-1R monoclonal antibody, in patients with chronic graft versus host disease (cGVHD). The Company now anticipates results from this trial in the second half of 2020. The objectives of this trial are to evaluate the safety and preliminary efficacy of SNDX-6352 in cGVHD and to identify a recommended Phase 2 dose and schedule.

Corporate Updates

Syndax announced the appointment of Michael A. Metzger to its Board of Directors. Mr. Metzger has served as Syndax's President and Chief Operating Officer since May 2015.

Second Quarter 2019 Financial Results

As of June 30, 2019, Syndax had cash, cash equivalents and short-term investments of $80.5 million and 31.6 million shares and share equivalents issued and outstanding.

Second quarter 2019 research and development expenses decreased to $12.3 million from $14.9 million. The second quarter decrease was primarily due to decreased development activities primarily in the ENCORE programs, and decreased CMC activities associated with SNDX-6352, partially offset by accrued milestone expenses associated with the development of SNDX-5613.

General and administrative expenses for the second quarter 2019 decreased to $3.5 million from $4.5 million. The decrease was primarily due to decreased professional fees and employee compensation expenses.

For the three months ended June 30, 2019, Syndax reported a net loss attributable to common stockholders of $14.9 million or $0.47 per share compared to $18.4 million or $0.74 per share for the prior year period.

Financial Guidance

Today the Company provided operating expense guidance for the third quarter and full year 2019. For the third quarter and full year 2019, research and development expenses are expected to be $11 to $12 million and $45 to $46 million, respectively, and total operating expenses are expected to be $15 to $16 million and $60 to $63 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, Wednesday, August 7, 2019.

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: 8959885
Domestic Dial-in Number: 855-251-6663
International Dial-in Number: 281-542-4259
Live Webcast: https://edge.media-server.com/mmc/p/d7szeya4

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's lead product candidate, entinostat, a once-weekly, oral, small molecule, class I HDAC inhibitor, is being tested in a phase 3 combination trial with exemestane for treatment of advanced HR+, HER2- breast cancer and has been evaluated in combination with several approved PD-1/PD-(L)1 antagonists. The Company's pipeline also includes SNDX-6352, a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor, and SNDX-5613, a highly selective inhibitor of the Menin–MLL binding interaction. 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 operating expense guidance for the third quarter and full year 2019. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during preclinical or clinical trials, 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

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

(In thousands)	June 30, 2019	December 31, 2018
Cash, cash equivalents, short-term and long-term investments	$ 80,520	$ 80,911
Total assets	$ 87,390	$ 83,938
Total liabilities	$ 32,115	$ 30,891
Total stockholders' equity (deficit)	$ 55,275	$ 53,047
Common stock outstanding	27,117,946	24,835,951
Common stock and common stock equivalents*	41,983,601	31,088,934
*Common stock and common stock equivalents:		
Common stock	27,117,946	24,835,951
Common stock warrants (pre-funded)	4,500,000	2,000,000
Common stock and pre-funded stock warrants	31,617,946	26,835,951
Options to purchase common stock	5,770,616	4,252,983
Common stock warrants (series 1 and 2)	4,595,039	-
Total common stock and common stock equivalents	41,983,601	31,088,934

Syndax

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

(In thousands, except share and per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
License fee revenue	$ 379	$ 379	$ 758	$ 758
Operating expenses:				
Research and development	12,290	14,851	23,569	30,190
General and administrative	3,463	4,479	7,374	9,270
Total operating expenses	15,753	19,330	30,943	39,460
Loss from operations	(15,374)	(18,951)	(30,185)	(38,702)
Other income, net	458	563	967	917
Net loss	$ (14,916)	$ (18,388)	$ (29,218)	$ (37,785)
Net loss attributable to common stockholders	$ (14,916)	$ (18,388)	$ (29,218)	$ (37,785)
Net loss per share attributable to common stockholders--basic and diluted	$ (0.47)	$ (0.74)	$ (1.00)	$ (1.54)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	31,605,279	24,705,441	29,327,029	24,592,483

Investor Contact

Melissa Forst
Argot Partners
melissa@argotpartners.com
Tel 212.600.1902

Media Contact

David Rosen
Argot Partners
david.rosen@argotpartners.com
Tel 212.600.1902

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