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): March 8, 2021

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 March 8, 2021, Syndax Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter ended December 31, 2020. 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated March 8, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: March 8, 2021

Syndax Pharmaceuticals Reports Fourth Quarter 2020 Financial Results and Provides Clinical and Business Update

- Phase 1 AUGMENT-101 data expected in late 1Q21 or early 2Q21; Phase 2 expansion cohorts expected to commence in 2Q21 -

- Enrollment underway in pivotal Phase 2 AGAVE-201 trial of axatilimab in cGVHD -

- End of year cash balance of $293.1 million provides cash runway into 2023 -

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

WALTHAM, Mass., March 8, 2021 (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 fourth quarter ended December 31, 2020. In addition, the Company provided a clinical and business update.

“We expect 2021 will be a year of immense progress across our two highly promising programs aimed at addressing key areas of unmet need, coupled with a sharp focus on pipeline expansion,” said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. “Notably, we plan to present data from the Phase 1 portion of our ongoing AUGMENT-101 trial of SNDX-5613, our selective menin inhibitor, in patients with acute leukemias. We presented promising initial clinical data at the 2020 AACR Annual Meeting that provided the first clinical evidence that disrupting the interaction between menin and MLL1 can induce rapid responses in difficult to treat acute leukemias. We look forward to sharing updated results which further expand on SNDX-5613’s potential to meaningfully alter the treatment paradigm in genetically-defined acute leukemias.”

Additionally, on the heels of positive data presented at the ASH Annual Meeting in December from our Phase 1 trial of axatilimab, our anti-CSF-1R monoclonal antibody, in patients with cGVHD, we are pleased to announce that our pivotal Phase 2 AGAVE-101 trial is now underway. Through inhibition of monocyte derived macrophages, axatilimab has demonstrated important clinical benefits in multiple organ systems. We believe axatilimab could represent a meaningful therapeutic option for additional fibrotic diseases where macrophages have been shown to play a significant role, and we are actively exploring additional indications.”

Recent Progress and Anticipated Milestones

SNDX-5613

Syndax plans to share data from the Phase 1 AUGMENT-101 trial of SNDX-5613, its highly selective, oral menin inhibitor, in patients with mixed lineage leukemia rearranged (MLL-r) and nucleophosmin (NPM1) mutant acute leukemias late in the first quarter or early in the second quarter of 2021. Additional details regarding the presentation, which will feature the trial’s principal investigator, Eytan M. Stein, M.D. Assistant Attending Physician and Director, Program for Drug Development in Leukemia, Department of Medicine at Memorial Sloan Kettering Cancer Center, will be announced in the coming weeks. The Company remains on track to initiate the Phase 2 portion of the trial in the second quarter of 2021, which could potentially serve as the basis for a regulatory filing.

Axatilamab

At the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition in December 2020, Syndax reported updated data from its Phase 1 trial of axatilimab, its anti-CSF-1R monoclonal antibody, in patients with chronic graft versus host disease (cGVHD). Data demonstrated deep, durable responses and multiorgan clinical benefit in patients refractory to multiple therapeutic agents.

The Company announced today that the pivotal Phase 2 AGAVE-201 trial, which will evaluate the safety and efficacy of three doses and schedules of axatilimab in patients with cGVHD, began enrolling patients earlier this quarter. The primary endpoint will assess objective response rate based on the 2014 NIH consensus criteria for GVHD, with key secondary endpoints including duration of response and improvement in modified Lee Symptom Scale score. The Company expects to report topline data in 2023.

Fourth Quarter 2020 Financial Results

As of December 31, 2020, Syndax had cash, cash equivalents and short-term investments of $293.1 million and 51.4 million shares and share equivalents issued and outstanding. This includes 3.6 million pre-funded warrants.

Fourth quarter 2020 research and development expenses increased to $15.5 million from $9.5 million, and for the full year increased to $50.4 million compared to $43.0 million for 2019. The fourth quarter and full year increases were primarily due to increased clinical trial activities, increased CMC activities and professional fees.

General and administrative expenses for the fourth quarter 2020 decreased to $4.7 million from $5.1 million, and, for the year ended December 31, 2020, increased to $22.5 million compared to $16.1 million for the prior year. The fourth quarter decrease is primarily due to decreased pre-commercialization expenses. The increase for the full year was primarily due to increased professional fees and employee related expenses.

For the three months ended December 31, 2020, Syndax reported a net loss attributable to common stockholders of $20.4 million or $0.44 per share compared to $14.0 million or $0.44 per share for the prior year period. For the year ended December 31, 2020, Syndax reported a net loss attributable to common stockholders of $77.8 million or $1.88 per share, compared to $56.0 million or $1.84 per share for the prior year. For the year ended December 31, 2020, this includes a deemed dividend of $3.9 million.

Financial Update and Guidance

In December 2020, Syndax issued 6,250,000 shares of its common stock at $23.00 per share. As a result of the offering, Syndax received gross proceeds of approximately $143.8 million.

For the first quarter of 2021, research and development expenses are expected to be $25 to $30 million, and total operating expenses are expected to be $30 to $35 million. For the full year of 2021, research and development expenses are expected to be $90 to $100 million, and total operating expenses are expected to be $110 to $120 million.

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, Monday, March 8, 2021.

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: 7949816
Domestic Dial-in Number: (855) 251-6663
International Dial-in Number: (281) 542-4259
Live webcast: https://edge.media-server.com/mmc/p/wdaqmgg3

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 pipeline includes SNDX-5613, a highly selective inhibitor of the Menin–MLL binding interaction, axatilimab, a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor, and entinostat, a class I HDAC inhibitor.

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, Syndax's fourth quarter and full-year 2020 net cash used in research and development and total operating activities, and first quarter and full year 2021 operating expense and cash guidance. 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, the COVID-19 pandemic may disrupt our business and that of the third parties on which we depend, including delaying or otherwise disrupting our clinical trials and preclinical studies, manufacturing and supply chain, or impairing employee productivity, 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 Contacts

Investor Contact

Melissa Forst
Argot Partners
melissa@argotpartners.com
Tel 212.600.1902

Media Contact

Ted Held
ted.held@gcihealth.com
Tel 212.798.9842

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

(In thousands)	December 31, 2020	December 31, 2019
Cash, cash equivalents and short-term investments	$ 293,065	$ 59,775
Total assets	$ 300,613	$ 63,525
Total liabilities	$ 48,425	$ 31,925
Total stockholders' equity (deficit)	$ 252,188	$ 31,600
Common stock outstanding	47,881,223	27,140,484
Common stock and common stock equivalents*	57,836,910	42,292,534
*Common stock and common stock equivalents:		
Common stock	47,881,223	27,140,484
Options to purchase common stock	6,379,235	6,057,011
Restricted Stock Units	18,500	-
Series 1 and 2 warrants	-	4,595,039
Pre-funded warrants	3,557,952	4,500,000
	57,836,910	42,292,534

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

(In thousands, except share and per share data)	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
License fee revenue	$ 380	$ 380	$ 1,517	$ 1,517
Operating expenses:				
Research and development	15,522	9,502	50,435	42,994
General and administrative	4,718	5,083	22,505	16,062
Total operating expenses	20,240	14,585	72,940	59,056
Loss from operations	(19,860)	(14,205)	(71,423)	(57,539)
Other income (expense), net	(563)	205	(1,735)	1,492
Net loss	$ (20,423)	$ (14,000)	$ (73,158)	$ (56,047)
Net loss attributable to common stockholders	$ (20,423)	$ (14,000)	$ (77,064)	$ (56,047)
Net loss per share attributable to common stockholders--basic and diluted	$ (0.44)	$ (0.44)	$ (1.87)	$ (1.84)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	46,054,850	31,640,484	41,308,242	30,490,783