

**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):  
December 7, 2020**

**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))

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

Title of each class  
**Common Stock**

Trading  
Symbol(s)  
**SNDX**

Name of each exchange  
on which registered  
**The Nasdaq Stock Market, LLC**

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 1.02. Termination of a Material Definitive Agreement.**

As previously disclosed, in August 2019, Syndax Pharmaceuticals, Inc. (the “*Company*”) entered into a sales agreement (the “*Sales Agreement*”) with Cowen and Company, LLC (“*Cowen*”), pursuant to the Company may offer and sell, from time to time at its sole discretion, shares of Common Stock having an aggregate offering price of up to \$50.0 million, through an “at the market” equity offering program under which Cowen acted as sales agent.

On December 7, 2020, the Company delivered written notice to Cowen, effective as of that date, to terminate the Sales Agreement pursuant to Section 11(b) thereof. Prior to termination, the Company had not sold, and the Company will not sell, any shares of Common Stock pursuant to the Sales Agreement.

A copy of the Sales Agreement was filed as Exhibit 1.2 to the Company’s Registration Statement on Form S-3, filed with the SEC on August 30, 2019 (the “*Form S-3*”). The description of the Sales Agreement contained in this Current Report on Form 8-K does not purport to be complete and is qualified in its entirety by reference to the copy of the Sales Agreement filed as Exhibit 1.2 to the Form S-3.

**Item 8.01 Other Events.**

On December 7, 2020, the Company filed with the SEC a preliminary prospectus supplement (the “*Preliminary Prospectus Supplement*”) in connection with the Offering described in Item 1.01 hereto. The Preliminary Prospectus Supplement contains an updated description of certain aspects of the Company’s business. Accordingly, the Company is filing this information with this Current Report on Form 8-K for the purpose of supplementing and updating disclosures contained in the Company’s prior filings with the SEC, including those discussed in the Company’s most recent Annual Report on Form 10-K for the ended December 31, 2019, filed with the SEC on March 5, 2020, as supplemented by any of the Company’s subsequent filings with the SEC. The updated disclosures are filed herewith as Exhibit 99.1 and are incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit</u>	<u>Description</u>
99.1	<a href="#">Updated Corporate Disclosure.</a>
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/ Luke J. Albrecht

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Luke J. Albrecht

General Counsel and Secretary

Dated: December 7, 2020

As used in this Exhibit 99.1, unless the context indicates otherwise, references to “Syndax,” “the Company,” “we,” “us,” “our” and similar references refer to Syndax Pharmaceuticals, Inc. and its wholly owned subsidiaries.

### Forward-Looking Statements

This document contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on our management’s current beliefs, expectations and assumptions about future events, conditions and results and on information currently available to us. Discussions containing these forward-looking statements may be found, among other places, in the sections titled “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” incorporated by reference from our most recent Annual Report on Form 10-K and our most recent Quarterly Report on Form 10-Q filed with the SEC, as well as any amendments thereto reflected in subsequent filings with the SEC (collectively, the “**SEC Reports**”).

Any statements in this document about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. Within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, these forward-looking statements include statements regarding:

- statements regarding the impact of the COVID-19 pandemic and its effects on our operations, research and development and clinical trials and potential disruption in the operations and business of third-party manufacturers, contract research organizations, or CROs, other service providers, and collaborators with whom we conduct business;
- our estimates regarding our expenses, future revenues, anticipated capital requirements and our needs for additional financing;
- the timing of the progress and receipt of data from the Phase 1/2 clinical trial of SNDX-5613 in patients with relapsed/refractory (R/R) acute leukemia and the potential use of SNDX-5613 to treat acute leukemias;
- the timing of the progress and receipt of data from the Phase 2 trial, AGAVE-201, of axatilimab in cGVHD
- our ability to replicate results in future clinical trials;
- our expectations regarding the potential safety, efficacy or clinical utility of our product candidates;
- our ability to obtain and maintain regulatory approval for our product candidates and the timing or likelihood of regulatory filings and approvals for such candidates;
- our ability to maintain our licenses with Bayer Pharma AG, Eddingpharm Investment Company Limited, Kyowa Kirin Co., Ltd., UCB Biopharma Sprl, and Vitae Pharmaceuticals, Inc., a subsidiary of AbbVie plc.;
- the potential milestone and royalty payments under certain of our license agreements;
- the implementation of our strategic plans for our business and development of our product candidates;
- the scope of protection we establish and maintain for intellectual property rights covering our product candidates and our technology;
- the market adoption of our product candidates by physicians and patients;
- developments relating to our competitors and our industry; and
- political, social and economic instability, natural disasters or public health crisis, including but not limited to the COVID-19 pandemic, in countries where we or our collaborators do business.

In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expects,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative or plural of those terms, and similar expressions intended to identify statements about the future, although not all forward-looking statements contain these words. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should refer to the risks and uncertainties described in the “Risk Factors” section contained in our SEC Reports for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Given these risks, uncertainties and other factors, many of which are beyond our control, we cannot assure you that the forward-looking statements in this document will prove to be accurate, and you should not place undue reliance on these forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to revise any forward-looking statements to reflect events or developments occurring after the date of this report, even if new information becomes available in the future.

## **Company Overview**

We are a clinical-stage biopharmaceutical company developing an innovative pipeline of cancer therapies. Our two lead product candidates are, SNDX-5613 and SNDX-6352, or axatilimab. We are developing SNDX-5613, targeting the binding interaction of menin with the mixed lineage leukemia 1 (MLL1) protein for the treatment of MLL-rearranged, or MLLr, acute leukemias and nucleophosmin 1, or NPM1, mutant acute myeloid leukemia (AML), as well as axatilimab, a monoclonal antibody that blocks the colony stimulating factor 1, or CSF-1 receptor. We have deprioritized the development of entinostat, our once-weekly, oral, small molecule, Class I HDAC inhibitor, to focus resources on advancing the remainder of our pipeline. We plan to continue to leverage the technical and business expertise of our management team and scientific collaborators to license, acquire and develop additional cancer therapies to expand our pipeline.

### ***SNDX-5613***

Our first clinical-stage product candidate, SNDX-5613, is a potent, orally active inhibitor of the high affinity interaction site on menin with the protein MLL1. This specific interaction is a key driver for two genetically defined acute leukemias: (i) MLLr and (ii) NPM1c AML. Both diseases have a poor prognosis. In preclinical testing, SNDX-5613 has demonstrated complete tumor regression and profound, dose-dependent and long-lasting survival benefit in leukemic models of disease. Initial clinical evidence with SNDX-5613 also supports the hypothesis that disruption of the Menin-MLL interaction can lead to responses in acute leukemias.

We are developing SNDX-5613 as a targeted therapy to potentially treat two genetically defined acute leukemias: (i) a genetically defined subset of acute leukemias with chromosomal rearrangements in the mixed lineage leukemia (MLL) gene, known as MLLr; and (ii) acute myeloid leukemia, or AML, with a somatic mutation in the nucleophosmin 1, or NPM1, gene, also known as NPM1c. Our near-term focus is to rapidly establish proof of concept that SNDX-5613 is a targeted therapy that can potentially provide meaningful clinical benefit to adult and pediatric leukemia patients having relapsed or refractory MLLr or NPM1c acute leukemias. Our IND application for SNDX-

5613 took effect with the U.S. Food and Drug Administration, or FDA, in the second quarter of 2019 and we commenced AUGMENT-101, a clinical trial consisting initially of a Phase 1 dose escalation portion to determine the maximum tolerated dose, or MTD, and recommended Phase 2 dose of SNDX-5613 in patients with acute leukemia. Upon completion of the Phase 1 portion of the trial and identification of the recommended Phase 2 dose, we will initiate the Phase 2 portion of the trial with patients to be enrolled in three indication-specific expansion cohorts to determine the efficacy, short- and long-term safety, and tolerability of SNDX-5613 in MLLr ALL, MLLr AML and NPM1c AML. We are conducting the trial at multiple centers in the United States and anticipate completing enrollment of the Phase 1 portion in the first half of 2021. In the first half of 2021, we anticipate commencing the Phase 2 portion, which we believe could serve as the basis for registration, with an expected total enrollment of up to 132 patients for the Phase 1/2 clinical trial. SNDX-5613 was previously granted Orphan Drug Designation for the treatment of adult and pediatric acute myeloid leukemia by the FDA.

### *Axatilimab*

We are also developing axatilimab a monoclonal antibody targeting the colony stimulating factor-1 receptor, or CSF-1R, a cell surface protein thought to control the survival and function of monocytes and macrophages. Axatilimab binds with high affinity to CSF-1R and blocks the binding of the two known CSF-1R ligands CSF-1 and IL-34. CSF-1R is expressed on the surface of specific immune cells known as macrophages and their precursor cells known as monocytes. CSF-1R signaling on these cells has been demonstrated in preclinical studies conducted in animal models of skin and lung chronic graft versus host disease, or cGVHD, to be the key regulatory pathway involved in the expansion and infiltration of the macrophages that mediate fibrosis and the cGVHD disease process. Blocking CSF-1R activity with an experimental CSF-1R antibody in these studies was shown to prevent and treat the symptoms of cGVHD. We believe that by inhibiting CSF-1R activation on monocytes and macrophages, that axatilimab has the potential to be used to treat cGVHD as well as other fibrotic diseases where monocyte-derived macrophages have been shown to play a significant role.

Our near-term focus is to rapidly establish proof of concept that axatilimab can provide meaningful clinical benefit in patients with advanced cGVHD where prior therapies are no longer effective and to establish the benefit of using axatilimab to treat other fibrotic diseases where monocyte-derived macrophages have been shown to play a role.

We announced that following our end of Phase 1 meeting with the FDA, we have aligned on a regulatory path for axatilimab, our anti-CSF-1R monoclonal antibody, for the treatment of chronic graft versus host disease (cGVHD). We plan to commence a pivotal Phase 2 trial, AGAVE-201, to assess the safety and efficacy of different doses and schedules of axatilimab for the treatment of patients with cGVHD. 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. We expect to begin enrollment by year-end 2020, with topline data anticipated in 2023. Upon initiation of AGAVE-201, we will cease enrollment in the Phase 2 portion of SNDX-6352-503, the Phase 1/2 trial evaluating axatilimab for the treatment of patients with cGVHD.

## Our Pipeline

<b>Axatilimab (SNDX-6352)</b>					
CSF-1R mAB	Preclin.	Phase I	Phase II	Phase III	Indication(s)
<b>SNDX-6352-503</b> (monotherapy)			●		<b>Chronic GVHD</b>
<b>SNDX-5613</b>					
Menin inhibitor	Preclin.	Phase I	Phase II	Phase III	Indication(s)
<b>AUGMENT-101</b> (monotherapy)		●			<b>MLLr leukemias, NPM1c AML</b>
<b>Entinostat (SNDX-275)</b>					
Class I HDAC inhibitor	Preclin.	Phase I	Phase II	Phase III	Indication(s)
<b>Entinostat</b>					<b>Under review</b>

### Recent Clinical Developments

On December 6, 2020, we presented the results of the Phase 1 portion of SNDX-6352-503 in an oral presentation during the American Society of Hematology (ASH) Virtual Annual Meeting.

During the presentation we shared that as of October 30, 2020 (data cutoff), a total of 15 patients were enrolled in the Phase 1 portion of the trial across five dose cohorts. Of 14 evaluable patients, responses were observed in ~60% (n=8) of patients with refractory disease who received a median of four prior systemic therapies, including ibrutinib, ruxolitinib and belumosudil (formerly KD-025). Deep and sustained responses were observed at all dose levels in several organs, including the esophagus (n=1/1), lower gastrointestinal (GI) tract (n=1/1), mouth (n=5/9), joints/fascia (n=6/11), lungs (n=2/5), skin (n=4/10), and eyes (n=4/12). Of note, clinical benefit was seen in difficult to treat sclerodermatous cGVHD, and complete responses were observed in multiple organs, including the esophagus, lower GI tract, mouth, and eyes. As of the data cutoff date, 67% of evaluable patients (n=8/12) experienced a clinically meaningful improvement in symptoms, as measured by at least a 7-point decrease in Lee Symptom Scale score.

Axatilimab was generally observed to be well tolerated. The most common observed adverse events were consistent with on-target effects on liver enzyme pharmacology. There was no incidence of cytomegalovirus (CMV) or other viral reactivation and no apparent increases in risk for infection. Enrollment remains ongoing in the Phase 2 portion of the Phase 1/2 trial at a dose of 1 mg/kg every two weeks.

### Termination of Our At-the-Market Program

In August 2019, we entered into a sales agreement with Cowen and Company, LLC, pursuant to which we may offer and sell, from time to time, through Cowen and Company, LLC, as sales agent, shares of our common stock having an aggregate offering price of up to \$50.0 million. In connection with this offering, we have terminated the sales agreement. Prior to the termination, we had not sold any shares of our common stock pursuant to the sales agreement.