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): September 24, 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 1.01. Entry Into a Material Definitive Agreement.

On September 24, 2021, Syndax Pharmaceuticals, Inc. (the "***Company***") entered into a Collaboration and License Agreement (the "***Collaboration Agreement***") with Incyte Corporation ("***Incyte***"), covering the worldwide development and commercialization of SNDX-6352 (axatilimab). Axatilimab is a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor, that is currently in clinical development by the Company. The Company has exclusive worldwide development and commercialization rights to axatilimab under a July 2016 license agreement with UCB Biopharma Sprl.

Under the terms of the Collaboration Agreement, Incyte will receive exclusive commercialization rights outside of the United States, subject to its royalty payment obligations set forth below. In the United States, Incyte and the Company will co-commercialize axatilimab, with the Company having the right to co-promote the product with Incyte, subject to the Company's exercise of its co-promotion option. Incyte will be responsible for leading all other aspects of commercialization, including booking all revenue from sales of axatilimab in the United States. The Company and Incyte will share equally the profits and losses from the co-commercialization efforts in the United States. The Company and Incyte have agreed to co-develop axatilimab and to share development costs associated with global and U.S.-specific clinical trials, with Incyte responsible for 55% of such costs and the Company responsible for 45% of such costs. Each company will be responsible for funding any independent development activities. All development costs related to the collaboration will be subject to a joint development plan.

Incyte has agreed to pay the Company an upfront non-refundable payment of $117 million. The Company will be eligible to receive up to $220 million in future contingent development and regulatory milestones and up to $230 million in commercialization milestones as well as tiered royalties ranging in the mid-teens percentage on net sales of the licensed product comprising axatilimab in Europe and Japan and low double digit percentage in the rest of the world outside of the United States. The Company's right to receive royalties in any particular country will expire upon the last to occur of (a) the expiration of licensed patent rights covering the licensed product in that particular country, (b) a specified period of time after the first post-marketing authorization sale of a licensed product in that country, and (c) the expiration of any regulatory exclusivity for that licensed product in that country (the "***Royalty Term***").

The Collaboration Agreement contains provisions for termination by (a) the Company upon a challenge of certain licensed patents specified in the Collaboration Agreement by Incyte, (b) either party for an uncured material breach, (c) Incyte for convenience, and (d) either party upon the insolvency of the other party. Unless terminated earlier in accordance with its terms, the Collaboration Agreement will continue on a country-by-country and licensed product-by-licensed product basis (y) in each country outside of the United States until the end of applicable the Royalty Term of such licensed product in such country and (z) with respect to the United States, for so long as Incyte is developing or commercializing such licensed product in the United States.

The Collaboration Agreement contains, among other provisions, customary representation and warranties, indemnification obligations and confidentiality and intellectual property provisions.

The effectiveness of the Collaboration Agreement and Purchase Agreement described below are conditioned on the early termination or expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "***HSR Waiting Period***"); however, certain confidentiality, antitrust filing and other provisions became effective upon execution of the Collaboration Agreement.

In addition, under the Collaboration Agreement and pursuant to a stock purchase agreement (the "***Purchase Agreement***"), Incyte has agreed to purchase 1,421,523 shares (the "***Shares***") of common stock, par value $0.0001 per share, of the Company (the "***Common Stock***") for an aggregate purchase price of $35 million, or $24.62 per share. The price per Share represents a 30% premium to the simple average of the daily closing volume weighted average price of the Common Stock for the 10 trading days immediately prior to the execution date of the Collaboration Agreement. Under the Purchase Agreement, Incyte has agreed, subject to limited exceptions, not to sell or otherwise transfer any of the Shares for a six-month period. Closing of the purchase of the Shares is expected to occur concurrently with the effectiveness of the Collaboration Agreement following early termination or expiration of the HSR Waiting Period and is subject to customary conditions, as well as the continued effectiveness of the Collaboration Agreement.

The foregoing descriptions of the terms of each of the Collaboration Agreement and the Purchase Agreement do not purport to be complete and are qualified in their entirety by the full text of each agreement. The Company intends to file a copy of each of the Collaboration Agreement and the Purchase Agreement with its Quarterly Report on Form 10-Q for the quarter ending September 30, 2021.

Item 7.01. Regulation FD Disclosure.

On September 27, 2021, the Company and Incyte issued a press release relating to the Collaboration Agreement. A copy of the press release is furnished herewith as Exhibit 99.1.

The information in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached 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 liability under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "***Securities Act***"), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Forward-Looking Statements.

This Current Report on Form 8-K includes "forward-looking statements," within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. These statements express a belief, expectation or intention and are generally accompanied by words that convey projected future events or outcomes such as "believe," "may," "will," "estimate," "continue," "anticipate," "assume," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "would" or by variations of such words or by similar expressions. The forward-looking statements include statements relating to, among other things, the Company's proposed collaboration with the Incyte and the Company's worldwide development and commercialization of SNDX-6352 (axatilimab). The Company has based these forward-looking statements on its current expectations and assumptions and analyses made by the Company in light of its experience and its perception of historical trends, current conditions and expected future developments, as well as other factors the Company believes are appropriate under the circumstances. However, whether actual results and developments will conform with the Company's expectations and predictions is subject to a number of risks and uncertainties, including the anticipated completion of the Company's proposed transaction with Incyte, the outcome of the Company's proposed collaboration with Incyte and other factors, many of which are beyond the control of the Company. Refer to the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2020 and comparable "risk factors" sections of the Company's Quarterly Reports on Form 10-Q and other filings, which have been filed with the U.S. Securities and Exchange Commission (the "***SEC***") and are available on the SEC's website at www.sec.gov. All of the forward-looking statements made in this Current Report on Form 8-K are expressly qualified by the cautionary statements contained or referred to herein. The actual results or developments anticipated may not be realized or, even if substantially realized, they may not have the expected consequences to or effects on the Company or its businesses or operations. Such statements are not guarantees of future performance and actual results or developments may differ materially from those projected in the forward-looking statements. Readers are cautioned not to rely too heavily on the forward-looking statements contained in this Current Report on Form 8-K. These forward-looking statements speak only as of the date of this Current Report on Form 8-K. Except as required by law, the Company does not undertake any obligation, and specifically declines any obligation, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated September 27, 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: September 27, 2021

Syndax Pharmaceuticals and Incyte Announce Global Collaboration to Develop and Commercialize Axatilimab for Chronic Graft-Versus-Host Disease and Other Fibrotic Diseases

– Syndax to receive $152 million in cash ($117 million upfront plus a $35 million equity investment), with potential for $450 million in additional milestone payments; 50:50 profit share in the U.S. and double-digit royalties on ex-U.S. sales –

– The two companies expect to expand development of axatilimab in chronic graft-versus-host disease (cGVHD) with additional monotherapy and combination trials planned in 2022 –

– Syndax to commence Phase 2 proof of concept trial in idiopathic pulmonary fibrosis (IPF) in early 2022 –

– Incyte to lead U.S. and global commercial activities; Syndax retains option to co-promote in the U.S. –

– Syndax to host conference call today at 8:00 a.m. ET; Incyte to host conference call today at 10:00 a.m. ET –

WALTHAM, Mass. and WILMINGTON, Del., September 27, 2021 (PRNEWSWIRE) – Syndax Pharmaceuticals, Inc. (Nasdaq: SNDX) and Incyte (Nasdaq: INCY) announced today that they have entered into an exclusive worldwide collaboration and license agreement to develop and commercialize axatilimab, Syndax's anti-CSF-1R monoclonal antibody.

"This partnership has the potential to significantly expand and maximize the axatilimab program across multiple lines of treatment in chronic graft-versus-host Disease (cGVHD), as well as additional indications in which the monocyte-macrophage lineage plays a vital role in the fibrotic disease process, such as idiopathic pulmonary fibrosis (IPF)," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "Incyte is a proven leader in the development and commercialization of many important innovative therapies, including a treatment for GVHD. We are thrilled to be working alongside this talented and determined team to combine our expertise as we strive to provide new treatment options for patients in desperate need of effective interventions."

"We are excited to partner with Syndax and for the opportunity to bring another potential treatment to patients with life-threatening conditions, like GVHD," said Hervé Hoppenot, Chief Executive Officer of Incyte. "Collaborations between companies like Incyte and Syndax, who are both dedicated to scientific advancement, contribute to the development of new innovative medicines that may benefit patient communities around the world."

Syndax and Incyte are seeking to develop axatilimab as a backbone therapy for patients with cGVHD as well as in additional immune-mediated diseases where CSF-1R-dependent monocytes and macrophages are believed to contribute to organ fibrosis. Syndax recently completed a Phase 1/2 trial of axatilimab in patients with cGVHD. Data from the Phase 1 portion of the trial highlighting the tolerability and high response rate of axatilimab in cGVHD patients refractory to multiple therapeutic agents were reported during an oral presentation at the American Society of Hematology Annual Meeting in December 2020. Updated results from the Phase 1 portion and preliminary results from the Phase 2 expansion portion of the study, which evaluated 1 mg/kg of axatilimab every two weeks, are expected to be presented at a medical meeting in the fourth quarter of 2021.

Enrollment continues in the ongoing global pivotal Phase 2 AGAVE-201 trial of axatilimab monotherapy in patients with cGVHD, with topline data expected in 2023. The companies also plan to initiate additional trials of axatilimab in patients with cGVHD in 2022, including a Phase 2 trial in combination with a JAK inhibitor in patients with steroid-refractory cGVHD. Beyond cGVHD, Syndax plans to commence a Phase 2 proof of concept trial of axatilimab early next year in patients with IPF, a serious, life-limiting orphan disease for which axatilimab could represent a much-needed treatment option with a novel mechanism of action.

Terms of the Collaboration

Under the terms of the agreement, Incyte will lead global commercial activities for axatilimab across all indications. The companies will participate in a 50:50 profit share in the U.S., and Syndax will receive double-digit royalties on sales outside of the U.S. Syndax will retain the option to co-promote axatilimab for any approved indications in the U.S. In connection with the agreement, Syndax will receive an upfront payment of $117 million plus a $35 million equity investment, which will be purchased at $24.62 per share, a 30% premium to the volume weighted average price over the 10 days prior to September 24, 2021. Syndax will also be eligible to receive up to an additional $450 million in potential regulatory, development and commercial milestone payments.

The companies will share development costs associated with global and U.S.-specific trials for all agreed upon trials at a rate of 55% (Incyte) and 45% (Syndax), with Incyte responsible for 100% of future development costs for trials that are specific to ex-U.S. countries. Syndax will fund the initial development of axatilimab in IPF and Incyte will have the option to co-fund late-stage development for this indication.

The agreement between Syndax and Incyte, including the upfront payment and equity investment, is subject to clearance by the U.S. antitrust authorities under the Hart-Scott-Rodino Act and will become effective as soon as these conditions have been met.

Goldman Sachs & Co. LLC is acting as the exclusive financial advisor to Syndax.

Syndax Conference Call and Webcast

In connection with this announcement, Syndax's management team will host a conference call and live audio webcast at 8:00 a.m. ET today, September 27, 2021.

The live audio webcast may be accessed through the Events & Presentations page in the Investors section of Syndax's website at www.syndax.com. Alternatively, the conference call may be accessed through the following:

Conference ID: 9875536
Domestic Dial-in Number: (855) 251-6663
International Dial-in Number: (281) 542-4259
Live webcast: https://edge.media-server.com/mmc/p/7qge5abd

For those unable to participate in the conference call or webcast, a replay will be available for 30 days on the Investors section of Syndax's website, www.syndax.com.

Incyte Conference Call and Webcast

Incyte will also host an analyst and investor conference call and webcast at 10:00 a.m. ET to discuss today's news and the Company's recent product approval in chronic GVHD. The live and archived webcast will be available via investor.incyte.com.

To access the conference call, please dial 877-407-3042 for domestic callers or +1-201-389-0864 for international callers (conference identification number 13723505).

If you are unable to participate, a replay will be available for 90 days. The replay dial-in number for the United States is 877-660-6853 and the dial-in number for international callers is +1-201-612-7415 (conference identification number 13723505).

About Chronic Graft-Versus-Host Disease

Chronic graft-versus-host disease (cGVHD), an immune response of the donor-derived hematopoietic cells against recipient tissues, is a serious, potentially life-threatening complication of allogeneic hematopoietic stem cell transplantation (HSCT) which can last for years. Chronic GVHD is estimated to develop in approximately 40% of transplant recipients, and affects approximately 14,000 patients in the U.S.[1,2] Chronic GVHD typically manifests across multiple organ systems, with skin and mucosa being commonly involved, and is characterized by the development of fibrotic tissue.[3]

About Idiopathic Pulmonary Fibrosis

Idiopathic Pulmonary Fibrosis (IPF) is a serious, life-limiting chronic lung disease characterized by fibrosis and scarring of lung tissue with a median survival of 3-5 years after diagnosis. Patients with IPF experience debilitating symptoms including progressive shortness of breath, particularly with exertion, chronic cough, fatigue, weakness, and chest discomfort. Currently approved drugs slow but do not halt disease progression and the only curative therapy is lung transplant, which is an option for less than 5% of patients. Estimates indicate that IPF could affect approximately 150,000 patients in the U.S. and approximately 260,000 patients across the seven major pharmaceutical markets (U.S., Japan, UK, Spain, Germany, Italy, and France).[4]

About Axatilimab

Axatilimab is an investigational monoclonal antibody that targets colony stimulating factor-1 receptor, or CSF-1R, a cell surface protein thought to control the survival and function of monocytes and macrophages. In pre-clinical models, inhibition of signaling through the CSF-1 receptor has been shown to reduce the number of disease-mediating macrophages along with their monocyte precursors, which has been shown to play a key role in the fibrotic disease process underlying diseases, such as chronic graft-versus-host disease (cGVHD) and idiopathic pulmonary fibrosis (IPF). Axatilimab data has demonstrated deep, durable responses and multiorgan clinical benefit in patients with cGVHD refractory to multiple therapeutic agents, and is currently being evaluated in the global pivotal Phase 2 AGAVE-201 trial in patients with cGVHD. Axatilimab was granted Orphan Drug Designation by the U.S. Food and Drug Administration for the treatment of patients with cGVHD and IPF. Axatilimab is being developed under an exclusive worldwide license from UCB entered into between Syndax and UCB in 2016.

About Incyte

Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development, and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @Incyte.

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. For more information, please visit www.syndax.com or follow the Company on Twitter and LinkedIn.

Incyte Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding whether or when axatilimab might provide a successful treatment option for patients with steroid-refractory cGVHD or other diseases; Incyte’s plans to develop and commercialize axatilimab, either as a monotherapy or in combination with other therapies; and Incyte’s expectations for its collaboration with Syndax, contain predictions, estimates, and other forward-looking statements.

These forward-looking statements are based on Incyte’s current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials and the ability to enroll subjects in accordance with planned schedules; the effects of the COVID-19 pandemic and measures to address the pandemic on Incyte’s clinical trials supply chain and other third-party providers and development and discovery operations; determinations

made by the U.S. antitrust authorities, the FDA or other regulatory authorities; Incyte's dependence on its relationships with its collaboration partners; the efficacy or safety of the Incyte's products and the products of Incyte's collaboration partners; the acceptance of the Company's products and the products of the Incyte's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its annual report and its quarterly report on Form 10-Q for the quarter ended June 30, 2021. Incyte disclaims any intent or obligation to update these forward-looking statements.

Syndax 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 regarding whether or when axatilimab might provide a successful treatment option for patients with steroid-refractory cGVHD or other diseases; Syndax's plans to develop and commercialize axatilimab, either as a monotherapy or in combination with other therapies; Syndax's expectations for its collaboration with Incyte; the design, progress, timing, clinical development and scope of clinical trials, plans for initiating future clinical trials, reporting of clinical data for Syndax's product candidates, the association of data with treatment outcomes. 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 Securities and Exchange Commission, including the "Risk Factors" sections contained in its annual report of Form 10-K for the year ended December 31, 2020 and its quarterly report on Form 10-Q for the quarter ended June 30, 2021. 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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References

1. SmartAnalyst 2020 SmartImmunology Insights chronic GVHD report.
2. Bachier, CR. et al. ASH annual meeting 2019; abstract #2109 Epidemiology and Real-World Treatment of Chronic Graft-Versus-Host Disease Post Allogeneic Hematopoietic Cell Transplantation: A U.S. Claims Analysis.
3. Kantar 2020 GVHD Expert Interviews N=32 interviews.
4. SMARTImmunology Insights. "Idiopathic Pulmonary Fibrosis." Presentation, March 2020.

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