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): May 9, 2022

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 May 9, 2022, Syndax Pharmaceuticals, Inc. (the "***Company***") issued a press release announcing its financial results for the quarter ended March 31, 2022. 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 contained in this Item 2.02 and in Exhibit 99.1 attached hereto is intended to be furnished and 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 (the "***Securities Act***"), 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 May 9, 2022
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/ Michael A. Metzger
Michael A. Metzger
Chief Executive Officer

Dated: May 9, 2022

Syndax Pharmaceuticals Reports First Quarter 2022 Financial Results and Provides Clinical and Business Update

– Topline data from revumenib (SNDX-5613) and axatilimab pivotal programs expected starting in 1H23; Company remains on track for two FDA filings in 2023 –

– BEAT-AML and AUGMENT-102 trials assessing revumenib (SNDX-5613) in combination with venetoclax-azacitidine for newly diagnosed patients and in combination with chemotherapy for R/R patients both underway; topline data expected starting in 1H23 –

– Axatilimab granted Fast Track by U.S. FDA for the treatment of cGVHD after failure of two or more lines of systemic therapy –

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

WALTHAM, Mass., May 9, 2022 (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 first quarter ended March 31, 2022. In addition, the Company provided a clinical and business update.

“Throughout the first quarter, we continued to realize significant progress advancing our two pivotal programs, for which we expect to report topline data starting in the first half of 2023," said Michael A. Metzger, Chief Executive Officer. “We firmly believe revumenib (SNDX-5613) is positioned to serve as a first-to-market and best-in-class menin inhibitor for patients with NPM1 and MLLr acute leukemias. We have also begun exploring its activity beyond use as a monotherapy agent through initiation of two new trials, including in combination with venetoclax-azacitidine for use as a frontline treatment, and in combination with chemotherapy for relapsed/refractory (R/R) disease. Beyond acute leukemias, we intend to assess revumenib’s (SNDX-5613) potential in additional areas where menin inhibition could have a strong therapeutic benefit, and we look forward to commencing a proof-of-concept clinical trial in patients with advanced colorectal cancer (CRC), a highly underserved area lacking effective therapeutic options, in the fourth quarter of the year.”

“Additionally, enrollment continues in the ongoing global pivotal Phase 2 AGAVE-201 trial of axatilimab in chronic graft-versus-host disease (cGVHD), with topline data expected in the first half of 2023 and a potential Biologic License Application (BLA) filing in 2023. Supported by recent receipt of Fast Track Designation (FTD) by the U.S. Food and Drug Administration (FDA), we believe axatilimab has the potential to play a meaningful role in the cGVHD treatment landscape. Furthermore, as previously announced, we are committed to unlocking axatilimab’s full potential in additional fibrotic diseases where the monocyte-macrophage lineage plays a vital role, and remain on track to commence a Phase 2 trial in idiopathic pulmonary fibrosis (IPF) in the fourth quarter of this year.”

Recent Pipeline Progress and Anticipated Milestones

Revumenib (SNDX-5613)

- The pivotal Phase 2 portion of AUGMENT-101 is ongoing and the Company continues to expect completion of enrollment in at least one of the three pivotal cohorts later this year. The trials are expected to enroll a total of 64 adult and up to 10 pediatric patients across each of three distinct trial populations: patients with NPM1 mutant acute myeloid leukemia (AML), patients with MLLr AML, and patients with MLLr acute lymphocytic leukemia (ALL). Based on discussions with the U.S. FDA, AUGMENT-101 may serve as the basis for regulatory filings in each of the three distinct populations. The Company expects to receive initial topline data from the trials starting in the first half of 2023, with the potential for the first New Drug Application filing in 2023.

- Two additional trials, BEAT-AML and AUGMENT-102, are now underway to assess the safety, tolerability, and preliminary anti-leukemic efficacy of revumenib (SNDX-5613) and establish an appropriate Phase 2 dose. BEAT-AML is a front-line combination trial of revumenib (SNDX-5613) with venetoclax and azacitidine being conducted as part of the Leukemia & Lymphoma Society's Beat® AML Master Clinical Trial. The primary endpoint of the Phase 1 portion of the BEAT-AML trial is to determine the recommended Phase 2 dose of the combination. The Company also initiated a trial in combination with chemotherapy in patients with R/R NPM1 or MLLr acute leukemias, known as AUGMENT-102. The primary endpoint of AUGMENT-102 will assess the safety, tolerability, and recommended Phase 2 dose criteria. Topline data from the trials are expected beginning in 2023.

- The Company today announced it intends to initiate a proof-of-concept clinical trial to evaluate revumenib (SNDX-5613) in patients with unresectable metastatic microsatellite stable CRC, which represents the second leading cause of cancer death in the U.S. with an estimated incidence of over 55,000 patients per year[1,2]. Activation of the Wnt/b-catenin signaling pathway is believed to be a key initiating step and growth driver for the majority of CRC tumors. The menin-MLL1 protein complex has recently been shown to regulate b-catenin activity and in preclinical models, disrupting this complex through menin inhibition blocks growth of Wnt/b-catenin driven CRC tumors. The Company is expected to commence the trial in the fourth quarter of 2022.

Axatilimab

- The Company today announced that the U.S. FDA has granted FTD to axatilimab for the treatment of patients with cGVHD after failure of two or more lines of systemic therapy. FTD is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fulfill an unmet medical need, enabling drugs to reach patients earlier.
- Enrollment is ongoing in the Company's global pivotal Phase 2 AGAVE-201 trial of axatilimab in patients with cGVHD. The trial is evaluating the safety and efficacy of three doses and schedules of axatilimab. The primary endpoint will assess objective response rate based on the 2014 NIH consensus criteria for cGVHD, with key secondary endpoints including duration of response and improvement in modified Lee Symptom Scale score.

The Company remains on track to report topline data in the first half of 2023, with the potential for a BLA filing in 2023.

First Quarter 2022 Financial Results

As of March 31, 2022, Syndax had cash, cash equivalents and short-term investments of $397.9 million and 59.0 million shares and share equivalents issued and outstanding. This includes 4.0 million pre-funded warrants.

First quarter 2022 research and development expenses increased to $30.0 million from $21.9 million for the prior year period. The increase was primarily due to increased clinical and manufacturing activities.

General and administrative expenses for the first quarter 2022 increased to $6.8 million from $5.7 million for the prior year period. The increase is primarily due to increased compensation and professional fees.

For the three months ended March 31, 2022, Syndax reported a net loss attributable to common stockholders of $37.2 million or $0.63 per share compared to a net loss attributable to common stockholder of $27.7 million or $0.54 per share for the prior year period.

Financial Update and Guidance

For the second quarter of 2022, research and development expenses are expected to be $30 to $35 million, and total operating expenses are expected to be $38 to $42 million. For the full year of 2022, research and development expenses are expected to be $130 to $140 million, and total operating expenses are expected to be $160 to $170 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, May 9, 2022.

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: 1394554
Domestic Dial-in Number: (855) 251-6663
International Dial-in Number: (281) 542-4259
Live webcast: https://edge.media-server.com/mmc/p/49kx4w4n

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.

References

1. SmartOncology Tumor Insights report July 2021
2. Gatalica, et. al., Fam Cancer. 2016; 15: 405–412

About Syndax Pharmaceuticals, Inc.

Syndax Pharmaceuticals is a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. Highlights of the Company's pipeline include revumenib (SNDX-5613), a highly selective inhibitor of the Menin–MLL binding interaction, and axatilimab, a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor, both currently in pivotal trials. For more information, please visit www.syndax.com or follow the Company on Twitter and LinkedIn.

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, the reporting of clinical data for Syndax's product candidates, the potential use of our product candidates to treat various cancer indications and fibrotic diseases, Syndax's expected second quarter and full year research and development expenses, and expected total operating expenses. 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.

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

(In thousands)	March 31, 2022	December 31, 2021
Cash, cash equivalents and short-term investments	$ 397,930	$ 439,936
Total assets	$ 422,222	$ 449,657
Total liabilities	$ 47,673	$ 41,289
Total stockholders' equity (deficit)	$ 374,549	$ 408,368
Common stock outstanding	55,030,890	54,983,105
Common stock and common stock equivalents*	67,682,038	66,011,976
*Common stock and common stock equivalents:		
Common stock	55,030,890	54,983,105
Options to purchase common stock	8,419,541	6,921,514
Restricted Stock Units	256,583	132,333
Pre-funded warrants	3,975,024	3,975,024
	67,682,038	66,011,976

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

(In thousands, except share and per share data)	Three Months Ended March 31, 2022	2021
License fee revenue	$ -	$ 379
Operating expenses:		
Research and development	30,022	21,870
General and administrative	6,836	5,672
Total operating expenses	36,858	27,542
Loss from operations	(36,858)	(27,163)
Other income (expense), net	(311)	(560)
Net loss	$ (37,169)	$ (27,723)
Net loss attributable to common stockholders	$ (37,169)	$ (27,723)
Net loss per share attributable to common stockholders--basic and diluted	$ (0.63)	$ (0.54)
Weighted-average number of common stock used to compute net loss per share attributable to common stockholders--basic and diluted	58,978,615	51,499,831