Syndax Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Business Update

February 26, 2026

– Total revenue of $68.7 million in 4Q25 and $172.4 million in FY2025 –

– Revuforj® (revumenib) net revenue of $44.2 million in 4Q25, a 38% increase vs 3Q25, and $124.8 million in FY2025 –

– Niktimvo™ (axatilimab-csfr) net revenue of $56.0 million in 4Q25, a 22% increase vs 3Q25, and $151.6 million in FY2025, resulting in Syndax collaboration revenue of $42.4 million in FY2025 –

– Completed enrollment in Phase 2 IPF trial of axatilimab; topline data expected in 4Q26 –

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

NEW YORK, Feb. 26, 2026 (GLOBE NEWSWIRE) -- Syndax Pharmaceuticals (Nasdaq: SNDX), a commercial-stage biopharmaceutical company advancing innovative cancer therapies, today reported its financial results for the fourth quarter and full year ended December 31, 2025, and provided a business update.

"We solidified our leadership position and proved the strength of Syndax's R&D and commercial capabilities in 2025, achieving our third FDA approval and successfully launching two first- and best-in-class medicines. We reached thousands of patients with Revuforj and Niktimvo and generated over $275 million in 2025 sales, rapidly advancing the company towards profitability," said Michael A. Metzger, Chief Executive Officer. "With strong momentum and multiple growth drivers for both products, including increasing uptake of Revuforj in R/R NPM1m AML and the post-transplant setting, Syndax is well positioned for continued growth in 2026 and beyond."

Mr. Metzger continued, "We've also made excellent progress advancing our development programs designed to further unlock multi-billion-dollar opportunities for both our medicines. We are positioned to be first to frontline AML with a menin inhibitor, and to expand our impact on chronic GVHD and other fibrotic diseases through CSF-1R inhibition. Earlier this year, we completed enrollment in our Phase 2 IPF trial and remain on track for topline data later this year which could further unlock Niktimvo's potential as a novel antifibrotic."

Recent Business Highlights and Anticipated Milestones

Revuforj® (revumenib)

- Achieved $44.2 million in Revuforj net revenue in the fourth quarter of 2025, a 38% increase over the third quarter of 2025. Revuforj net revenue for the full year 2025 totaled $124.8 million.

- Observed continued acceleration in demand following the FDA's approval on October 24, 2025, of Revuforj for the treatment of relapsed or refractory (R/R) acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 mutation (NPM1m) in adult and pediatric patients one year and older who have no satisfactory alternative treatment options. Total Revuforj prescriptions in the fourth quarter of 2025 were approximately 1,150, an approximate 35% increase over the third quarter of 2025.

- Initiated REVEAL-ND, a Phase 3, randomized, double-blind, placebo-controlled trial of revumenib in combination with intensive chemotherapy in newly diagnosed patients with NPM1m AML in November 2025. The trial has dual primary endpoints of measurable residual disease (MRD) negative complete remission (CR) and event free survival (EFS) to support the potential for accelerated approval and full approval, respectively.
- Received the 'Best New Drug' award for Revuforj at the Scrip Awards in December 2025. The award recognizes excellence in pharmaceutical development and the drug that represents the best therapeutic advance in its area.
- Highlighted the company's leadership in menin inhibition with the presentation of 12 revumenib abstracts, including three oral presentations, at the 67th American Society of Hematology (ASH) Annual Meeting in December 2025. The presentations reported compelling results with revumenib in multiple acute leukemia subtypes across the R/R, frontline, and post-stem cell transplant maintenance setting.
  - The data presented included the first real-world evidence for a menin inhibitor. The results showed an overall response rate (ORR) of 77% (10/13), a measurable residual disease (MRD) negativity rate of 75% (9/12), and favorable tolerability among primarily R/R NPM1m, KMT2Ar, and NUP98r acute leukemia patients who received revumenib in combination with standard of care therapies or as a monotherapy outside of a clinical trial.

- Multiple clinical trials evaluating revumenib across the acute leukemia treatment continuum are ongoing, such as:
  - EVOLVE-2: A pivotal, Phase 3, randomized, double-blind, placebo-controlled trial of revumenib in combination with venetoclax and azacitidine in newly diagnosed NPM1m (primary efficacy analysis population) and KMT2Ar AML patients who are unfit for intensive chemotherapy. The trial is being conducted in collaboration with the HOVON network, a leading cooperative clinical trial group with extensive experience studying novel therapies for hematologic malignancies.

  - REVEAL-ND: A pivotal, Phase 3, randomized, double-blind, placebo-controlled trial of revumenib in combination with intensive chemotherapy in newly diagnosed NPM1m AML patients.

  - SAVE: A Phase 1/2 trial evaluating an all-oral combination of revumenib with venetoclax and decitabine/cedazuridine in pediatric and adult patients with newly diagnosed and R/R AML or mixed-lineage acute leukemia (MPAL) harboring either NPM1m, KMT2Ar, or NUP98r alterations. The trial is being conducted by investigators from MD Anderson Cancer Center. New data presented at the 2025 ASH Annual Meeting from the first cohort of newly diagnosed patients showed a complete remission (CR) rate of 76% (16/21), an ORR of 86% (18/21), and a MRD negativity rate among responders of 100% (18/18).

- Intensive chemotherapy: Two ongoing Phase 1 trials evaluating the combination of revumenib with intensive chemotherapy (7+3) in newly diagnosed NPM1m or KMT2Ar acute leukemia patients. Preliminary data presented from both trials at the 2025 ASH Annual Meeting showed that the safety profile of the combination was consistent with the profile for intensive chemotherapy alone, along with high rates of response and MRD negativity.

- BEAT AML: A Phase 1 trial evaluating the combination of revumenib with venetoclax and azacitidine in newly diagnosed older adults (≥60 years) with NPM1m or KMT2Ar AML. The trial is being conducted as part of the Leukemia & Lymphoma Society's Beat AML® Master Clinical Trial. Data presented at the 2025 European Hematology Association (EHA) Congress and simultaneously published in the *Journal of Clinical Oncology* showed a CR rate of 67% (29/43), an ORR of 88% (38/43), and a MRD negativity rate of 100% (37/37) among responders.

- Post-transplant maintenance: A Phase 1 trial evaluating the safety and preliminary efficacy of revumenib as post-transplant maintenance after hematopoietic stem cell transplant (HSCT) in patients with KMT2Ar or NPM1m acute leukemia. The trial is being conducted by investigators from the City of Hope Medical Center.

- Break *Through* Cancer: A Phase 2 trial studying whether the combination of revumenib and venetoclax can eliminate MRD in patients with AML and extend progression-free survival. The trial is being conducted by Break *Through* Cancer, a collaboration between leading U.S. cancer research centers.

- INTERCEPT: A Phase 1 trial evaluating the use of novel therapies, including revumenib, to target MRD and early relapse in AML. The trial is being conducted by the Australasian Leukaemia and Lymphoma Group as part of the INTERCEPT AML master clinical trial.

- The Company expects to present additional revumenib data at major medical meetings throughout 2026, including additional real-world evidence and data from the frontline and post-HSCT maintenance setting.

- The Company expects the RAVEN trial to initiate in the second half of 2026. RAVEN is a Phase 2 collaborative trial of revumenib in combination with venetoclax and azacitidine in newly diagnosed KMT2Ar patients who would be considered eligible, or fit, for intensive chemotherapy.

Niktimvo™ (axatilimab-csfr)

- Achieved $56.0 million in Niktimvo net revenue in the fourth quarter of 2025, a 22% increase over the third quarter of 2025. Niktimvo net revenue for the full year 2025 totaled $151.6 million. Syndax and Incyte are co-commercializing Niktimvo. Syndax records 50% of the Niktimvo net commercial profit, defined as net product revenue minus the cost of sales and commercial expenses. Syndax's share of the Niktimvo product contribution, reported as collaboration revenue, was $19.4 million and $42.4 million in the fourth quarter and full year 2025, respectively.

- Presented data from 11 axatilimab abstracts, including three oral presentations, at the 2025 ASH Annual Meeting. The abstracts highlighted the potential for axatilimab to provide long-term benefit in recurrent or refractory chronic graft-versus-host disease (GVHD) and the tolerability of axatilimab with ruxolitinib in newly diagnosed chronic GVHD.

- Presented data from nine axatilimab abstracts, including one oral presentation, at the Tandem Meetings (Transplantation & Cellular Therapy Meetings of ASTCT® and CIBMTR®) in February 2026. The data presented included a comprehensive analysis of axatilimab in patients with chronic GVHD-related bronchiolitis obliterans syndrome (BOS) in two clinical studies. The results show clinical and symptom responses across a spectrum of lung involvement.

- Two trials evaluating axatilimab in combination with standard of care therapies in newly diagnosed chronic GVHD patients are ongoing, including:
  - A Phase 2, open-label, randomized, multicenter trial of axatilimab in combination with ruxolitinib in patients ≥ 12 years of age with newly diagnosed chronic GVHD.

  - A pivotal Phase 3, randomized, double-blind, placebo-controlled, multi-center trial of axatilimab in combination with corticosteroids in patients ≥ 12 years of age with newly diagnosed chronic GVHD.

- Completed enrollment in MAXPIRe, a Phase 2, 26-week randomized, double-blinded, placebo-controlled trial of axatilimab on top of standard of care in patients with idiopathic pulmonary fibrosis (IPF) in the first quarter of 2026. The Company expects to report topline data in the fourth quarter of 2026.

Fourth Quarter and Full Year 2025 Financial Results

As of December 31, 2025, Syndax had cash, cash equivalents, and short-term investments of $394.1 million and 87.7 million common shares and prefunded warrants outstanding.

Total revenue for the fourth quarter of 2025 was $68.7 million, which consisted of $44.2 million in Revuforj net revenue, $19.4 million in Niktimvo collaboration revenue, and $5.1 million in milestone, license and royalty revenue. Total revenue for the full year 2025 was $172.4 million, which consisted of $124.8 million in Revuforj net revenue, $42.4 million in Niktimvo collaboration revenue, and $5.1 million in milestone, license and royalty revenue. The Niktimvo collaboration revenue is derived from the $151.6 million in Niktimvo net revenue that was previously reported by the Company's partner Incyte for the full year 2025. Syndax records 50% of the Niktimvo net commercial profit, defined as net revenue (recorded by Incyte) minus the cost of sales and commercial expenses.

Fourth quarter 2025 research and development expenses increased to $78.6 million from $65.5 million for the comparable prior year period, and for the full year 2025 increased to $258.8 million compared to $241.6 million for 2024. The year-over-year increase was primarily due to increased clinical, medical, and employee-related expenses.

Fourth quarter 2025 selling, general and administrative expenses increased to $49.9 million from $37.7 million for the comparable prior year period, and for the full year 2025 increased to $179.7 million compared to $120.9 million for 2024. The year-over-year increase was primarily due to increased employee-related expenses and increased sales and marketing expenses related to the U.S. commercial launches of Revuforj and Niktimvo.

For the three months ended December 31, 2025, Syndax reported a net loss attributable to common stockholders of $68.0 million, or $0.78 per share, compared to a net loss attributable to common stockholders of $94.2 million, or $1.10 per share, for the comparable prior year period. For the year ended December 31, 2025, Syndax reported a net loss attributable to common stockholders of $285.4 million or $3.29 per share, compared to a net loss attributable to common stockholders of $318.8 million or $3.72 per share for the comparable prior year period.

Financial Guidance

For the full year of 2026, the Company expects total research and development plus selling, general and administrative expenses to be approximately $400 million, excluding the impact of $50 million in estimated non-cash stock compensation expense.

Syndax expects that its operating expense base will remain stable over the next couple of years. As a result, Syndax expects that its cash, cash equivalents and short-term investments, combined with its anticipated product revenue, collaboration revenue and interest income, will enable the Company to reach profitability.

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, Thursday, February 26, 2026.

The live audio webcast and accompanying slides may be accessed through the Events & Presentations page in the Investors section of the Company's website. Alternatively, the conference call may be accessed through the following:

Conference ID: Syndax4Q25
Domestic Dial-in Number: (800) 590-8290
International Dial-in Number: (240) 690-8800
Live webcast: https://sndx-4q25.open-exchange.net

For those unable to participate in the conference call or webcast, a replay will be available on the Investors section of the Company's website at www.syndax.com approximately 24 hours after the conference call and will be available for 90 days following the call.

About Revuforj® (revumenib)

Revuforj (revumenib) is an oral, first-in-class menin inhibitor that is FDA approved for the treatment of relapsed or refractory (R/R) acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation as determined by an FDA-authorized test in adult and pediatric patients one year and older. Revuforj is also indicated for the treatment of R/R acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (NPM1) mutation in adult and pediatric patients one year and older who have no satisfactory alternative treatment options.

Multiple trials of revumenib are ongoing or planned across the treatment landscape, including in combination with standard of care therapies in newly diagnosed patients with NPM1m or KMT2Ar AML.

Revumenib was previously granted Orphan Drug Designation for the treatment of AML, ALL and acute leukemias of ambiguous lineage (ALAL) by the U.S. FDA and for the treatment of AML by the European Commission. The U.S. FDA also granted Fast Track designation to revumenib for the treatment of adult and pediatric patients with R/R acute leukemias harboring a KMT2A rearrangement or NPM1 mutation and Breakthrough Therapy Designation for the treatment of adult and pediatric patients with R/R acute leukemia harboring a KMT2A rearrangement.

About Niktimvo™ (axatilimab-csfr)

Niktimvo (axatilimab-csfr) is a first-in-class colony stimulating factor-1 receptor (CSF-1R)-blocking antibody approved for use in the U.S. for the treatment of chronic graft-versus-host disease (GVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg (88.2 lbs).

In 2016, Syndax licensed exclusive worldwide rights to develop and commercialize axatilimab from UCB. In September 2021, Syndax and Incyte entered into an exclusive worldwide co-development and co-commercialization license agreement for axatilimab in chronic GVHD and any future indications.

Axatilimab is being studied in frontline combination trials in chronic GVHD, including a Phase 2 combination trial with ruxolitinib (NCT06388564) and a Phase 3 combination trial with steroids (NCT06585774). Axatilimab is also being studied in an ongoing Phase 2 trial in patients with idiopathic pulmonary fibrosis (NCT06132256).

About Syndax

Syndax Pharmaceuticals is a commercial-stage biopharmaceutical company advancing innovative cancer therapies. Highlights of the Company's pipeline include Revuforj® (revumenib), an FDA-approved menin inhibitor, and Niktimvo™ (axatilimab-csfr), an FDA-approved monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor. Fueled by our commitment to reimagining cancer care, Syndax is working to unlock the full potential of its pipeline and is conducting several clinical trials across the continuum of treatment. For more information, please visit www.syndax.com/ or follow the Company on X and LinkedIn.

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 "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative or plural of those terms, 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 acceptance of Syndax and its partners' products in the marketplace, sales, marketing, manufacturing and distribution requirements, the potential use of its product candidates to treat various cancer indications and fibrotic diseases, and Syndax's expected full year total operating expenses, including its estimated non-cash stock compensation expense. 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 to Revuforj's or Niktimvo's commercial availability; 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.

Niktimvo is a trademark of Incyte.
All other trademarks are the property of their respective owners.

References

1. Overall response rate (ORR) includes CR, CRh, CRp, CRi, MLFS, and PR; Composite complete remission (CRc) includes CR, CRh, CRp, and CRi.
CR = Complete remission
CRh = Complete remission with partial hematologic recovery
CRp = Complete remission with incomplete platelet recovery
CRi = Complete remission with incomplete count recovery
MLFS = Morphologic leukemia-free state
PR = Partial response

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

(In thousands)	December 31, 2025	December 31, 2024
Cash, cash equivalents, short and long-term investments	$ 394,070	$ 692,404
Total assets	$ 529,706	$ 724,816
Total liabilities	$ 465,076	$ 436,692
Total stockholders' equity	$ 64,630	$ 288,124
Common stock outstanding	87,405,979	85,694,443
Common stock and common stock equivalents*	103,437,561	98,972,323
*Common stock and common stock equivalents:		
Common stock	87,405,979	85,694,443
Common stock warrants (pre-funded)	285,714	285,714
Common stock and pre-funded stock warrants	87,691,693	85,980,157
Options to purchase common stock	13,128,306	11,688,079
Restricted Stock Units	2,617,562	1,304,087
Total common stock and common stock equivalents	103,437,561	98,972,323

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

(In thousands, except share and per share data)	Three Months Ended December 31, 2025	Three Months Ended December 31, 2024	Year Ended December 31, 2025	Year Ended December 31, 2024
Revenue				
Product revenue, net	$ 44,195	7,680	$ 124,844	7,680
Collaboration revenue, net	19,392	—	42,367	—
Milestone, license and royalty revenue	5,141	—	5,141	16,000
Total revenues	68,728	7,680	172,352	23,680
Operating expenses:				
Cost of product sales	$ 2,706	826	$ 6,970	826
Research and development	78,641	65,529	258,784	241,647
Selling, general and administrative	49,929	37,690	179,682	120,879
Total operating expenses	131,276	104,045	445,436	363,352
Loss from operations	(62,548)	(96,365)	(273,084)	(339,672)
Other (expense) income, net	(5,466)	2,195	(12,338)	20,914
Net loss	$ (68,014)	$ (94,170)	$ (285,422)	$ (318,758)
Net loss attributable to common stockholders	$ (68,014)	$ (94,170)	$ (285,422)	$ (318,758)

Net loss per share:				
Basic loss per share attributable to common stockholders	$ (0.78)	$ (1.10)	$ (3.29)	$ (3.72)
Diluted loss per share attributable to common stockholders	$ (0.78)	$ (1.10)	$ (3.29)	$ (3.72)
Weighted-average common shares used in calculating:				
Basic loss per share attributable to common stockholders	87,359,323	85,791,198	86,625,610	85,622,065
Diluted loss per share attributable to common stockholders	87,359,323	85,791,198	86,625,610	85,622,065

Source: Syndax Pharmaceuticals, Inc.