Syndax Reports Third Quarter 2025 Financial Results and Provides Business Update

November 3, 2025

– $45.9 million in total revenue, representing 21% growth over 2Q25 –

– $32.0 million Revuforj® (revumenib) net revenue; total Revuforj prescriptions in 3Q25 increased 25% over 2Q25, highlighting strong demand –

– $45.8 million Niktimvo™ (axatilimab-csfr) net revenue reported by Incyte;$13.9 million in collaboration revenue reported by Syndax –

– Revuforj FDA-approved in R/R NPM1m AML on October 24, 2025 –

– $456.1 million in cash, cash equivalents and investments expected to fund the company to profitability –

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

NEW YORK, Nov. 03, 2025 (GLOBE NEWSWIRE) -- Syndax Pharmaceuticals (Nasdaq: SNDX), a commercial-stage biopharmaceutical company advancing innovative cancer therapies, today reported its financial results for the third quarter ended September 30, 2025, and provided a business update.

"The third quarter was another remarkable period of commercial and pipeline execution for Syndax. Demand remained strong for Revuforj and Niktimvo with over $75 million in combined net sales for the quarter," said Michael A. Metzger, Chief Executive Officer. "We also furthered our leadership in menin inhibition with the addition of Revuforj to the NCCN Guidelines for R/R NPM1m AML in late September followed by FDA approval in late October. Our expansion into this second indication is underway and we are making great progress driving awareness and generating demand. Additionally, we continue to advance the development of both Revuforj and Niktimvo in the frontline setting, further unlocking their multi-billion-dollar potential."

Recent Business Highlights and Anticipated Milestones

Revuforj® (revumenib)

- Achieved $32.0 million in Revuforj net revenue in the third quarter of 2025, representing a 12% increase over the second quarter of 2025. Total Revuforj prescriptions in the third quarter of 2025 were approximately 850, a 25% increase over total prescriptions in the second quarter of 2025.
- Received U.S. FDA approval for Revuforj on October 24, 2025, for the treatment of R/R acute myeloid leukemia (AML) with a susceptible NPM1 mutation in adult and pediatric patients one year and older who have no satisfactory alternative treatment options. Revuforj is now the first and only FDA-approved therapy for both R/R AML with an NPM1 mutation and R/R acute leukemia with a KMT2A translocation.
- Announced the inclusion of revumenib in the National Comprehensive Cancer Network® Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for AML as a category 2A recommended treatment option for R/R NPM1m AML on September 18, 2025. The guideline update was based on positive pivotal results from the AUGMENT-101 trial of revumenib which were published in the journal *Blood* in 2025.
- Announced that data from 12 revumenib abstracts, including 3 oral presentations, will be highlighted at the 67th American Society of Hematology (ASH) Annual Meeting. The abstracts present compelling results with revumenib in multiple acute leukemia subtypes across the R/R, frontline, and post-stem cell transplant settings.
- Multiple trials evaluating revumenib in NPM1m and KMT2Ar acute leukemia across the treatment landscape are ongoing. These trials include:
  - EVOLVE-2: A pivotal, Phase 3, randomized, double-blind, placebo-controlled trial evaluating revumenib in combination with venetoclax and azacitidine in newly diagnosed NPM1m 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.
  - 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. Data from the first cohort of newly diagnosed patients will be highlighted at the ASH 2025 Annual Meeting in an oral presentation.
  - Intensive chemotherapy: Two ongoing Phase 1 trials evaluating the combination of revumenib with intensive chemotherapy (7+3) followed by revumenib maintenance treatment in newly diagnosed NPM1m or KMT2Ar acute leukemia patients. Preliminary data from both trials will be presented at the ASH 2025 Annual Meeting.
  - 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.
  - 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.

- Start-up activities are underway for two trials, known as the REVEAL trials, that will evaluate revumenib in combination with standard of care regimens in newly diagnosed acute leukemia patients with NPM1m or KMT2A-rearranged AML who are fit to receive intensive chemotherapy, with trial initiation expected by the end of 2025.

- The Company is evaluating revumenib in patients with R/R metastatic microsatellite stable (MSS) colorectal cancer (CRC). The Company expects to report data from the trial at a medical conference in the first quarter of 2026.

Niktimvo™ (axatilimab-csfr)

- Achieved $45.8 million in Niktimvo net revenue in the third quarter of 2025, representing a 27% increase over the second quarter of 2025. 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. For the third quarter of 2025, Syndax's share of the Niktimvo product contribution, reported as collaboration revenue, was $13.9 million.

- Announced that data from 11 axatilimab abstracts, including 3 oral presentations, will be showcased at the 2025 ASH Annual Meeting. The abstracts highlight the potential for axatilimab to provide long-term benefit in recurrent or refractory chronic GVHD and the tolerability of axatilimab with ruxolitinib in newly diagnosed chronic GVHD.

- 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.

- Enrollment is ongoing 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). The Company expects to complete enrollment in the trial by the end of 2025 with topline data anticipated in the second half of 2026.

Third Quarter 2025 Financial Results

As of September 30, 2025, Syndax had cash, cash equivalents, and short- and long-term investments of $456.1 million and 87.2 million common shares and prefunded warrants outstanding.

Total revenue for the third quarter of 2025 was $45.9 million, which consisted of $32.0 million in Revuforj net revenue and $13.9 million in Niktimvo collaboration revenue. The collaboration revenue is derived from the $45.8 million in Niktimvo net revenue that was previously reported by the Company's partner Incyte. Syndax records 50% of the Niktimvo net commercial profit, defined as net revenue (recorded by Incyte) minus the cost of sales and commercial expenses.

Third quarter 2025 research and development expenses decreased to $56.3 million from $71.0 million for the comparable prior year period. The decrease was primarily the result of a $15 million milestone payment paid by the Company upon Niktimvo's approval, incurred in the third quarter of 2024 and not incurred in the 2025 period. Also contributing to the decrease was lower revumenib-related costs due the completion of the registrational trial in R/R NPM1m AML that was ongoing in the prior period and a reduction in CMC expenses due to the capitalization of inventory for commercial use.

Third quarter 2025 selling, general and administrative expenses increased to $44.9 million from $31.1 million for the comparable prior year period. The increase was primarily due to higher commercial costs and personnel and stock-based compensation expenses related to the commercial launches of Revuforj and Niktimvo in the 2025 period.

For the three months ended September 30, 2025, Syndax reported a net loss attributable to common stockholders of $60.7 million, or $0.70 per share, compared to a net loss attributable to common stockholders of $84.1 million, or $0.98 per share, for the comparable prior year period.

Financial Guidance

For the full year of 2025, the Company expects total research and development plus selling, general and administrative expenses to be $380 to $385 million, compared to prior guidance of $370 to $390 million, both estimates excluding an estimated $45 million in non-cash stock compensation expense.

Syndax expects that its operating expense base will remain stable over the next few years. As a result, Syndax expects that its cash, cash equivalents and short- and long-term investments, combined with its anticipated product 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, Monday, November 3, 2025.

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: Syndax3Q25
Domestic Dial-in Number: 800-590-8290
International Dial-in Number: 240-690-8800
Live webcast: https://sndx-3q25.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.

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)	September 30, 2025	December 31, 2024
Cash, cash equivalents, short and long-term investments	$ 456,125	$ 692,404
Total assets	$ 551,792	$ 724,816
Total liabilities	$ 436,362	$ 436,692
Total stockholders' equity	$ 115,430	$ 288,124
Common stock outstanding	86,905,343	85,694,443
Common stock and common stock equivalents*	103,502,892	98,972,323
*Common stock and common stock equivalents:		
Common stock	86,905,343	85,694,443
Common stock warrants (pre-funded)	285,714	285,714
Common stock and pre-funded stock warrants	87,191,057	85,980,157
Options to purchase common stock	13,506,676	11,688,079
Restricted Stock Units	2,805,159	1,304,087
Total common stock and common stock equivalents	103,502,892	98,972,323

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

(In thousands, except share and per share data)	Three Months Ended September 30, 2025	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Revenue				
Product revenue, net	$ 32,007	—	$ 80,649	—
Collaboration revenue, net	13,864	—	22,975	—
Milestone and license revenue	—	12,500	—	16,000
Total revenues	45,871	12,500	103,624	16,000
Operating expenses:				
Cost of product sales	$ 2,100	—	$ 4,264	—
Research and development	56,280	70,971	180,143	176,118
Selling, general and administrative	44,917	31,106	129,753	83,189
Total operating expenses	103,297	102,077	314,160	259,307
Loss from operations	(57,426)	(89,577)	(210,536)	(243,307)
Other (expense) income, net	(3,289)	5,451	(6,872)	18,718
Net loss	$ (60,715)	$ (84,126)	$ (217,408)	$ (224,589)
Net loss attributable to common stockholders	$ (60,715)	$ (84,126)	$ (217,408)	$ (224,589)
Net loss per share:				
Basic loss per share attributable to common stockholders	$ (0.70)	$ (0.98)	$ (2.51)	$ (2.63)
Diluted loss per share attributable to common stockholders	$ (0.70)	$ (0.98)	$ (2.51)	$ (2.63)
Weighted-average common shares used in calculating:				
Basic loss per share attributable to common stockholders	86,620,992	85,433,569	86,531,218	85,307,660
Diluted loss per share attributable to common stockholders	86,620,992	85,433,569	86,531,218	85,307,660

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Source: Syndax Pharmaceuticals, Inc.