Syndax Reports First Quarter 2026 Financial Results and Provides Business Update

April 30, 2026

– Total revenue of $64.9 million in 1Q26, a 224% year-over-year increase –

– Revuforj® (revumenib) net revenue of $48.9 million in 1Q26, highlighting leadership in menin inhibition and increasing uptake in R/R NPM1m AML –

– Niktimvo™ (axatilimab-csfr) net revenue of $55.1 million in 1Q26, resulting in Syndax collaboration revenue of $15.9 million –

– New revumenib real-world, frontline, and post-HSCT maintenance data anticipated in 2Q26 –

– Topline data expected in 4Q26 from Phase 2 trials of axatilimab in IPF and newly diagnosed chronic GVHD –

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

NEW YORK, April 30, 2026 (GLOBE NEWSWIRE) -- Syndax Pharmaceuticals (Nasdaq: SNDX), a commercial-stage biopharmaceutical company advancing innovative cancer therapies, today reported its financial results for the first quarter ended March 31, 2026, and provided a business update.

"We delivered over $100 million in combined Revuforj and Niktimvo net sales in the first quarter, highlighting strong demand for our medicines and advancing the company towards profitability. Revuforj net revenue totaled $49 million, underscoring our leadership in menin inhibition and strong adoption in both R/R NPM1m AML and KMT2Ar acute leukemia. Notably, recent analysis indicates that Revuforj is enabling nearly half of KMT2A patients to receive a stem cell transplant, providing the best chance for durable remission and positioning the franchise for long-term growth as an increasing number of patients return to therapy post-transplant," said Michael A. Metzger, Chief Executive Officer. "We are poised for continued commercial growth with robust prescriber bases, excellent payer coverage, and multiple evolving treatment patterns that should extend the average duration of treatment for both medicines."

Mr. Metzger continued, "We are nearing multiple important catalysts this year, including new Revuforj data which will further highlight its best-in-class profile and topline data from Phase 2 trials of Niktimvo in frontline chronic GVHD and IPF. As we look ahead, we are focused on unlocking the multi-billion-dollar opportunities for our medicines and are well-positioned to be first to frontline AML with a menin inhibitor, with strong global site initiation and patient enrollment underway in our pivotal trials."

Recent Business Highlights and Anticipated Milestones

Revuforj® (revumenib)

- Achieved $48.9 million in Revuforj net revenue in the first quarter of 2026, representing a 144% increase over the first quarter of 2025 and an 11% increase over the fourth quarter of 2025, driven primarily by increasing uptake in relapsed or refractory (R/R) NPM1 mutated (NPM1m) acute myeloid leukemia (AML). Total prescriptions increased by approximately 160% compared to the first quarter of 2025 and approximately 13% compared to the fourth quarter of 2025. Notably, recent analysis indicates that nearly half of R/R KMT2A translocated patients are proceeding to a hematopoietic stem cell transplant (HSCT) after receiving Revuforj, a significant increase from prior estimates of 33%. The Company expects this growing transplant rate to extend the average treatment duration as an increasing number of patients return to therapy after transplant.

- The Company expects the presentation of new revumenib data from multiple ongoing studies at major medical meetings throughout 2026.

  New/updated data expected in the second quarter of 2026:

  - Findings from a multicenter real-world study.
  - Post-HSCT maintenance data from multiple trials and centers.
  - R/R NUP98r acute leukemia data from patients treated in the AUGMENT-101 trial or via an expanded access program.
  - R/R data from the SAVE trial of revumenib in combination with venetoclax and decitabine/cedazuridine in NPM1m, KMT2Ar, and NUP98r acute leukemia.
  - Frontline data from the Phase 1 trial of revumenib in combination with intensive chemotherapy in NPM1m, KMT2Ar, or NUP98r AML.

  New/updated data expected in the second half of 2026:

  - Frontline data from the BEAT AML trial of revumenib in combination with venetoclax/azacitidine in NPM1m and KMT2Ar AML.
  - R/R data from the Phase 1 trial of revumenib in combination with gilteritinib in AML patients with a FLT3 mutation and a KMT2A translocation, NPM1m, or any other mutation associated with HOX-MEIS1 overexpression.

- 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.

- 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.

- 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.

- Post-transplant maintenance: A Phase 1 trial evaluating the safety and preliminary efficacy of revumenib as post-transplant maintenance after 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 measurable residual disease (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 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 $55.1 million in Niktimvo net revenue in the first quarter of 2026, representing significant growth compared to the $13.6 million in net revenue generated in the first quarter of 2025 from the first two months of the launch. 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 $15.9 million in the first quarter of 2026.

- 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 graft-versus-host disease (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. Topline data is now anticipated in the fourth quarter of 2026.

  - A pivotal Phase 3, randomized, double-blind, placebo-controlled, multicenter trial of axatilimab in combination with corticosteroids in patients ≥ 12 years of age with newly diagnosed chronic GVHD. Topline data is anticipated in early 2028.

- 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.

First Quarter 2026 Financial Results

As of March 31, 2026, Syndax had cash, cash equivalents, and short-term investments of $352.1 million and 88.8 million common shares and prefunded warrants outstanding.

Total revenue for the first quarter of 2026 was $64.9 million, which consisted of $48.9 million in Revuforj net revenue and $15.9 million in Niktimvo collaboration revenue. The Niktimvo collaboration revenue is derived from the $55.1 million in Niktimvo net revenue that was previously reported by the Company's partner Incyte for the first quarter 2026. Syndax records 50% of the Niktimvo net commercial profit, defined as net revenue (recorded by Incyte) minus the cost of sales and commercial expenses.

First quarter 2026 research and development expenses decreased to $58.8 million from $61.6 million for the comparable prior year period. The year-over-year decrease was primarily due to a decrease in Niktimvo related development milestone expense recognized in the first quarter of 2025, offset by an increase in Revuforj related clinical trial and personnel expenses.

First quarter 2026 selling, general and administrative expenses decreased to $37.6 million from $41.0 million for the comparable prior year period. The year-over-year decrease was primarily due to a decrease in commercial-related expenses due to launch costs incurred in the first quarter of 2025 for Revuforj and Niktimvo that were not incurred in the same period in 2026 offset by a decrease in personnel expenses related to higher accrued compensation costs in 2025 for the achievement of corporate objectives.

For the three months ended March 31, 2026, Syndax reported a net loss attributable to common stockholders of $42.7 million, or $0.48 per share, compared to a net loss attributable to common stockholders of $84.8 million, or $0.98 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, April 30, 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: Syndax1Q26
Domestic Dial-in Number: 800-590-8290
International Dial-in Number: 240-690-8800
Live webcast: https://sndx-1q26.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.

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

(In thousands, except share data)	March 31, 2026	December 31, 2025
Cash, cash equivalents and short -term investments	$ 352,064	$ 394,070
Total assets	$ 472,668	$ 529,706
Total liabilities	$ 431,046	$ 465,076
Total stockholders' equity	$ 41,622	$ 64,630
Common stock outstanding	88,543,881	87,405,979
Common stock and common stock equivalents*	106,213,646	103,437,561
*Common stock and common stock equivalents:		
Common stock	88,543,881	87,405,979
Common stock warrants (pre-funded)	285,714	285,714
Common stock and pre-funded stock warrants	88,829,595	87,691,693
Options to purchase common stock	13,949,602	13,128,306
Restricted Stock Units	3,434,449	2,617,562
Total common stock and common stock equivalents	106,213,646	103,437,561

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

(In thousands, except share and per share data)	Three Months Ended March 31, 2026	2025
Revenue:		
Product revenue	$ 48,923	$ 20,042
Collaboration revenue	$ 15,941	$ -
Total revenue	64,864	20,042
Operating expenses:		
Cost of product sales	$ 2,633	$ 885
Research and development	58,845	61,636
Selling, general and administrative	37,588	41,031
Collaboration loss	-	247
Total operating expenses	99,066	103,799
Loss from operations	(34,202)	(83,757)
Other (expense) income, net:		
Royalty interest expense	(11,846)	(8,049)
Other interest expense	-	(2)
Interest income	3,561	7,183
Other (expense) income, net	(186)	(221)
Total other (expense) income, net	(8,471)	(1,089)
Net loss	$ (42,673)	$ (84,846)
Net loss attributable to common stockholders	$ (42,673)	$ (84,846)
Net loss per share:		
Basic loss per share attributable to common stockholders	$ (0.48)	$ (0.98)
Diluted loss per share attributable to common stockholders	$ (0.48)	$ (0.98)
Weighted-average common shares used in calculating:		
Basic loss per share attributable to common stockholders	88,255,636	86,171,889
Diluted loss per share attributable to common stockholders	88,255,636	86,171,889

Source: Syndax Pharmaceuticals, Inc.