UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2025

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to

Commission File Number: 001-37708

Syndax Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**32-0162505**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
730 Third Avenue, 9th Floor New York, New York	**10017**
(Address of Principal Executive Offices)	**(Zip Code)**

(781) 419-1400
(Registrant's Telephone Number, Including Area Code)

Securities 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: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. **Yes** ☒ **No** ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). **Yes** ☒ **No** ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
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 accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). **Yes** ☐ **No** ☒

As of October 31, 2025, there were 86,914,838 shares of the registrant's Common Stock, par value $0.0001 per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or this Quarterly Report, contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. All statements other than statements of historical fact are “forward-looking statements” for purposes of this Quarterly Report on Form 10-Q. In some cases, you can identify forward-looking statements by terminology 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.

Forward-looking statements include, but are not limited to, statements about:

- our estimates regarding our expenses, future revenues, anticipated capital requirements and our needs for additional financing;
- the initiation, cost, timing, progress and results of our research and development activities, clinical trials and preclinical studies;
- our ability to replicate results in future clinical trials;
- our expectations regarding the potential safety, efficacy or clinical utility of our product candidates as well as the potential use of our product candidates to treat various cancer indications and fibrotic diseases;
- our ability to obtain and maintain regulatory approval for our product candidates and the timing or likelihood of regulatory filings and approvals for such candidates;
- our ability to maintain our licenses with UCB Biopharma Sprl, and Vitae Pharmaceuticals, LLC, a subsidiary of AbbVie Inc.;
- the success of our collaboration with Incyte Corporation, or Incyte, to further develop and commercialize axatilimab;
- the potential milestone and royalty payments under certain of our license agreements;
- the implementation of our strategic plans for our business and development of our product candidates;
- the scope of protection we establish and maintain for intellectual property rights covering our product candidates and our technology;
- the market adoption of REVUFORJ® (revumenib) and NIKTIMVO™ (axatilimab-csfr) and our other product candidates by physicians and patients;
- developments relating to our competitors and our industry; and
- the impact of geopolitical actions, including tariffs, war or the perception that hostilities may be imminent (such as the ongoing war between Russia and Ukraine), adverse global economic conditions, terrorism, public health crises, funding shortages at governmental and regulatory agencies on which we rely, or natural disasters on our operations, research and development and clinical trials and potential disruption in the operations and business of third-party manufacturers, contract research organizations, or CROs, other service providers, and collaborators with whom we conduct business.

These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry’s actual results, levels of activity, performance, or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in this report in greater detail in the section titled “Risk Factors” and elsewhere in this report. You should not rely upon forward-looking statements as predictions of future events.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by law, we are under no duty to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise.

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Part I: FINANCIAL INFORMATION

Item 1: Financial Statements

SYNDAX PHARMACEUTICALS, INC.
(unaudited)
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	September 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 116,808	$ 154,083
Short-term investments	319,171	418,801
Accounts receivable, net	25,403	7,602
Inventory	25,000	366
Short-term deposits	18,195	10,029
Other receivable, net	—	3,635
Collaboration receivable, net	15,736	—
Prepaid expenses and other current assets	9,517	8,541
Total current assets	529,830	603,057
Long-term investments	20,146	119,520
Property and equipment, net	128	—
Right-of-use asset, net	1,471	2,022
Restricted cash	217	217
Total assets	$ 551,792	$ 724,816
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 13,826	$ 11,626
Collaboration payable, net	—	19,231
Accrued expenses and other current liabilities	77,105	60,096
Current portion of royalty interest financing liability	22,925	12,116
Current portion of right-of-use liability	329	471
Current portion of capital lease	2	9
Total current liabilities	114,187	103,549
Long-term liabilities:		
Royalty interest financing liability, less current portion	320,985	331,565
Right-of-use liability, less current portion	1,190	1,578
Total long-term liabilities	322,175	333,143
Total liabilities	436,362	436,692
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized; 0 shares outstanding at September 30, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value, 200,000,000 shares authorized; 86,905,343 and 85,694,443 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	9	9
Additional paid-in capital	1,553,462	1,509,110
Accumulated other comprehensive gain	525	163
Accumulated deficit	(1,438,566)	(1,221,158)
Total stockholders' equity	115,430	288,124
Total liabilities and stockholders' equity	$ 551,792	$ 724,816

The accompanying notes are an integral part of these unaudited consolidated financial statements.

SYNDAX PHARMACEUTICALS, INC.
(unaudited)
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	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:				
Royalty interest expense	(8,283)	—	(24,186)	—
Other interest expense	—	(23)	(6)	(123)
Interest income	5,269	5,442	18,402	18,982
Other (expense) income	(275)	32	(1,082)	(141)
Total other (expense) income, net	(3,289)	5,451	(6,872)	18,718
Net loss	$ (60,715)	$ (84,126)	$ (217,408)	$ (224,589)
Other Comprehensive loss:				
Unrealized gain on marketable securities	240	1,188	362	153
Other Comprehensive loss	(60,475)	(82,938)	(217,046)	(224,436)
Net loss per share:				
Basic and diluted loss per share attributable to common stockholders	$ (0.70)	$ (0.98)	$ (2.51)	$ (2.63)
Weighted-average common shares used in calculating:				
Basic and diluted loss per share attributable to common stockholders	86,620,992	85,433,569	86,531,218	85,307,660

The accompanying notes are an integral part of these unaudited consolidated financial statements.

SYNDAX PHARMACEUTICALS, INC.
(unaudited)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share and per share data)

(In thousands, except share data)	Nine months ended September 30, 2025					
	Common Stock $0.0001 Par Value		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss)/Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2024	85,694,443	$ 9	$ 1,509,110	$ 163	$ (1,221,158)	$ 288,124
Stock purchase under ESPP	104,115	—	—	—	—	—
Stock-based compensation expense	—	—	10,487	—	—	10,487
Unrealized loss on investments	—	—	—	364	—	364
Vesting of RSUs	205,527	—	—	—	—	—
Employee withholdings ESPP	—	—	545	—	—	545
Proceeds from exercise of stock options	42,947	—	385	—	—	385
Net loss	—	—	—	—	(84,846)	(84,846)
Balance as of March 31, 2025	86,047,032	$ 9	$ 1,520,527	$ 527	$ (1,306,004)	$ 215,059
Stock-based compensation expense	—	—	13,903	—	—	13,903
Unrealized loss on investments	—	—	—	(242)	—	(242)
Vesting of RSUs	417	—	—	—	—	—
Employee withholdings ESPP	—	—	468	—	—	468
Proceeds from exercise of stock options	11,628	—	83	—	—	83
Net loss	—	—	—	—	(71,847)	(71,847)
Balance as of June 30, 2025	86,059,077	$ 9	$ 1,534,981	$ 285	$ (1,377,851)	$ 157,424
Stock-based compensation expense	—	—	12,203	—	—	12,203
Unrealized gains on investments	—	—	—	240	—	240
Stock purchase under ESPP	60,737	—	—	—	—	—
Employee withholdings ESPP	—	—	(80)	—	—	(80)
Vesting of RSUs	75,122	—	—	—	—	—
Proceeds from exercise of stock options	710,407	—	6,358	—	—	6,358
Net loss	—	—	—	—	(60,715)	(60,715)
Balance as of September 30, 2025	86,905,343	$ 9	$ 1,553,462	$ 525	$ (1,438,566)	$ 115,430

The accompanying notes are an integral part of these unaudited consolidated financial statements.

SYNDAX PHARMACEUTICALS, INC.
(unaudited)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share and per share data)

(In thousands, except share data)	Common Stock $0.0001 Par Value		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss)/Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2023	84,826,632	$ 8	$ 1,456,370	$ 218	$ (902,400)	$ 554,196
Stock purchase under ESPP	35,463	—	—	—	—	—
Stock-based compensation expense	—	—	8,899	—	—	8,899
Unrealized loss on investments	—	—	—	(974)	—	(974)
Vesting of RSUs	3,750	—	—	—	—	—
Employee withholdings ESPP	—	—	309	—	—	309
Proceeds from exercise of stock options	113,841	—	1,859	—	—	1,859
Net loss	—	—	—	—	(72,400)	(72,400)
Balance as of March 31, 2024	84,979,686	$ 8	$ 1,467,437	$ (756)	$ (974,800)	$ 491,889
Stock-based compensation expense	—	—	9,896	—	—	9,896
Unrealized loss on investments	—	—	—	(61)	—	(61)
Vesting of RSUs	1,603	—	—	—	—	—
Employee withholdings ESPP	—	—	237	—	—	237
Proceeds from exercise of stock options	47,340	—	439	—	—	439
Par value adjustment	—	1	—	—	—	1
Net loss	—	—	—	—	(68,063)	(68,063)
Balance as of June 30, 2024	85,028,629	$ 9	$ 1,478,009	$ (817)	$ (1,042,863)	$ 434,338
Stock-based compensation expense	—	—	11,934	—	—	11,934
Unrealized gains on investments	—	—	—	1,188	—	1,188
Stock purchase under ESPP	29,440	—	—	—	—	—
Employee withholdings ESPP	—	—	535	—	—	535
Vesting of RSUs	19,057	—	—	—	—	—
Proceeds from exercise of stock options	208,362	—	2,563	—	—	2,563
Net loss	—	—	—	—	(84,126)	(84,126)
Balance as of September 30, 2024	85,285,488	$ 9	$ 1,493,041	$ 371	$ (1,126,989)	$ 366,432

The accompanying notes are an integral part of these unaudited consolidated financial statements.

SYNDAX PHARMACEUTICALS, INC.
(unaudited)
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Nine Months Ended September 30,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (217,408)	$ (224,589)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	3	8
Accretion of investments	(9,223)	(10,528)
Non-cash operating lease expense	551	781
Stock-based compensation	36,249	30,729
Amortization of debt issuance costs	229	—
Provision for credit losses	3,667	—
Changes in operating assets and liabilities:		
Accounts receivable	(17,801)	—
Inventory	(24,290)	—
Prepaid expenses and other assets	(9,142)	(11,567)
Collaboration (payable) receivable, net	(34,967)	(1,726)
Other receivable	(32)	(3,507)
Other assets	—	463
Accounts payable	2,200	(5,063)
Accrued expenses and other liabilities	16,472	7,484
Net cash used in operating activities	(253,492)	(217,515)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(131)	—
Purchases of short and long-term investments	(132,691)	(180,738)
Proceeds from sales and maturities of short-term investments	341,280	229,936
Net cash provided by investing activities	208,458	49,198
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from Employee Stock Purchase Plan	933	1,081
Proceeds from stock option exercises	6,826	4,861
Net cash provided by financing activities	7,759	5,942
NET DECREASE CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(37,275)	(162,375)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH—beginning of period	154,300	295,611
CASH, CASH EQUIVALENTS AND RESTRICTED CASH —end of period	$ 117,025	$ 133,236

The accompanying notes are an integral part of these unaudited consolidated financial statements.

SYNDAX PHARMACEUTICALS, INC.
(unaudited)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business

Syndax Pharmaceuticals, Inc. is a commercial-stage biopharmaceutical company advancing innovative cancer therapies. We currently have two commercially approved products and a robust slate of clinical development programs. We were incorporated in Delaware in 2005. We have operations in New York, NY, and we operate in one segment. References in these notes to unaudited consolidated financial statements to "Syndax," "the Company," "we," "us" or "our" refer to Syndax Pharmaceuticals, Inc. and its wholly owned subsidiaries.

We are subject to challenges and risks specific to our business and our ability to execute on our strategy, as well as risks and uncertainties common to companies in the pharmaceutical industry with development and commercial operations, including, without limitation, risks and uncertainties associated with: revenue generation from Revuforj and Niktimvo; obtaining regulatory approval of additional indications for our approved products; delays or problems in the supply of our products, loss of single source suppliers or failure to comply with manufacturing regulations; identifying, acquiring or in-licensing additional products or product candidates; pharmaceutical product development and the inherent uncertainty of clinical success; the challenges of protecting and enhancing our intellectual property rights; and complying with applicable regulatory requirements.

2. Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles, or U.S. GAAP. Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification, or ASC, and Accounting Standards Updates, or ASU, of the Financial Accounting Standards Board, or FASB.

Certain prior amounts reported in the accompanying consolidated financial statements and notes thereto have been reclassified to conform to the current year presentation. Specifically, the change in royalty payable presented within the consolidated balance sheet for the period ended December 31, 2024, of $0.3 million was originally reported within the caption royalty payable and has been separately presented in the comparative presentation. For the period ended September 30, 2025, the royalty payable to AbbVie and UCB, based on net sales of Revuforj and Niktimvo, is included in accrued expenses and other current liabilities. Such reclassification did not affect loss from operations, total assets, total liabilities, cash used in operations, or net loss.

In the opinion of management, the accompanying unaudited interim financial statements include all normal and recurring adjustments (which consist primarily of accruals and estimates that impact the financial statements) considered necessary to present fairly the Company's financial position as of September 30, 2025 and its results of operations for the three and nine months ended September 30, 2025 and 2024 and cash flows for the nine months ended September 30, 2025 and 2024. Operating results for the three and nine months ended September 30, 2025 are not necessarily indicative of the results that may be expected for the year ending December 31, 2025. The unaudited interim financial statements presented herein do not contain the required disclosures under U.S. GAAP for annual financial statements. The accompanying unaudited interim financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2024 contained in the Company's annual report on Form 10-K, filed with the Securities and Exchange Commission, or SEC, on March 3, 2025.

In 2011, the Company established a wholly owned subsidiary in the United Kingdom, which the Company dissolved in June 2024. In 2014, the Company established a wholly owned U.S. subsidiary, which the Company dissolved in July 2025. In 2021, the Company established a wholly owned subsidiary in the Netherlands. To date, there have been no material activities for these entities. All intercompany balances and transactions have been eliminated in consolidation.

3. Summary of Significant Accounting Policies

The Company's significant accounting policies, which are disclosed in the audited consolidated financial statements for the year ended December 31, 2024, and the notes thereto are included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 3, 2025. Since the date of filing, there have been no material changes to the Company's significant accounting policies, except as noted below.

Use of Estimates

The preparation of the unaudited consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the unaudited consolidated financial statements and the reported amounts of costs and expenses during the reporting period. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis.

Estimates and assumptions about future events and their effects cannot be determined with certainty and therefore require the exercise of judgment. As of the date of issuance of these unaudited consolidated financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update its estimates, assumptions and judgments or revise the carrying value of its assets or liabilities. These estimates may change as new events occur and additional information is obtained and are recognized in the unaudited consolidated financial statements as soon as they become known. Actual results could differ from those estimates and any such differences may be material to the Company's unaudited consolidated financial statements.

Income taxes

In accordance with Topic ASC 270, *Interim Reporting*, and Topic ASC 740, *Income Taxes*, the Company is required at the end of each interim period to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the nine months ended September 30, 2025 and 2024, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. As of September 30, 2025 and December 31, 2024, the Company concluded that a full valuation allowance would be necessary for all of its net deferred tax assets. The Company had no amounts recorded for uncertain tax positions, interest or penalties in the accompanying unaudited consolidated financial statements.

On July 4, 2025, the One Big Beautiful Bill Act, or OBBBA, was enacted in the United States. The OBBBA includes significant changes to the Internal Revenue Code of 1986, or the Tax Code, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act of 2017, or the TCJA, modifications to certain aspects of the international tax framework and the restoration of favorable tax treatment for certain business expense provisions. The OBBBA introduced several U.S. tax law changes, including the ability to immediately expense domestic research and experimental, or R&E, expenditures starting in 2025, and an election to accelerate any unamortized domestic R&E expenditures over a one or two year period beginning with the 2025 tax year. In accordance with ASC 740, *Accounting for Income Taxes*, the impacts of the OBBBA did not affect the Company's U.S. deferred tax assets or liabilities, as the Company continues to maintain a full valuation allowance against those balances.

Other comprehensive income

Comprehensive loss consists of two components, net loss and other comprehensive loss, net of tax. The Company's other comprehensive loss, net of tax, consists of unrealized gains (losses) on the Company's investments.

Collaboration revenue, net

In September 2021, the Company entered into the Incyte License and Collaboration Agreement, or the Incyte License, with Incyte Corporation, or Incyte, covering the worldwide development and commercialization of axatilimab. In August 2024, the U.S. Food and Drug Administration, or FDA, approved Niktimvo for the treatment of chronic graft-versus host disease, or cGVHD, after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg (88.2 lbs). See Note 4 — Significant Collaborative Research and License Agreements — Incyte Collaboration for further details on the Incyte License and Collaboration Agreement.

In accordance with Topic ASC 808, *Collaboration Arrangements,* Incyte has been identified as the principal in product sales, therefore, the Company will recognize its share of any profits or losses in the amount of net product sales less cost of goods sold and shared commercial costs, royalties and other expenses, in the period in which the underlying sales and costs are recognized. The Company's share of net profits in connection with commercialization of products will be presented as "Collaboration revenue, net" and its share of net losses will be presented as "Collaboration loss" within operating expenses. The year to date "Collaboration revenue, net" or "Collaboration loss" will be presented as the net cumulative amount for all periods reported on in the financial statements. The Company will continue to recognize the costs associated with ongoing development services in the R&D operating expense line, including any cost-sharing components with Incyte.

Recently Issued and Adopted Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other accounting standard setting bodies that we adopt as of the specified effective date. Unless otherwise discussed below, we do not believe that the adoption of recently issued standards have or may have a material impact on our unaudited consolidated financial statements or disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses (ASU "2024-03")*. Among other items, the requirements include expanded disclosures around employee compensation and selling expenses. ASU 2024-03 will be effective for the Company for the year ending December 31, 2027. The Company is still evaluating the impact of this new guidance on its unaudited consolidated financial statements but expects the adoption to result in disclosure changes only.

4. Significant Collaborative Research and License Agreements

Incyte Collaboration

In September 2021, the Company entered into the Incyte License with Incyte, covering the worldwide development and commercialization of axatilimab. Also in September 2021, the Company entered into a share purchase agreement with Incyte, or the Incyte Share Purchase Agreement. These agreements are collectively referred to as the Incyte Agreements. Under the terms of the Incyte Agreements, Incyte received exclusive commercialization rights outside of the United States, subject to certain royalty payment obligations set forth below. In the United States, Incyte and the Company are co-commercializing and co-promoting axatilimab as Niktimvo™ (axatilimab-csfr). The Company and Incyte share equally the profits and losses from co-commercialization efforts in the United States.

The Company and Incyte have agreed to continue to co-develop axatilimab and to share development costs associated with global and additional 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 of its own independent development activities. Incyte is responsible for 100% of future development costs for trials that are specific to ex-U.S. countries. All development costs related to the collaboration will be subject to a joint development plan.

Under the terms of the Incyte Agreements, in December 2021, Incyte paid the Company a non-refundable cash payment of $117.0 million and the Company issued 1,421,523 shares of common stock with an aggregate purchase price of $35.0 million, or $24.62 per share. Additionally, under the terms of the Incyte Agreements, the Company is eligible to receive up to $220.0 million in future contingent development and regulatory milestones and up to $230.0 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.

In August 2024, the FDA approved Niktimvo for the treatment of cGVHD after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg (88.2 lbs).

For the three and nine months ended September 30, 2025, the Company has recognized collaboration revenue of $13.9 million and $23.0 million, respectively. As of September 30, 2025, the Company has recorded approximately $20.9 million as a collaboration receivable due from Incyte related to the Collaboration revenue and the Company's development and pre-commercialization costs under the Incyte Agreements and has recorded approximately $5.2 million as a collaboration payable due to Incyte for development and pre-commercialization costs incurred by Incyte, research and development expense and cost offset are recorded as part of operating expenses. The Company's share of Collaboration profit or loss is based on net sales of Niktimvo and the collaborative commercialization expenses.

Vitae Pharmaceuticals, Inc.

In October 2017, the Company entered into a license agreement, or the Vitae License Agreement, with Vitae Pharmaceuticals, Inc., or Vitae, a subsidiary of AbbVie, Inc., or AbbVie, under which the Company was granted an exclusive, sublicensable, worldwide license to a portfolio of preclinical, orally available, small molecule inhibitors of the Menin–KMT2A binding interaction, or the Menin Assets. Upon execution of the Vitae License Agreement, the Company agreed to pay Allergan (the predecessor in interest to AbbVie) up to $99.0 million in one-time development and regulatory milestone payments over the term of the Vitae License Agreement, subject to the achievement of certain milestone events. In the event that the Company or any of its affiliates or sublicensees commercializes the Menin Assets, the Company will also be obligated to pay Vitae low single to low double-digit percentage royalties on sales, subject to reduction in certain circumstances, as well as up to an aggregate of $70.0 million in potential

one-time, sales-based milestone payments based on achievement of certain annual sales thresholds. The Company is solely responsible for the development and commercialization of the Menin Assets. Each party may terminate the Vitae License Agreement for the other party's uncured material breach or insolvency, and the Company may terminate the Vitae License Agreement at any time upon advance written notice to Vitae. Vitae may terminate the Vitae License Agreement if the Company or any of its affiliates or sublicensees institutes a legal challenge to the validity, enforceability, or patentability of the licensed patent rights. Unless terminated earlier in accordance with its terms, the Vitae License Agreement will continue on a country-by-country and product-by-product basis until the later of: (i) the expiration of all of the licensed patent rights in such country; (ii) the expiration of all regulatory exclusivity applicable to the product in such country; and (iii) 10 years from the date of the first commercial sale of the product in such country.

As of the date of the Vitae License Agreement, the asset acquired had no alternative future use nor had it reached a stage of technological feasibility. As the processes or activities that were acquired along with the license do not constitute a "business," the transaction has been accounted for as an asset acquisition. In the second quarter of 2025 the Company submitted a supplemental New Drug Application to the FDA for a second indication for Revuforj. As a result, an expense of $5.0 million was recognized under the Vitae License Agreement for the successful completion of the first pivotal trial of a second indication for Revuforj. Since the inception of the Vitae License Agreement, we have recognized, in the aggregate, $31.0 million of expense for the achievement of development and regulatory milestones. AbbVie is eligible to receive up to $68.0 million of additional future contingent development and regulatory milestones. The Company has not recognized any expense for the achievement of sales-based milestones since the inception of the Vitae License Agreement.

UCB Biopharma Sprl

In 2016, the Company entered into a license agreement, or the UCB License Agreement, as amended from time to time, with UCB Biopharma Sprl, or UCB, under which UCB granted to the Company a worldwide, sublicensable, exclusive license to UCB6352, which the Company refers to as axatilimab, an anti-CSF-1R monoclonal antibody. Upon execution of the agreement, the Company agreed to pay UCB up to $119.5 million in one-time development and regulatory milestone payments over the term of the UCB License Agreement, subject to the achievement of certain milestone events. In the event that the Company or any of its affiliates or sublicensees commercializes axatilimab, the Company will also be obligated to pay UCB low double-digit percentage royalties on sales, subject to reduction in certain circumstances, as well as up to an aggregate of $250.0 million in potential one-time, sales-based milestone payments based on achievement of certain annual sales thresholds. Under certain circumstances, the Company may be required to share a percentage of non-royalty income from sublicensees, subject to certain deductions, with UCB. The Company is solely responsible for the development and commercialization of axatilimab, except that UCB was responsible for performing a limited set of transitional chemistry, manufacturing and control tasks related to axatilimab. Each party may terminate the UCB License Agreement for the other party's uncured material breach or insolvency, and the Company may terminate the UCB License Agreement at any time upon advance written notice to UCB. UCB may terminate the UCB License Agreement if the Company or any of its affiliates or sublicensees institutes a legal challenge to the validity, enforceability, or patentability of the licensed patent rights. Unless terminated earlier in accordance with its terms, the UCB License Agreement will continue on a country-by-country and product-by-product basis until the later of: (i) the expiration of all of the licensed patent rights in such country; (ii) the expiration of all regulatory exclusivity applicable to the product in such country; and (iii) 10 years from the date of the first commercial sale of the product in such country.

As of the date of the UCB License Agreement, the asset acquired had no alternative future use nor had it reached a stage of technological feasibility. As the processes or activities that were acquired along with the license do not constitute a "business," the transaction has been accounted for as an asset acquisition. As a result, in 2016, the upfront payment of $5.0 million was recorded as research and development expense in the consolidated statements of operations. In connection with its most recent amendment of the UCB License Agreement, in the second quarter of 2022 the Company paid UCB $5.8 million, which was recognized as a milestone expense. In the first quarter of 2025, the Company paid a $10.0 million milestone as a result of the first patient dosed in a Phase III Study with the licensed compound in a combination with another agent for any indication. Since the inception of the agreement, we have recognized in the aggregate, $41.0 million of expense for the achievement of development and regulatory milestones. UCB is eligible to receive up to $78.5 million of additional future contingent development and regulatory milestones. The Company has not recognized any expense for the achievement of sales-based milestones since the inception of the agreement.

5. Net Loss per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Because the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods. The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
	(In thousands, except share and per share data)		(In thousands, except share and per share data)	
Numerator—basic and diluted:				
Net loss	$ (60,715)	$ (84,126)	$ (217,408)	$ (224,589)
Net loss attributable to common stockholders—basic and diluted	$ (60,715)	$ (84,126)	$ (217,408)	$ (224,589)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.70)	$ (0.98)	$ (2.51)	$ (2.63)
Denominator—basic and diluted:				
Weighted-average number of common shares used to compute net loss per share attributable to common stockholders—basic and diluted	86,620,992	85,433,569	86,531,218	85,307,660

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding because such securities have an antidilutive impact due to losses reported (in common stock equivalent shares):

	September 30,	
	2025	2024
Options to purchase common stock	13,506,676	12,205,960
Employee Stock Purchase Plan	141,069	73,200
Non-vested restricted stock units (RSUs)	2,805,159	1,461,005

For additional information related to the Company's common stock see Note 12 — Stock Based Compensation.

6. Other Receivables, net

In April 2024, entinostat received marketing approval in China, and as a result, the Company recorded $3.5 million of milestone revenue in 2024. As of September 30, 2025, the Company had recorded a $3.7 million receivable related to milestones (plus accrued interest) under the license agreement with Eddingpharm. As the receivable remains outstanding, the Company has recorded a full reserve against the asset as a selling, general and administrative expense as of September, 30, 2025.

7. Fair Value Measurements

The carrying amounts of cash and cash equivalents, restricted cash, accounts payable, and accrued expenses approximated their estimated fair values due to the short-term nature of these financial instruments. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value are performed in a manner to maximize the use of observable inputs and minimize the use of unobservable inputs. The accounting standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, which are the following:

Level 1— Quoted prices (unadjusted) in active markets that are accessible at the market date for identical unrestricted assets or liabilities.

Level 2— Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs for which all significant inputs are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3— Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The table below presents information about the Company's assets and liabilities that are regularly measured and carried at fair value and indicate the level within the fair value hierarchy of valuation techniques the Company utilized to determine such fair values (in thousands):

	Fair Value Measurements Using			
	Total Carrying Value	Quoted Prices (unadjusted) in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	(In thousands)			
September 30, 2025				
Assets:				
Cash and cash equivalents	$ 116,808	$ 116,808	$ —	$ —
Short-term investments	319,171	—	319,171	—
Long-term investments	20,146	—	20,146	—
Total assets	$ 456,125	$ 116,808	$ 339,317	$ —
December 31, 2024				
Assets:				
Cash and cash equivalents	$ 154,083	$ 129,187	$ 24,896	$ —
Short-term investments	418,801	—	418,801	—
Long-term investments	119,520	—	119,520	—
Total assets	$ 692,404	$ 129,187	$ 563,217	$ —

There have been no material impairments of our assets measured and carried at fair value during the periods ended September 30, 2025 and 2024. In addition, there have been no changes in valuation techniques during the periods ended September 30, 2025 and 2024. The fair value of Level 1 instruments classified as cash equivalents are valued using quoted market prices in active markets. The fair value of Level 2 instruments classified as short and long-term investments are determined based on quoted prices in active markets, which are either directly or indirectly observable as of the reporting date with fair value being determined using models or other valuation methodologies.

The Company's short and long-term investments are classified as available-for-sale securities. As of September 30, 2025, the remaining contractual maturities of the available-for-sale securities were 1 to 14 months, and the balance in the Company's accumulated other comprehensive gain was comprised solely of activity related to the Company's available-for-sale securities. There were no realized gains or losses recognized on the sale or maturity of available-for-sale securities, during the three and nine months ended September 30, 2025 and 2024. As a result, the Company did not reclassify any amounts out of accumulated other comprehensive gain for the same periods.

The following table summarizes the available-for-sale securities:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(In thousands)			
September 30, 2025				
Commercial paper	$ 154,914	$ 50	$ —	$ 154,964
Corporate bonds	24,675	47	—	24,722
US Treasury	159,203	428	—	159,631
	$ 338,792	$ 525	$ —	$ 339,317
December 31, 2024				
Commercial paper	$ 263,952	$ —	$ (56)	$ 263,896
Corporate bonds	40,261	—	—	40,261
US Treasury	233,945	219	—	234,164
	$ 538,158	$ 219	$ (56)	$ 538,321

8. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	September 30, 2025	December 31, 2024
Prepaid insurance	$ 1,967	$ 1,276
Interest receivable on investments	1,926	2,634
Prepaid subscription	1,778	1,605
Prepaid state and local taxes	349	298
Prepaid rent	19	107
Prepaid inventory	2,505	2,009
Other	973	612
Total prepaid expenses and other current assets	$ 9,517	$ 8,541

9. Inventory

Inventory consisted of the following (in thousands):

	September 30, 2025	December 31, 2024
Raw materials	$ 21,404	$ —
Work-in-process	1,380	330
Finished goods	2,216	36
Total Inventory	$ 25,000	$ 366

Inventories are stated at the lower of cost or net realizable value, as determined on a first-in, first-out basis.

10. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2025	December 31, 2024
Product revenue allowances	$ 6,743	$ 849
Accrued clinical study and trial costs	18,398	23,869
Accrued selling, general, and administrative costs	7,616	4,258
Accrued compensation and related costs	15,643	14,477
Accrued professional fees	—	385
Accrued milestone costs	—	10,600
Accrued royalty payable	5,862	307
Accrued royalty interest financing expense	22,248	4,930
Other	595	421
Total accrued expenses and other current liabilities	$ 77,105	$ 60,096

11. Royalty Interest Financing Liability

On November 4, 2024, the Company entered into a Purchase and Sale Agreement, or the Purchase and Sale Agreement, with Royalty Pharma Development Funding, LLC, or Royalty Pharma, pursuant to which Royalty Pharma purchased rights to certain revenue streams from net sales of products comprising or containing axatilimab (including Niktimvo™) by the Company, its affiliates and its licensees in the United States and its respective territories, districts, commonwealths and possessions (including Guam and Puerto Rico) in exchange for an upfront fee of $350 million.

Pursuant to the Purchase and Sale Agreement, Royalty Pharma purchased the right to receive a percentage of net sales equal to a royalty rate of 13.8% on quarterly net sales of Niktimvo in the United States and its respective territories; provided that the royalty rate is subject to certain adjustments based on future aggregate net sales of the product in the United States and its respective territories, or the Revenue Participation Right. Aggregate payments made to Royalty Pharma in respect of the Revenue Participation Right will be capped at $822.5 million, or the Royalty Cap.

The Purchase and Sale Agreement contains customary representations, warranties and indemnities of the Company and Royalty Pharma and customary covenants relating to the royalty payments, including the grant of a back-up security interest in the purchased royalties and certain assets related to the product and restrictions on the incurrence of additional indebtedness and on the existence of liens on the Company's assets related to the product.

Upon a change of control, the Company will have the right, but not the obligation, to repurchase the Revenue Participation Right at a repurchase price set forth in the Purchase and Sale Agreement. In addition, the Purchase and Sale Agreement provides that if certain events of default occur, including certain bankruptcy events or certain termination events with respect to the Company's license agreement with UCB Biopharma Srl, Royalty Pharma may require the Company to repurchase Royalty Pharma's interests in the Revenue Participation Right at a repurchase price equal to the Royalty Cap.

The Company assessed the Purchase and Sale Agreement and identified it as a sale of future revenue in the form of a debt instrument to be accounted for as a liability under Topic ASC 470, *Borrower's Accounting for Debt Modifications*. The Company has elected to use the prospective method in its calculation of its effective interest rate and will update this calculation quarterly when there are changes in the projected sales. The debt is allocated on the balance sheet as short term and long term. The short term portion represents the royalty payments owed over the next 12 months. The long term portion is recorded on the balance sheet as net of issuance costs. Issuance costs pursuant to the Purchase and Sale Agreement consisted primarily of bank and legal fees and totaled $6.3 million. These issuance costs were recorded as a direct deduction to the carrying amount of the liability and will be amortized under the effective interest method over the estimated period the liability will be repaid. For the period ended September 30, 2025, the Company estimated an effective annual interest rate of approximately 9.14%. Over the course of the Purchase and Sale Agreement, the annual interest rate will be affected by the amount and timing of net Niktimvo revenue recognized and change in timing of forecasted net Niktimvo revenue. On a quarterly basis, the Company reassesses the expected timing of the net Niktimvo revenue, recalculates the amortization and effective interest rate, and adjusts the accounting prospectively, as needed. For the three and nine months ended September 30, 2025, the Company recognized royalty interest expense of $8.3 million and $24.2 million, respectively, related to the Purchase and Sale Agreement.

	September 30, 2025	December 31, 2024
Current portion of royalty interest financing liability	$ 22,925	$ 12,116
Royalty interest financing liability, less current portion	327,075	337,884
Debt issuance costs	(6,090)	(6,319)
Total royalty interest financing liability, net	$ 343,910	$ 343,681

12. Stock-Based Compensation

In January 2025, the number of shares of common stock available for issuance under the Company's 2015 Omnibus Incentive Plan, or the 2015 Plan, was increased by 3,427,778 shares of common stock due to the automatic annual provision to increase shares of common stock available under the 2015 Plan. Additionally in July 2024 and in December 2024, the Company's board of directors approved increases of 500,000 shares and 1,200,000 shares, respectively, of common stock available for issuance under the Company's 2023 Inducement Plan, or the Inducement Plan.

As of September 30, 2025, there were 4,238,174 shares of common stock available for issuance under the 2015 Plan and 717,779 shares of common stock available for issuance under the Inducement Plan.

The Company recognized stock-based compensation expense related to the issuance of stock option awards and restricted stock units to employees and non-employees and related to the Company's 2015 Employee Stock Purchase Plan, or ESPP, in the consolidated statements of comprehensive loss as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development	$ 4,278	$ 5,886	$ 12,142	$ 14,347
Selling, general and administrative	7,804	6,048	24,107	16,382
Total	$ 12,082	$ 11,934	$ 36,249	$ 30,729

Compensation expense by type of award in the three and nine months ended September 30, 2025 and 2024 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Stock options	$ 8,080	$ 9,300	$ 24,472	$ 24,285
RSUs	3,856	2,455	11,188	6,071
ESPP	146	179	589	373
Total	$ 12,082	$ 11,934	$ 36,249	$ 30,729

In addition, stock-based compensation expense of $0.3 million was capitalized to inventory as of September 30, 2025, which represents the stock-based compensation expense incurred related to employees involved in the manufacturing process of finished goods and samples. No stock-based compensation expense was capitalized to inventory in 2024.

As of September 30, 2025, there were $86.1 million of unrecognized compensation costs related to employee and non-employee unvested stock options and RSUs granted under the Inducement Plan, 2015 Plan and the Company's 2007 Stock Plan, which are expected to be recognized over a weighted-average remaining service period of 2.50 years.

Employee Benefit Plan

The Company maintains a defined contribution 401(k) retirement plan. For the three and nine months ended September 30, 2025, the Company made $0.3 million and $3.0 million of contributions to the plan, respectively. For the three and nine months ended September 30, 2024, the Company made $0.4 million and $2.5 million of contributions to the plan, respectively. The Company's contributions are made in cash.

13. Stockholders' Equity

Pre-Funded Warrants

In December 2021, the Company sold pre-funded warrants to purchase 1,142,856 shares of common stock. As of September 30, 2025, 285,714 pre-funded warrants were issued and outstanding.

14. Commitments and Contingencies

License Agreements

The Company is obligated to pay royalties pursuant to the Vitae License Agreement and the UCB License Agreement as a percentage of net product sales for direct licensed products, such as Revuforj and Niktimvo. The obligation to pay royalties expires, on a country-by-country basis and licensed product-by-licensed product basis at the later of (i) the expiration of all of the licensed patent rights in such country; (ii) the expiration of all regulatory exclusivity applicable to the product in such country; and (iii) 10 years from the date of the first commercial sale of the product in such country. These fees were recorded as cost of product sales.

From time to time, the Company may be subject to various claims and proceedings in the ordinary course of business. If the potential loss from any claim, asserted or unasserted, or proceeding is considered probable and the amount is reasonably estimable, the Company will accrue a liability for the estimated loss. There were no contingent liabilities recorded as of September 30, 2025.

15. Segment Reporting

The Company manages its business activities on a consolidated basis and operate as a single operating and reportable segment: Syndax Pharmaceuticals. The Company primarily derives revenue in the United States through milestone revenue and product sales on the approved products, Revuforj® (revumenib) and Niktimvo™ (axatilimab-csfr). The accounting policies of the segment are the same as those described in Note 3 – Summary of Significant Accounting Policies.

To assess performance, the Company's Chief Operating Decision Maker, or CODM, Michael Metzger, uses consolidated net loss as the segment's measure of segment profit or loss. The CODM uses net loss in the budget and forecasting process and considers budget-to actual variances on a quarterly basis when making decisions about the allocation of operating and capital resources.

The following table provides the operating financial results of our biopharmaceutical cancer therapeutics segment:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
September 30, 2025				
Total Revenue	$ 45,871	$ 12,500	$ 103,624	$ 16,000
Less: Significant and other segment expenses				
Cost of product sales	2,100	—	4,264	—
Research and development expenses				
Revumenib-related costs	21,747	24,454	70,707	76,421
Axatilimab-related costs	9,447	24,204	38,211	38,309
Other R&D programs	694	669	3,441	2,169
Personnel cost and other expenses	20,114	15,807	55,642	44,922
General and administrative expenses				
Commercial-related expenses	12,210	7,620	32,949	21,012
Personnel cost and other expenses	15,797	13,535	54,186	33,635
Other SG&A expenses	9,106	3,854	18,511	12,111
Stock-based compensation	12,082	11,934	36,249	30,729
Royalty interest expense	8,283	—	24,186	—
Interest (income) expense, net	(5,269)	(5,419)	(18,396)	(18,860)
Other expense (income), net	275	(32)	1,082	141
Segment net loss	$ (60,715)	$ (84,126)	$ (217,408)	$ (224,589)

16. Subsequent Events

On October 24, 2025, the Company announced FDA approval of Revuforj® (revumenib) for the treatment of relapsed or refractory (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. As a result of the approval, a development and regulatory milestone of $7 million was triggered under the Vitae License Agreement for the first commercial sale in the second indication in the United States. The milestone expense was recognized in October 2025.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K that was filed with the Securities and Exchange Commission, or SEC, on March 3, 2025.

Company Overview

We are a commercial-stage biopharmaceutical company advancing innovative cancer therapies. We currently have two commercially approved products, Revuforj® (revumenib) and Niktimvo™ (axatilimab-csfr), and a robust slate of clinical development programs. Revuforj is our first-in-class menin inhibitor that was approved by the U.S. Food and Drug Administration, or FDA, in November 2024 for the treatment of relapsed or refractory, or R/R, acute leukemia with a lysine methyltransferase 2A gene, or KMT2A, translocation in adult and pediatric patients one year and older. In October 2025, Revuforj received a second approval from the FDA for the treatment of R/R acute myeloid leukemia, or AML, with a susceptible nucleophosmin 1 mutation, or NPM1m, in adult and pediatric patients one year and older who have no satisfactory alternative treatment option. We are also studying revumenib in combination with standard-of-care agents in NPM1m AML or KMT2A-rearranged acute leukemia across the treatment landscape, including in newly diagnosed patients. Additionally, we are exploring the use of revumenib as a treatment in solid tumors, specifically its activity in metastatic colorectal cancer. Niktimvo is our first-in-class colony stimulating factor-1 receptor, or CSF-1R, blocking antibody that was approved by the FDA in August 2024 for the treatment of chronic graft-versus-host disease, or cGVHD, after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg. Axatilimab is in development for the treatment of newly diagnosed cGVHD patients in combination with standard-of-care therapies, as well for the treatment of idiopathic pulmonary fibrosis, or IPF. We plan to continue to leverage the technical and business expertise of our management team and scientific collaborators to license, acquire and develop additional therapeutics to expand our pipeline.

We have begun generating product revenue from sales of Revuforj and collaboration revenue from sales of Niktimvo. We continue to incur significant research and development and other expenses related to our ongoing operations. Except for 2021, we have not been profitable and have incurred losses in each period since our inception in 2005. For the nine months ended September 30, 2025 and 2024, we reported a net loss of $217.4 million and $224.6 million, respectively. As of September 30, 2025, we had an accumulated deficit of $1.4 billion. As of September 30, 2025, we had cash, cash equivalents and short- and long-term investments of $456.1 million.

Business Update

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 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, or ASH, Annual Meeting. We believe 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 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 colorectal cancer. 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. We are co-commercializing Niktimvo with Incyte. We record 50% of the Niktimvo net commercial profit/loss, defined as net product revenue minus the cost of sales and commercial expenses. For the third quarter of 2025, our 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 cGVHD and the tolerability of axatilimab with ruxolitinib in newly diagnosed cGVHD.
- 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 cGVHD.
  - 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 cGVHD.
- 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 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.

Financial Operations Overview

Product Revenue, net

Our second FDA-approved product, Revuforj, was approved by the FDA for commercial sale in the U.S. on November 15, 2024. In accordance with GAAP, we determine net product revenue for Revuforj, with specific assumptions for variable consideration components including, but not limited to, trade discounts and allowances, co-pay assistance programs and payor rebates.

We generated no product revenue during the three and nine months ended September 30, 2024.

Collaboration revenue, net

In September 2021, we entered into the Incyte License and Collaboration Agreement, or the Incyte License, with Incyte covering the worldwide development and commercialization of axatilimab. In August 2024, the FDA approved Niktimvo for the

treatment of cGVHD 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 accordance with Topic ASC 808, *Collaboration Arrangements,* Incyte has been identified as the principal in product sales, therefore, we will recognize its 50% share of any profits or losses in the amount of net product sales less cost of goods sold and shared commercial and other expenses, in the period in which the underlying sales and costs are recognized. Our share of net profits in connection with commercialization of Niktimvo will be presented as "Collaboration revenue, net" and our share of net losses will be presented as "Collaboration loss" within operating expenses. Collaboration revenue or expense is made up of our share of the 50% profit with Incyte. We record collaboration revenue net of commercial expenses, including any royalties owed on license agreements. We will continue to recognize the costs associated with ongoing development services in the R&D operating expense line, including any cost-sharing components with Incyte.

Cost of Product Sales

Our cost of product sales includes the cost of goods sold and royalties associated with Revuforj sales in the United States.

Research and Development

Since our inception, we have primarily focused on our clinical development programs. Research and development expenses consist primarily of costs incurred for the development of our product candidates and include:

- expenses incurred under agreements related to our clinical trials, including the costs for investigative sites and contract research organizations that conduct our clinical trials;
- employee-related expenses associated with our research and development activities, including salaries, benefits, travel and non-cash stock-based compensation expenses;
- manufacturing process-development, clinical supplies and technology-transfer expenses;
- license fees and milestone payments under our license agreements;
- consulting fees paid to third parties;
- allocated facilities and overhead expenses; and
- costs associated with regulatory operations and regulatory compliance requirements.

Internal and external research and development costs are expensed as they are incurred. Cost-sharing amounts received by us are recorded as reductions to research and development expense. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations or other information provided to us by our vendors.

Research and development activities are central to our business model. Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of late-stage clinical trials. We plan to continue to spend a significant amount of our resources on research and development activities for the foreseeable future as we continue to advance the development of our product candidates. The amount of research and development expenses allocated to external spending will continue to grow, while we expect our internal spending to grow at a slower and more controlled pace.

It is difficult to determine, with certainty, the duration and completion costs of our current or future preclinical programs, research studies and clinical trials of our product candidates. The duration, costs and timing of research studies and clinical trials of our product candidates will depend on a variety of factors that include, but are not limited to, the following:

- per patient costs;
- the number of patients that participate;
- the number of clinical trial sites;
- the countries in which the clinical trials are conducted;
- the length of time required to enroll eligible patients;
- the potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient monitoring;
- the efficacy and safety profile of the product candidates; and

- timing and receipt of any regulatory approvals.

In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of our product candidates for the period, if any, in which material net cash inflows from these potential drug candidates may commence. Clinical development timelines, the probability of success and development costs can differ materially from expectations.

Selling, General and Administrative

Selling, general and administrative expenses consist primarily of commercialization costs as well as employee-related expenses, including salaries, benefits, non-cash stock-based compensation and travel expenses, for our employees in executive, finance, human resources, information technology, business development and support functions, as well as sales and marketing expenses to support the launch and commercialization of Revuforj and Niktimvo. Other selling, general and administrative expenses include facility-related costs not otherwise allocated to research and development expenses and accounting, tax, legal, information technology and consulting services. We anticipate that our selling, general and administrative expenses will remain stable in the next few years.

Royalty Interest Expense

Royalty interest expense consists of interest expense related to the Purchase and Sale Agreement with Royalty Pharma.

Other Interest Expense

Other interest expense consists of interest expense related to our operational and capital leases.

Interest Income

Interest income consists of income earned on our cash, cash equivalents and short- and long-term investment balances.

Other Expense

Other expense includes expense consisting of revaluation of foreign currency related to trade payables and amortization of debt issuance costs.

Recent Accounting Pronouncements

For a discussion of new accounting pronouncements please read Note 3 - Summary of Significant Accounting Policies to our unaudited consolidated financial statements included in this Quarterly Report.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, revenue and expenses and related disclosures of contingent assets and liabilities. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. In making estimates and judgments, management employs critical accounting policies.

There have been no material changes to our critical accounting estimates described in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

Results of Operations

Comparison of the three and nine months ended September 30, 2025 and 2024:

	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2025	2024	$	2025	2024	$
		(In thousands)			(In thousands)	
Revenue:						
Product revenue, net	$ 32,007	$ —	$ 32,007	$ 80,649	$ —	80,649
Collaboration revenue, net	13,864	—	13,864	22,975	—	22,975
Milestone and license revenue	—	12,500	(12,500)	—	16,000	(16,000)
Total revenues	45,871	12,500	33,371	103,624	16,000	87,624
Operating expenses:						
Cost of goods sold	$ 2,100	$ —	$ 2,100	$ 4,264	$ —	4,264
Research and development	56,280	70,971	(14,691)	180,143	176,118	4,025
Selling, general and administrative	44,917	31,106	13,811	129,753	83,189	46,564
Total operating expenses	103,297	102,077	1,220	314,160	259,307	54,853
Loss from operations	(57,426)	(89,577)	(32,151)	(210,536)	(243,307)	(32,771)
Other (expense) income, net:						
Royalty interest expense	(8,283)	—	(8,283)	(24,186)	—	(24,186)
Other interest expense	—	(23)	23	(6)	(123)	117
Interest income	5,269	5,442	(173)	18,402	18,982	(580)
Other (expense) income	(275)	32	(307)	(1,082)	(141)	(941)
Total other (expense) income, net	(3,289)	5,451	(8,740)	(6,872)	18,718	(25,590)
Net loss	$ (60,715)	$ (84,126)	$ (23,411)	$ (217,408)	$ (224,589)	$ (7,181)

Product Revenue, net

In November 2024, we began to generate product revenue from sales of Revuforj in the United States. We record product revenue net of estimated discounts, chargebacks, rebates, product returns, and other gross-to-net revenue deductions. Product revenue, net from sales of Revuforj was $32.0 million and $80.6 million for the three and nine months ended September 30, 2025, respectively.

Collaboration Revenue, net

In February 2025, we began to generate sales of Niktimvo in the United States in collaboration with our partner, Incyte. Our Collaboration revenue, net was $13.9 million for the three months ended September 30, 2025. Our Collaboration revenue, net was $23.0 million for the nine months ended September 30, 2025, and includes the $0.2 million of Collaboration loss recognized in the first quarter.

Cost of Product Sales

Our cost of product sales were $2.1 million and $4.3 million for the three and nine months ended September 30, 2025, respectively, resulting from increased sales of Revuforj. Included in cost of product sales are royalties owed to AbbVie on Revuforj sales as part of the Vitae License Agreement.

Research and Development

The following table summarizes the research and development expenses for the three and nine months ended September 30, 2025 and 2024:

	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2025	2024	$	2025	2024	$
		(In thousands)			(In thousands)	
Revumenib-related costs	$ 21,747	$ 24,454	$ (2,707)	$ 70,707	$ 76,421	$ (5,714)
Axatilimab-related costs	9,447	24,204	(14,757)	38,211	38,309	(98)
Other research and development programs	694	669	25	3,441	2,169	1,272
Personnel cost and other expenses	20,114	15,807	4,307	55,642	44,922	10,720
Stock-based compensation	4,278	5,837	(1,559)	12,142	14,297	(2,155)
Total research and development expenses	$ 56,280	$ 70,971	$ (14,691)	$ 180,143	$ 176,118	$ 4,025

For the three months ended September 30, 2025, our total research and development expenses decreased by $14.7 million from the comparable prior year period. The decrease was primarily due to:

- A decrease in revumenib-related costs due to completion of a relapse or refractory NPM1m AML registrational trial that was ongoing in 2024 and a reduction in CMC expenses due to capitalization of inventory for commercial use, offset by 2025 period expenses in planning for and initiation of frontline trials evaluating revumenib in NPM1m and KM2Ar acute leukemias.
- The majority of the period-over-period decrease in expense was driven by an axatilimab-related $15.0 million milestone payment for Niktimvo's approval, incurred in the third quarter of 2024 and not incurred in the 2025 period. This decrease was partially offset by costs incurred in the 2025 period for the ongoing Phase 2 IPF trial as well as the frontline cGVHD combination trial with ruxolitinib.

For the nine months ended September 30, 2025, total research and development expenses increased $4.0 million from the comparable prior year period. The increase was primarily due to:

- 2025 period expenses in planning for and initiation of frontline trials evaluating revumenib in NPM1m and KM2Ar acute leukemias, offset by a decrease in revumenib-related costs due to completion of a relapse or refractory NPM1m AMLregistrational trial that was ongoing in 2024 and a reduction in CMC expenses due to capitalization of inventory for commercial use.
- Higher costs incurred in the 2025 period for the ongoing Phase 2 IPF trial as well as the frontline cGVHD combination trial with ruxolitinib, offset by an axatilimab-related $15.0 million milestone payment for Niktimvo's approval incurred in the 2024 period and not incurred in the 2025 period.
- An increase in personnel costs to support on-going clinical trials, preparation of a supplemental New Drug Application, and medical affairs activities in support of commercialization of Revuforj and Niktimvo.

Selling, General and Administrative

The following tables summarizes the selling, general and administrative expenses for the three and nine months ended September 30, 2025 and 2024:

	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2025	2024	$	2025	2024	$
		(In thousands)			(In thousands)	
Commercial related expenses	$ 12,210	$ 7,620	$ 4,590	$ 32,949	$ 21,012	$ 11,937
Other selling, general and administrative expenses	9,106	3,854	5,252	18,511	12,111	6,400
Personnel cost and other expenses	15,797	13,535	2,262	54,186	33,635	20,551
Stock-based compensation	7,804	6,097	1,707	24,107	16,431	7,676
Total selling, general and administrative expenses	$ 44,917	$ 31,106	$ 13,811	$ 129,753	$ 83,189	$ 46,564

For the three and nine months ended September 30, 2025, our total selling, general and administrative expenses increased $13.8 million and $46.6 million, respectively, from the comparable prior year period. The increases were primarily due to commercial-related costs, driven by ongoing activities in 2025 associated with the commercial launches for Revuforj and Niktimvo. The increases in personnel and stock-based compensation costs were primarily related to higher costs in headcount in 2025 to support the commercialization of Revuforj and Niktimvo.

Royalty Interest Expense

For the three and nine months ended September 30, 2025, royalty interest expense increased due to the interest expense recognized related to the Royalty Pharma Purchase and Sale Agreement signed in November 2024.

Other Interest Expense

For the three and nine months ended September 30, 2025, other interest expense decreased from the comparable period due to less interest expense recognized related to capital leases.

Interest Income

For the three and nine months ended September 30, 2025, interest income decreased from the comparable period. The decrease of interest income was primarily due to the fluctuation of interest rates and the average balance of cash equivalents and short and long-term investments.

Other Expense

For the three and nine months ended September 30, 2025, other expense increased from the comparable period primarily related to the current period amortization of debt issuance costs related to the Royalty Pharma Purchase and Sale Agreement.

Liquidity and Capital Resources

Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each period set forth below:

	Nine Months Ended September 30,	
	2025	2024
	(In thousands)	
Net cash used in operating activities	$ (253,492)	$ (217,515)
Net cash provided by investing activities	208,458	49,198
Net cash provided by financing activities	7,759	5,942
Net decrease cash, cash equivalents and restricted cash	$ (37,275)	$ (162,375)

Net Cash Used in Operating Activities

Net cash used in operating activities increased from $217.5 million for the nine months ended September 30, 2024 to $253.5 million for the nine months ended September 30, 2025, primarily due to an increase in accounts receivable, inventory, collaboration receivable, and short term deposits, and a decrease in collaboration payable.

Net Cash Provided by Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2025, was $208.5 million and was related to $341.3 million from the maturities of available-for-sale securities, offset by the purchase of $132.7 million of available-for-sale securities.

Net cash provided by investing activities for the nine months ended September 30, 2024, was $49.2 million and was related to $229.9 million from the maturities of available-for-sale securities, offset by the purchase of $180.7 million of available-for-sale securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2025, increased by $1.8 million from the comparable prior year period primarily due to an increase in proceeds from the exercise of stock options in the current period.

Purchase and Sale Agreement

In October 2024, we entered into a purchase and sale agreement with Royalty Pharma, pursuant to which Royalty Pharma purchased the right to receive 13.8% on quarterly net sales of Niktimvo in the United States and its respective territories, districts, commonwealths and possessions (including Guam and Puerto Rico) in exchange for an upfront payment of $350.0 million (gross) at closing, received in November 2024. Aggregate payments to Royalty Pharma pursuant to the Royalty Agreement will be capped at $822.5 million or 2.35 times the funded amount.

For additional details on our purchase and sale agreement with Royalty Pharma, see Note 11 - “Royalty Interest Financing Liability” to our consolidated financial statements in this Quarterly Report.

Future Funding Requirements

We believe that the combination of our available cash, cash equivalents, short-term and long-term investments, as well as our expected Revuforj gross contribution and Niktimvo collaboration revenue, is sufficient to fund existing and planned cash requirements. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, clinical costs, commercialization costs, legal and other regulatory expenses and general overhead costs. We have based our estimates on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we currently expect.

Additionally, the process of testing product candidates in clinical trials is costly, and the timing, progress and outcomes in these trials is uncertain. We cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability.

Our future capital requirements will depend on many factors, including:

- our growth rate;
- the initiation, progress, timing, costs and results of clinical trials of our product candidates;
- the outcome, timing and cost of seeking and obtaining additional regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more trials than we currently expect;
- the cost to establish, maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- market acceptance of our product candidates;
- the cost and timing of selecting, auditing and developing manufacturing capabilities, and potentially validating manufacturing sites for commercial-scale manufacturing;
- the cost and timing for obtaining pricing and reimbursement, which may require additional trials to address pharmacoeconomic benefit;
- the cost of maintaining sales, marketing and distribution capabilities for our products;
- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the interruption of key clinical trial activities, such as clinical trial site monitoring;
- the cost of disruption to our supply chain and operations, and associated delays in the manufacturing and supply of our products, which would adversely impact our ability to continue our clinical trial operations;
- the effect of competing technological and market developments; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems, as we grow our company.

We expect to continue to support our future cash needs through a combination of equity offerings, debt financings and additional funding from license and collaboration arrangements. Except for any obligations of our collaborators to reimburse us for research and development expenses or to make milestone or royalty payments under our agreements with them, we will not have any committed external source of liquidity.

Our material contractual obligations and commitments as of September 30, 2025, primarily relate to our maturities of operating leases for office space and equipment and capital leases for office equipment. As of September 30, 2025, we have $0.3 million payable within 12 months.

Except as disclosed above, we have no material non-cancelable purchase commitments with service providers, as we have generally contracted on a cancelable, purchase-order basis. We enter into contracts in the normal course of business with equipment and reagent vendors, CROs, contract manufacturing organizations, and other third parties for clinical trials, preclinical research studies and testing and manufacturing services. These contracts are cancelable by us upon prior notice. Payments due upon cancellation

consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. These payments are not determinable.

We have incurred losses and cumulative negative cash flows from operations since our inception, excluding the year ended December 31, 2021. As of September 30, 2025, we had an accumulated deficit of $1.4 billion. We anticipate that we will likely continue to incur significant losses for at least the next couple years. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

At-the-Market Offering Program

In May 2023, we entered into a sales agreement with Cowen and Company, LLC, or TD Cowen, under which we could, from time to time, issue and sell shares of our common stock having aggregate sales proceeds of up to $200.0 million, in a series of one or more at-the-market equity offerings, or the 2023 ATM Program. TD Cowen is not required to sell any specific share amounts but acts as the Company's sales agent, using commercially reasonable efforts consistent with its normal trading and sales practices. Pursuant to the sales agreement, shares will be sold under the shelf registration statement on Form S-3ASR (Registration No. 333-277424), which became automatically effective upon filing on February 27, 2024. Our common stock will be sold at prevailing market prices at the time of the sale, and as a result, prices may vary. For the three and nine months ended September 30, 2025, we did not sell any shares of common stock under the 2023 ATM Program. As of September 30, 2025, we had $157.9 million available under the 2023 ATM Program.

Significant Risks and Uncertainties

Unfavorable interest rates and geo-political unrest could result in further economic uncertainty and volatility in the capital markets in the near term and, as a result, could negatively affect our operations and could make it difficult for us to obtain traditional financing on acceptable terms, if at all. Furthermore, such economic conditions have produced downward pressure on share prices. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, the return of a high inflationary environment could increase our operating costs, including our labor costs and research and development costs. These costs may also be negatively impacted due to supply chain constraints, geopolitical tensions, including tariffs, the ongoing wars between Russia and Ukraine and Israel and Hamas as well as other conflicts in the Middle East, including between Israel and Hezbollah, worsening macroeconomic conditions and employee availability and wage increases, which may result in additional stress on our working capital.

Additionally, we are subject to other challenges and risks specific to our business and our ability to execute on our strategy, as well as risks and uncertainties common to companies in the pharmaceutical industry with development and commercial operations, including, without limitation, risks and uncertainties associated with: obtaining regulatory approval of additional indications for our approved products; identifying, acquiring or in-licensing additional products or product candidates; pharmaceutical product development and the inherent uncertainty of clinical success; the challenges of protecting and enhancing our intellectual property rights; and complying with applicable regulatory requirements. See the section titled "Risk Factors" located elsewhere in this report for additional information.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2025, we had cash and cash equivalents of $116.8 million, consisting of overnight investments, interest-bearing money market funds and commercial paper, and short and long-term investments of $339.3 million, consisting of commercial paper, highly rated corporate bonds and treasuries. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the interest income, we receive from our marketable securities without significantly increasing risk. We have established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity. Due to the relative short-term maturities of our cash equivalents and the low risk profile of our short and long-term investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and short and long-term investments. We have the

ability to hold our investments until maturity, and therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investment portfolio.

We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures

Disclosure Controls and Procedures and Internal Control over Financial Reporting

Controls and Procedures

We have carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act), as of September 30, 2025. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective in ensuring that:

(a) the information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms; and

(b) the information is accumulated and communicated to our management, including our principal executive officer and principal financial officer as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the quarter ended September 30, 2025, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, as of September 30, 2025, we were not party to any material legal or arbitration proceedings. No governmental proceedings are pending or, to our knowledge, contemplated against us.

Item 1A. Risk Factors

In addition to the other information contained elsewhere in this report, you should carefully consider the risks and uncertainties described in "Part I, Item 1A—Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2024, or 2024 Form 10-K, filed with the Securities and Exchange Commission, or SEC, on March 3, 2025, and in "Part II, Item 1A—Risk Factors" of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, or Q1 2025 Form 10-Q, filed with the SEC on May 5, 2025, which could materially and adversely affect our business, prospects, financial condition and results of operations. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition and results of operations. The risk factors disclosure in our 2024 Form 10-K and Q1 2025 Form 10-Q is qualified by the information that is described in this Quarterly Report on Form 10-Q. The risks described in our 2024 Form 10-K and Q1 2025 Form 10-Q are not our only risks. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results. There have been no material changes in our risk factors previously disclosed in our 2024 Form 10-K and Q1 2025 Form 10-Q, except as indicated below.

Our products and product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial scope of their approved use, or result in significant negative consequences following any marketing approval.

Undesirable side effects caused by our products and product candidates could cause the interruption, delay or halting of the trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other foreign regulatory authorities. For example, the Revuforj U.S. Prescribing Information label contains a boxed warning for differentiation syndrome, which can be fatal, as well as QTc prolongation and Torsades de Pointes. Results of the clinical trials may reveal a high and unacceptable severity and prevalence of side effects or other unexpected characteristics. In such event, the trials could be suspended or terminated, or the FDA or foreign regulatory authorities could deny approval of our product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects.

Additionally, if our product candidates receive marketing approval, and we or others later identify undesirable side effects, a number of potentially significant negative consequences could result, including:

- we may suspend marketing of, or withdraw or recall, the product;
- regulatory authorities may withdraw approvals;
- regulatory authorities may require additional warnings on the product labels;
- the FDA or other regulatory authorities may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about the product;
- the FDA may require the establishment or modification of a risk evaluation and mitigation strategy or foreign regulatory authorities may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of the product and impose burdensome implementation requirements on us;
- regulatory authorities may require that we conduct post-marketing studies;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates for use in targeted indications or otherwise materially harm its commercial prospects, if approved, and could harm our business, results of operations and prospects.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

Revuforj, Niktimvo and any product candidate that receives approval in the future would face significant competition from other therapies in the relevant indication. For example, cGVHD has historically been managed by off-label treatments. However, in the past several years, the FDA has approved three drugs, ibrutinib (*Imbruvica*®), belomosidil (*Rezurock*®) and ruxolitinib (*Jakafi*®), for use in patients with cGVHD after failure of one or more lines of systemic therapy. All three of these drugs may compete with Niktimvo in patients diagnosed with cGVHD.

We initially developed revumenib for the treatment of R/R adult and pediatric patients with KMT2Ar ALL, KMT2Ar AML and NPM1 mutant AML. At this time, other than Revuforj, there are no drugs approved for these defined populations and patients are managed using the standard of care treatment regimens developed for general AML and ALL populations. However, there are other agents in development for similar populations that may in the future be approved for these defined populations and that may prove to be more effective than Revuforj. We are also advancing a pipeline of frontline trials of revumenib in combination with standard of care therapies to support potential additional listings in the National Comprehensive Cancer Network, or NCCN, Guidelines® and/or label expansion opportunities.

Existing or potential competitors have or may have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of product candidates and the commercialization of those products. Our competitors may be more successful than us in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective or more effectively marketed and sold than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

We believe that our ability to successfully compete will depend on, among other things:

- the market adoption of Revuforj, Niktimvo and our product candidates by physicians and patients;
- the efficacy and safety profile of our product candidates relative to marketed products and product candidates in development by third parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- our ability to commercialize Revuforj, Niktimvo and our product candidates if they receive regulatory approval;
- the price of Revuforj, Niktimvo and our product candidates, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- our ability to manufacture commercial quantities of Revuforj, Niktimvo and our product candidates, if they receive regulatory approval; and
- our ability to negotiate preferential formulary status for our product candidates.

Even if we obtain regulatory approval of our other product candidates, the availability, commercial formulary placement, and price of our competitors' products could limit the demand and the price we are able to charge. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment, or if physicians switch to other new drug or biologic products or choose to reserve our drugs for use in limited circumstances.

Off-label use or misuse of our products may harm our reputation in the marketplace or result in injuries that lead to costly product liability suits.

We have received regulatory approval to market Revuforj in the U.S. for the treatment of (i) R/R acute leukemia with a KMT2A translocation in adult and pediatric patients one year old and older and (ii) R/R AML with a susceptible NPM1 mutation in adult and pediatric patients one year and older who have no satisfactory alternative treatment options, and regulatory approval to market Niktimvo for the treatment of cGVHD after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg. We may only promote or market Revuforj, Niktimvo, and our other product candidates, if approved by the FDA, for their specifically approved indications and in a manner consistent with the approved labeling. We train our marketing and sales force against promoting our product candidates for uses outside of the approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment, he or she deems it appropriate. Furthermore, the use of our products for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for any off-label uses, which could lead to product liability lawsuits that might require significant financial and management resources and that could harm our reputation. Additionally, the FDA imposes stringent restrictions on manufacturers' communications

regarding off-label uses and if we, or our collaborators, do not promote our products in a manner consistent with the approved labeling, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the Federal Food, Drug, and Cosmetic Act, or FCA, and other statutes, including the FCA, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws.

Disruptions at the FDA, the SEC and other government agencies and regulatory authorities caused by funding shortages or a government shutdown could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA and comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, government shutdowns, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies and comparable regulatory authorities may also slow the time necessary for new drugs or biologics to be reviewed and/or approved by necessary government agencies and regulatory authorities, which would adversely affect our business. For example, over the last several years, including the ongoing government shutdown that began on October 1, 2025, and previously from December 22, 2018 to January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If the current government shutdown continues or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business

Item 5. Other Information

Trading Arrangements

During the three months ended September 30, 2025, none of our directors and officers (as defined in Rule 16a-1 (f) under the Exchange Act) adopted or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement,” as defined in Regulation S-K Item 408 for the purchase or sale of our securities.

Item 6. Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-37708), as filed with the SEC on March 8, 2016).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-37708), as filed with the SEC on May 18, 2023).
3.3	Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-37708), as filed with the SEC on March 8, 2016).
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL Document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover page formatted as Inline XBRL and contained in Exhibit 101.

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: November 3, 2025

By: /s/ Michael A. Metzger
Michael A. Metzger
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Keith A. Goldan
Keith A. Goldan
Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATIONS

I, Michael A. Metzger, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Syndax Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in exchange act rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2025

By: /s/ Michael A. Metzger
Michael A. Metzger
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Keith A. Goldan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Syndax Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in exchange act rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2025

By: /s/ Keith A. Goldan
Keith A. Goldan
Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Syndax Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his or her knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 3, 2025

By /s/ Michael A. Metzger
Michael A. Metzger
Chief Executive Officer

Date: November 3, 2025

By /s/ Keith A. Goldan
Keith A. Goldan
Chief Financial Officer and Treasurer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Syndax Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.