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 June 30, 2022

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.)**
35 Gatehouse Drive, Building D, Floor 3 Waltham, Massachusetts	**02451**
(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 August 5, 2022, there were 56,565,165 shares of the registrant's Common Stock, par value $0.0001 per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements and information within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, which are subject to the "safe harbor" created by those sections. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expect," "would," "plan," "anticipate," "believe," "estimate," "predict," "potential," "intend," "project" or "continue," or the negative or plural of these terms or other comparable terminology.

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

- the impact of the ongoing COVID-19 pandemic and its effects 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;
- our estimates regarding our expenses, future revenues, anticipated capital requirements and our needs for additional financing;
- the timing of the progress and receipt of data from the pivotal Phase 2 cohorts of the AUGMENT-101 trial of revumenib in patients with relapsed/refractory, or R/R, acute leukemias;
- the timing of the progress and receipt of data from the AUGMENT-102 trial of revumenib in combination with chemotherapy in patients with R/R mutant nucleophosmin, NPM1, or mixed lineage leukemia rearranged, MLLr, acute leukemias, as well as the combination trials as part of the Leukemia & Lymphoma Society's Beat® AML Master Clinical Trial and as part of the Australian Leukemia and Lymphoma Group (ALLG) INTERCEPT Master Clinical Trial;
- the timing of the progress and receipt of data from the pivotal Phase 2 trial, AGAVE-201, of axatilimab in chronic Graft Versus Host Disease, or cGVHD;
- 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 Bayer Pharma AG, Eddingpharm Investment Company Limited, UCB Biopharma Sprl, and Vitae Pharmaceuticals, Inc., a subsidiary of Allergan plc, which was acquired by 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 our product candidates by physicians and patients;
- developments relating to our competitors and our industry; and
- business interruptions resulting from geo-political actions, including war or the perception that hostilities may be imminent, including the Russia Ukraine war and terrorism, or natural disasters and public health epidemics.

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)
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	June 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 120,239	$ 221,965
Restricted cash	115	115
Short-term investments	246,552	217,971
Short-term deposits	9,887	6,894
Collaboration receivable, net	13,102	-
Prepaid expenses and other current assets	2,392	1,451
Total current assets	392,287	448,396
Long-term investments	12,125	-
Property and equipment, net	256	278
Right-of-use asset, net	774	983
Other assets	995	—
Total assets	$ 406,437	$ 449,657
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,438	$ 5,669
Accrued expenses and other current liabilities	16,974	14,465
Current portion of term loan	7,212	—
Current portion of right-of-use liability	299	361
Current portion of capital lease	2	1
Derivative liability	—	187
Total current liabilities	30,925	20,683
Long-term liabilities:		
Right-of-use liability, less current portion	570	711
Capital lease, less current portion	8	—
Term loan, less current portion	12,994	19,895
Total long-term liabilities	13,572	20,606
Total liabilities	44,497	41,289
Commitments		
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized; 0 shares outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized; 56,399,734 and 54,983,105 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	6	6
Additional paid-in capital	981,712	952,019
Accumulated other comprehensive (income) loss	(1,335)	45
Accumulated deficit	(618,443)	(543,702)
Total stockholders' equity	361,940	408,368
Total liabilities and stockholders' equity	$ 406,437	$ 449,657

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue:				
License fees	$ —	$ 379	$ —	$ 758
Total revenues	—	379	—	758
Operating expenses:				
Research and development	29,734	16,871	59,756	38,742
General and administrative	7,990	5,842	14,827	11,513
Total operating expenses	37,724	22,713	74,583	50,255
Loss from operations	(37,724)	(22,334)	(74,583)	(49,497)
Other income (expense):				
Interest expense	(695)	(634)	(1,346)	(1,258)
Interest income	878	108	1,103	229
Other (expense) income, net	(31)	(50)	85	(107)
Total other income (expense)	152	(576)	(158)	(1,136)
Net loss	$ (37,572)	$ (22,910)	$ (74,741)	$ (50,633)
Other comprehensive loss:				
Unrealized (loss) gain on marketable securities	$ (695)	$ 8	$ (1,380)	$ 21
Comprehensive loss	$ (38,267)	$ (22,902)	$ (76,121)	$ (50,612)
Net loss attributable to common stockholders	$ (37,572)	$ (22,910)	$ (74,741)	$ (50,633)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.62)	$ (0.44)	$ (1.25)	$ (0.98)
Weighted-average number of common shares used to compute net loss per share attributable to common stockholders —basic and diluted	60,156,653	51,603,286	59,570,888	51,551,844

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

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

	Six Months Ended June 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (74,741)	$ (50,633)
Adjustments to reconcile net loss to net cash from operating activities:		
Depreciation	22	25
Amortization and accretion of investments	(320)	300
Non-cash operating lease expense	209	197
Non-cash interest expense	311	234
Changes in fair value of derivative liability	(187)	—
Stock-based compensation	7,416	6,007
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(4,930)	(2,357)
Other receivables	(13,102)	—
Accounts payable	769	116
Deferred revenue	—	(758)
Accrued expenses and other liabilities	2,316	235
Net cash used in operating activities	(82,237)	(46,634)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of short-term investments	(164,632)	(126,548)
Proceeds from sales and maturities of short-term investments	122,866	119,000
Net cash used in investing activities	(41,766)	(7,548)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock in at-the-market stock offering, net	19,427	5,131
Proceeds from Employee Stock Purchase Plan	150	143
Proceeds from stock option exercises	2,700	1,706
Net cash provided by financing activities	22,277	6,980
NET DECREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(101,726)	(47,202)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH—beginning of period	222,080	115,358
CASH, CASH EQUIVALENTS AND RESTRICTED CASH —end of period	$ 120,354	$ 68,156
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for interest	$ 960	$ 996

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

1. Nature of Business

Syndax Pharmaceuticals, Inc. ("we," "us," "our" or the "Company") is a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. We were incorporated in Delaware in 2005. We base our operations in Waltham, Massachusetts and we operate in one segment.

2. Basis of Presentation

The Company has prepared the accompanying condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. The interim unaudited condensed financial statements have been prepared on the same basis as the annual audited financial statements and in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of June 30, 2022, and the results of operations and comprehensive loss for the three and six months ended June 30, 2022 and 2021, and cash flows for the six months ended June 30, 2022 and 2021. The results for the three and six months ended June 30, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022, any other interim periods, or any future year or period. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2021, and the notes thereto, which are included in the Company's Annual Report on Form 10-K as filed with the Securities and Exchange Commission ("SEC") on March 1, 2022.

In 2011, the Company established a wholly owned subsidiary in the United Kingdom, in 2014 the Company established a wholly owned U.S. subsidiary, and in 2021, the Company established a wholly owned subsidiary in the Netherlands. There have been no material activities for these entities to date. All intercompany balances and transactions have been eliminated in consolidation.

3. Summary of Significant Accounting Policies

Significant Accounting Policies

The Company's significant accounting policies, which are disclosed in the audited consolidated financial statements for the year ended December 31, 2021, and the notes thereto are included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 1, 2022. 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 condensed 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 condensed 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 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 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 financial statements.

Significant Risks and Uncertainties

We have implemented business continuity plans designed to address and mitigate the impact of the ongoing COVID-19 pandemic on our business. We anticipate that the COVID-19 pandemic could have an impact on the clinical development timelines for one or more of our clinical programs. The extent to which the COVID-19 pandemic impacts our business, our clinical development, manufacturing of clinical and commercial drug substance and drug product, and regulatory efforts, our corporate development objectives and the value of and market for our common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the U.S., Europe and other countries, and the effectiveness of actions taken globally to contain and treat the disease. The global economic slowdown, the overall disruption of global healthcare

systems and the other risks and uncertainties associated with the pandemic could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, 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 our late-stage product candidate; 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; and the challenges of protecting and enhancing our intellectual property rights; complying with applicable regulatory requirements. In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties discussed above.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("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 consolidated statements or disclosures.

4. Collaborative Research and License Agreements

Incyte Collaboration

In September 2021, the Company entered into the Incyte License and Collaboration Agreement with Incyte covering the worldwide development and commercialization of SNDX-6352 (axatilimab) (the "Incyte License") and the Company entered into a share purchase agreement with Incyte (the "Incyte Share Purchase Agreement") and collective with the Incyte License, the "Incyte Agreements"). These agreements are collectively referred to as the Incyte Agreements. Under the terms of the Incyte Agreements, Incyte will receive exclusive commercialization rights outside of the United States, subject to tiered royalty payment obligations. In the United States, Incyte and the Company will co-commercialize axatilimab, with the Company having the right to co-promote axatilimab, subject to the Company's exercise of its co-promotion option. Incyte will be responsible for leading all aspects of commercialization of axatilimab in the United States. The Company and Incyte have agreed to co-develop axatilimab and to share development costs associated with the global and U.S. – specific clinical trials, with Incyte responsible for 55% of such costs and the Company responsible for 45% of such costs. Incyte is responsible for 100% of future development costs for trials that are specific to ex-U.S. countries. Each company will be responsible for funding any of its own independent development of activities. All development costs related to the collaboration will be subject to a joint development plan.

The Company is eligible to receive up to $220 million in future contingent development and regulatory milestones and up to $230 million in commercialization milestones. In addition, the Company is eligible to receive tiered royalties on potential net sales of the licensed product comprising axatilimab ranging from the low to mid double-digit percentages.

In December 2021, the Company received the upfront cash payment of $117 million and the Company issued 1,421,523 shares of common stock for an aggregate purchase price of $35 million, or $24.62 per share. Additionally, Incyte and the Company entered into a letter agreement which permitted Incyte to terminate the Incyte Agreement under circumstances under which the upfront payment of $117 million would be returned to Incyte and a cash settlement on the sale of the Company's common stock would be made to make the parties whole (the "Letter Agreement"). In connection with the closing of this transaction in December 2021, the Company determined that the cash settlement feature of the Letter Agreement represented an embedded derivative requiring bifurcation and separate accounting recognition at fair value. Accordingly, the Company recorded the common stock issued to Incyte at fair value of $24.8 million, $0.6 million as a derivative liability and $126.6 million as license revenue as of December 31, 2021. The Letter Agreement terminated in March 2022.

As of June 30, 2022, the Company has recorded $13.5 million as a collaboration receivable due from Incyte related to development costs under the Agreement. Additionally, the Company has recorded approximately $0.4 million as a collaboration payable, due to Incyte for development costs incurred by Incyte. Both expense and cost offset are recorded as part of research and development expense.

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(In thousands, except share and per share data)		(In thousands, except share and per share data)	
Numerator—basic and diluted:				
Net loss	$ (37,572)	$ (22,910)	$ (74,741)	$ (50,633)
Net loss attributable to common stockholders—basic and diluted	$ (37,572)	$ (22,910)	$ (74,741)	$ (50,633)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.62)	$ (0.44)	$ (1.25)	$ (0.98)
Denominator—basic and diluted:				
Weighted-average number of common shares used to compute net loss per share attributable to common stockholders—basic and diluted	60,156,653	51,603,286	59,570,888	51,551,844

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):

	June 30,	
	2022	2021
Options to purchase common stock	8,046,741	7,406,760
Employee Stock Purchase Plan	10,805	8,214
Non-vested restricted stock units (RSUs)	259,788	124,083

In January 2020, the Company sold 3,036,719 shares of common stock at $8.00 per share and pre-funded warrants to purchase 1,338,287 shares of common stock. In February 2021, 250,000 pre-funded warrants were exchanged for shares of common stock in a cash exercise and in November 2021, 475,784 pre-funded warrants were exchanged for shares of common stock in a cashless exercise. As of June 30, 2022, 3,975,024 pre-funded warrants were considered issued and outstanding.

6. Significant Agreements

Vitae Pharmaceuticals, Inc.

In October 2017, the Company entered into a license agreement (the “Allergan License Agreement”) with Vitae Pharmaceuticals, Inc., a subsidiary of Allergan (“Allergan”), under which Allergan granted the Company an exclusive, sublicensable, worldwide license to a portfolio of preclinical, orally available, small molecule inhibitors of the interaction of menin with Mixed Lineage Leukemia (“MLL”) protein (the “Menin Assets”). Subject to the achievement of certain milestone events, the Company may be required to pay Allergan up to $99.0 million in one-time development and regulatory milestone payments over the term of the Allergan License Agreement. 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 Allergan low single to low double-digit 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 Allergan License Agreement for the other party’s uncured material breach or insolvency; and the Company may terminate the Allergan License Agreement at will at any time upon advance written notice to Allergan. Allergan may terminate the Allergan 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 Allergan 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 Allergan 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 June 2019, the Company achieved certain development and regulatory milestones and recorded $4.0 million as research and development expense. In February 2022, the Company achieved certain development and regulatory milestones and recorded $2.0 million as research and development expense.

UCB Biopharma Sprl

In 2016, the Company entered into a license agreement (the "UCB License Agreement"), as amended from time to time, with UCB Biopharma Sprl ("UCB"), under which UCB granted to the Company a worldwide, sublicenseable, exclusive license to UCB6352, which the Company refers to as axatilimab, an investigational new drug ("IND") ready anti-CSF-1R monoclonal antibody. Subject to the achievement of certain milestone events, the Company may be required to pay UCB up to $119.5 million in one-time development and regulatory milestone payments over the term of the UCB License Agreement. 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 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 is 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 will 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. Since the start of the license agreement, the Company achieved certain development and regulatory milestones and has recorded $6.0 million as research and development expense. Additionally, in connection with its most recent amendment of the UCB License Agreement, the Company paid UCB $5.8 million, which it recognized as a milestone expense in the six months ended June 30, 2022.

Bayer Pharma AG (formerly known as Bayer Schering Pharma AG)

In March 2007, the Company entered into a license agreement (the "Bayer Agreement") with Bayer Schering Pharma AG ("Bayer") for a worldwide, exclusive license to develop and commercialize entinostat and any other products containing the same active ingredient. The Company will pay Bayer royalties on a sliding scale based on net sales, if any, and make future milestone payments to Bayer of up to $150.0 million in the event that certain specified development and regulatory goals and sales levels are achieved.

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)			
June 30, 2022				
Assets:				
Cash and cash equivalents	$ 120,240	$ 68,248	$ 51,992	$ —
Short-term investments	246,552	—	246,552	—
Long-term investments	12,125	—	12,125	—
Total assets	$ 378,917	$ 68,248	$ 310,669	$ —
December 31, 2021				
Assets:				
Cash and cash equivalents	$ 221,965	$ 96,816	$ 125,149	$ —
Short-term investments	217,971	—	217,971	—
Total assets	$ 439,936	$ 96,816	$ 343,120	$ —
Liabilities:				
Derivative liability	187	—	—	187
Total liabilities	$ 187	$ —	$ —	$ 187

There have been no material impairments of our assets measured and carried at fair value during the period ended June 30, 2022 and 2021. In addition, there have been no changes in valuation techniques during the period ended June 30, 2022 and 2021. 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 cash equivalents and short – term investments was determined other than quoted prices in active markets, which are either directly or indirectly observable as of the reporting date and fair value is determined using models or other valuation methodologies. The fair value of the Level 3 instrument is determined using unobservable inputs and the Company utilized a Black Scholes valuation model as of December 9, 2021 (initial recognition) and December 31, 2021, respectively.

The following table summarizes the fair value rollforward (in thousands):

	Fair Value
Derivative Liability:	
Beginning Balance 12/31/21	$ 187
Change in fair value	(187)
Ending Balance 6/30/22	$ —

The change in fair value of the Level 3 instrument was directly related to the expiration of the Letter Agreement in March 2022. At the time of the expiration of the Letter Agreement, Incyte no longer had the ability to terminate the contract, as such the probability of payment to Incyte was assessed to be zero. Accordingly, the Company released the remaining $187,000 liability related to the Letter Agreement as of March 31, 2022.

The short-term and long-term investments are classified as available-for-sale securities. As of June 30, 2022, the remaining contractual maturities of the available-for-sale securities were 1 to 13 months, and the balance in the Company's accumulated other comprehensive income 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 six months ended June 30, 2022 and 2021. As a result, the Company did not reclassify any amounts out of accumulated other comprehensive income for the same periods. The Company has a limited number of available-for-sale securities in insignificant loss positions as of June 30, 2022, which the Company does not intend to sell and has concluded it will not be required to sell before recovery of the amortized cost for the investment at maturity

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

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
		(In thousands)		
June 30, 2022				
Commercial paper	$ 201,084	$ —	$ (697)	$ 200,387
Corporate bonds	4,067	1	—	4,068
US Treasury and federal bonds	106,852	—	(638)	106,214
	$ 312,003	$ 1	$ (1,335)	$ 310,669
December 31, 2021				
Commercial paper	$ 306,715	$ 70	$ (17)	$ 306,768
Corporate bonds	22,147	—	(6)	22,141
US Treasury and federal bonds	14,212	—	(2)	14,210
	$ 343,074	$ 70	$ (25)	$ 343,119

8. Prepaid Expenses and Other Current Assets

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

	June 30, 2022	December 31, 2021
Prepaid insurance	$ 1,564	$ 642
Interest receivable on investments	410	429
Prepaid subscription	235	230
Other	183	150
Total prepaid expenses and other current assets	$ 2,392	$ 1,451

9. Accrued Expenses and Other Current Liabilities

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

	June 30, 2022	December 31, 2021
Accrued clinical costs	$ 10,519	$ 7,760
Accrued compensation and related costs	2,736	4,342
Accrued professional fees	553	662
Other	3,166	1,701
Total accrued expenses and other current liabilities	$ 16,974	$ 14,465

10. Stock-Based Compensation

In January 2022, the number of shares of common stock available for issuance under the 2015 Omnibus Incentive Plan (“2015 Plan”) was increased by 2,198,134 shares due to the automatic annual provision to increase shares available under the 2015 Plan. As of June 30, 2022, the total number of shares of common stock available for issuance under the 2015 Plan was 1,647,345. The Company recognized stock-based compensation expense related to the issuance of stock option awards to employees and non-employees and related to the 2015 Employee Stock Purchase Plan (“ESPP”) in the condensed consolidated statements of comprehensive loss as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
			(In thousands)	
Research and development	$ 1,358	$ 1,093	$ 2,710	$ 1,996
General and administrative	2,580	2,147	4,706	4,011
Total	$ 3,938	$ 3,240	$ 7,416	$ 6,007

Compensation expense by type of award in the three and six months ended June 30, 2022 and 2021 was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
			(In thousands)	
Stock options	$ 3,188	$ 2,615	$ 6,113	$ 4,961
Restricted Stock Units	722	597	1,238	977
Employee Stock Purchase Plan	28	28	65	69
Total	$ 3,938	$ 3,240	$ 7,416	$ 6,007

During the six months ended June 30, 2022, the Company granted 1,993,450 stock options to certain executives, consultants and employees having service-based vesting conditions. The grant date fair value of the options granted in the six months ended June 30, 2022, was $21.8 million, or $10.93 per share on a weighted-average basis and will be recognized as compensation expense over the requisite service period of two to four years.

In 2019, the Company granted to certain employees 583,000 performance-based stock options ("2019 Performance Awards"), primarily related to the achievement of certain clinical and regulatory development milestones related to product candidates. Additionally, in 2022, the Company granted to certain employees 140,000 performance-based stock options ("2022 Performance Awards"), primarily related to the achievement of certain regulatory development milestones related to product candidates. Recognition of stock-based compensation expense associated with these performance-based stock options commences when the performance condition is probable of achievement, using management's best estimates, which consider the inherent risk and uncertainty regarding the future outcomes of the milestones.

In the fourth quarter of 2020 one of the performance milestones of the 2019 Performance Awards was achieved and of the associated 194,331 stock options, 64,777 stock options vested, and 388,669 options were cancelled. In 2021, 64,780 stock options vested. As of June 30, 2022, 56,999 options (net of cancellations) remain to vest. For the remaining milestones, the performance conditions were not met as of June 30, 2022. Therefore, no expense has been recognized related to these awards for the six months ended June 30, 2022, and 7,778 options were canceled in 2022.

In the first quarter of 2022, management estimated one of the milestones, for the 2022 Performance Awards, was probable of achievement and, as such, the Company recorded approximately $214,000 of stock compensation expense for these awards for the six months ended June 30, 2022. As of June 30, 2022, 140,000 stock options outstanding were unvested, and no options had been cancelled.

During the six months ended June 30, 2022, 286,572 options were exercised for cash proceeds of $2.7 million. During the six months ended June 30, 2021, 191,394 options were exercised for cash proceeds of $1.7 million.

Restricted stock units

RSUs awarded to Board of Directors or employees vest on either i) on the one – year anniversary date of the related grant or ii) 25% on each anniversary for 4 years. The following table summarizes our RSU activity:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested—December 31, 2021	132,333	$ 20.11
Granted (1)	131,205	$ 15.79
Vested	(3,750)	$ 9.47
Forfeited	-	$ -
Unvested—June 30, 2022	259,788	$ 18.08

(1) RSU's granted in 2022 and 2021 had a weighted average grant date fair value of $15.79 and $21.19, respectively. The fair values of RSU's vested in 2022 and 2021 totaled $36,000 and $60,000, respectively.

As of June 30, 2022, there was $35.9 million of unrecognized compensation costs related to employee and non-employee unvested stock options and RSUs granted under the 2015 and 2007 Plans, which is expected to be recognized over a weighted-average remaining service period of 2.9 years. Stock compensation costs have not been capitalized by the Company.

11. Loan Payable

In February 2020, the Company entered into a loan and security agreement (the "Loan Agreement") with Hercules Capital, Inc. ("Hercules"). In December 2021, the Company entered into Amendment No. 1 to the Company's Loan Agreement (the "First

Amendment" and the Loan Agreement, as amended, the "Amended Loan Agreement") with several banks and financial institutions or entities from time-to-time party thereto (collectively, the "Lender") and Hercules, in its capacity as administrative agent for itself and the Lender (in such capacity, the "Agent").

The First Amendment provides for an aggregate maximum borrowing of up to $80.0 million, consisting of (i) a term loan of up to $20 million (the "Initial Advance"), (ii) second tranche ("Tranche 2") of up to $30.0 million with $15.0 million being available at the Company's option through April 30, 2022 and the remaining $15.0 million being available at the Company's option through November 30, 2022, which availability period will be extended to April 30, 2023 if the first $15.0 million is drawn prior to April 30, 2022, and (iii) third tranche ('Tranche 3") of up to $30.0 million which is available, subject to the Agent's investment committee approval, through the Interest-Only Period. The Company did not draw the first $15.0 million from Tranche 2.

The Company is obligated to make monthly interest-only payments through January 1, 2023. Borrowings under the Amended Loan Agreement bear interest at an annual interest rate from the greater of (y) 9.25% or (z) 6.00% plus *the Wall Street Journal* prime rate. After the interest – only payment period, borrowings under the Amended Loan Agreement are repayable in equal monthly payments of principal and accrued interest until the maturity date of the loan, which is April 1, 2024. At the Company's option, the Company may prepay all, but not less than all, of the outstanding borrowings, subject to a prepayment premium equal to (i) 2.0% of the principal amount outstanding if the prepayment occurs during the first year following the First Amendment, (ii) 1.5% of the principal amount outstanding if the prepayment occurs during the second year following the First Amendment, and (iii) 1.0% of the principal amount outstanding at any time thereafter but prior to the Maturity Date. The Amended Loan Agreement also applies a 4.99% end of term charge to any future draws payable on the maturity date. The final payment will be accrued over the term of the debt.

Borrowings under the Amended Loan Agreement are collateralized by substantially all of the Company's and its subsidiaries personal property and other assets, other than its intellectual property. The Amended Loan Agreement includes a minimum cash covenant of $12.5 million, subject to reduction upon satisfaction of certain conditions as set forth in the Amended Loan Agreement. As of December 31, 2020, the conditions set forth in the Amended Loan Agreement were met. The cash covenant of $12.5 million was waived. In addition, the Amended Loan Agreement includes customary affirmative and restrictive covenants and representations and warranties, including a covenant against the occurrence of a "change in control," financial reporting obligations, and certain limitations on indebtedness, liens (including a negative pledge on intellectual property and other assets), investments, distributions (including dividends), collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, and deposit accounts. The Amended Loan Agreement also includes customary events of default, including payment defaults, breaches of covenants following any applicable cure period, the occurrence of certain events that could reasonably be expected to have a "material adverse effect" as set forth in the Amended Loan Agreement, cross acceleration to third-party indebtedness and certain events relating to bankruptcy or insolvency. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% may be applied to the outstanding principal balance, and Hercules may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Amended Loan Agreement.

In connection with the Amended Loan Agreement, the Company was required to enter into separate deposit account control agreements with the lender in order to perfect the lender's security interest in the cash collateral in the Company's operating accounts. In the event of a default under the Loan Agreement, the lender would have the right to take control of the operating accounts and restrict the Company's access to the operating accounts and the funds therein.

During the six months ended June 30, 2022 and 2021, the Company recognized $1.3 million and $1.2 million, respectively, of interest expense related to the Initial Advance pursuant to the Amended Loan Agreement.

As of June 30, 2022, the Company's maturities of principal obligations under its long-term debt are as follows (in thousands):

	Amount
Remainder of 2022	$ —
2023	14,765
2024	5,235
Total principal outstanding	20,000
Amortized final fee	293
Unamortized debt issuance costs	(87)
Total	20,206
Term loan, current portion	7,212
Term loan, less current portion	$ 12,994

12. Stockholders' Equity

The following table presents the changes in stockholders' equity for the three and six months ended June 30, 2022:

(In thousands, except share data)	Common Stock $0.0001 Par Value		Additional Paid-In Capital	Accumulated Other Comprehensive Income / (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2021	54,983,105	$ 6	$ 952,019	$ 45	$ (543,702)	$ 408,368
Stock purchase under ESPP	18,946	—	—	—	—	—
Stock-based compensation expense	—	—	3,478	—	—	3,478
Unrealized gains on short-term investments	—	—	—	(685)	—	(685)
Employee withholdings ESPP	—	—	92	—	—	92
Proceeds from exercise of stock options	28,839	—	465	—	—	465
Net loss	—	—	—	—	(37,169)	(37,169)
Balance as of March 31, 2022	55,030,890	$ 6	$ 956,054	$ (640)	$ (580,871)	$ 374,549
Proceeds from ATM sales	1,111,111	—	19,427	—	—	19,427
Stock-based compensation expense	—	—	3,938	—	—	3,938
Unrealized gains on short-term investments	—	—	—	(695)	—	(695)
Employee withholdings ESPP	—	—	58	—	—	58
Proceeds from exercise of stock options	257,733	—	2,235	—	—	2,235
Net loss	—	—	—	—	(37,572)	(37,572)
Balance as of June 30, 2022	56,399,734	$ 6	$ 981,712	$ (1,335)	$ (618,443)	$ 361,940

The following table presents the changes in stockholders' equity for the three and six months ended June 30, 2021:

(In thousands, except share data)	Common Stock $0.0001 Par Value		Additional Paid-In Capital	Accumulated Other Comprehensive Income / (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2020	47,881,223	$ 5	$ 820,815	$ (4)	$ (568,628)	$ 252,188
Stock purchase under ESPP	16,382	—	—	—	—	—
Stock-based compensation expense	—	—	2,767	—	—	2,767
Unrealized gains on short-term investments				13		13
Prefunded warrant exchange	250,000	—	—		—	—
Employee withholdings ESPP	—	—	79	—	—	79
Proceeds from exercise of stock options	100,954	—	881	—	—	881
Net loss	—	—	—	—	(27,723)	(27,723)
Balance as of March 31, 2021	48,248,559	$ 5	$ 824,542	$ 9	$ (596,351)	$ 228,205
Stock-based compensation expense	—	—	3,240	—	—	3,240
Unrealized gains on short-term investments	—	—	—	8	—	8
Employee withholdings ESPP	—	—	64	—	—	64
Proceeds from ATM Offering, net $200 offering expense	277,629	—	5,131	—	—	5,131
Proceeds from exercise of stock options	90,440	—	825		—	825
Net loss	—	—	—	—	(22,910)	(22,910)
Balance as of June 30, 2021	48,616,628	$ 5	$ 833,802	$ 17	$ (619,261)	$ 214,563

In March 2021, the Company entered into a new sales agreement with Cowen and Company, LLC ("Cowen") under which the Company may issue and sell shares of its common stock having aggregate sales proceeds of up to $75.0 million from time to time through Cowen, acting as agent, in a series of one or more ATM equity offerings (the "2021 ATM Program"). Cowen is not required to sell any specific amount but acts as the Company's sales agent using commercially reasonable efforts consistent with its normal trading and sales practices. Shares sold pursuant to the sales agreement will be sold pursuant to a shelf registration statement on Form S-3ASR (Registration No. 333-254661), which became automatically effective upon filing on March 24, 2021. The Company's common stock will be sold at prevailing market prices at the time of the sale; and as a result, prices may vary. For the period ended June 30, 2022, the Company sold 1,111,111 additional shares of common stock under the 2021 ATM Program, with net proceeds of approximately $19.4 million.

In December 2021, in connection with the Incyte License and Collaboration Agreement and Share Purchase Agreement, the Company issued 1,421,523 shares of common stock, with net proceeds of approximately $35.0 million. The Company recorded the equity issuance at a fair value of $24.8 million based on the market price of the stock on the date of issuance.

The Company has reserved for future issuance the following shares of common stock related to the potential warrant exercise, exercise of stock options and the employee stock purchase plan:

	June 30, 2022
Common stock issuable under pre-funded warrants	3,975,024
Options to purchase common stock	9,953,874
Employee Stock Purchase Plan	1,527,464

13. Commitments and Contingencies

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 June 30, 2022, or 2021.

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 1, 2022.

Company Overview

We are a clinical-stage biopharmaceutical company developing an innovative pipeline of cancer therapies. Our two lead product candidates are, SNDX-5613, or revumenib, and SNDX-6352, or axatilimab. We are developing revumenib, targeting the binding interaction of menin with the mixed lineage leukemia 1 (MLL1) protein for the treatment of MLL-rearranged, or MLLr, acute leukemias and nucleophosmin 1, or NPM1, mutant acute myeloid leukemia (AML), as well as axatilimab, a monoclonal antibody that blocks the colony stimulating factor 1, or CSF-1 receptor. We have deprioritized the development of entinostat, our once-weekly, oral, small molecule, Class I HDAC inhibitor, to focus resources on advancing the remainder of our pipeline. 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 no products approved for commercial sale and have not generated any product revenues from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. We have generated minimal license revenue, except for in 2021. Other than in 2021, we are not and have never been profitable and have incurred losses in each period since our inception in 2005. For the six months ended June 30, 2022 and 2021, we reported a net loss of $74.7 million and $50.6 million, respectively. We reported a net loss attributable to stockholders of $74.7 million and $50.6 million for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, we had an accumulated deficit of $618.4 million, which included non-cash charges for stock-based compensation, preferred stock accretion and extinguishment charges. As of June 30, 2022, we had cash, cash equivalents and short-term and long-term investments of $378.9 million.

COVID-19 Business Update

We continue to address and mitigate the impact of the ongoing COVID-19 pandemic on our employees and our business. While we are not experiencing financial impacts at this time, given the changes in global macroeconomic conditions, the overall disruption of global healthcare systems, potential limitations to the efficacy of vaccines for COVID-19, the evolution of multiple variants of the virus and other risks and uncertainties associated with the pandemic, our business, financial condition, results of operations and growth prospects could be materially adversely affected. We continue to closely monitor the COVID-19 situation as we evolve our business continuity plans and response strategy. We have reopened our offices to allow employees to return to the office, while also supporting distributed working options.

We are working closely with our third-party manufacturers, distributors and other partners to manage our supply chain activities and mitigate potential disruptions to our product supplies as a result of the ongoing COVID-19 pandemic. We currently expect to have adequate supplies of revumenib and axatilimab. If the COVID-19 pandemic continues to persist and if it impacts essential distribution systems such as FedEx and postal delivery or if it results in facility closures for cleaning and/or insufficient staff, we could experience disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our products, and to our clinical trial operations.

With respect to clinical development, we continue to take measures to implement remote and virtual approaches, including remote patient monitoring where possible, to maintain patient safety and trial continuity and to preserve study integrity. We have, and may continue to experience, disruptions and/or delays in our ability to initiate trial sites and enroll and assess patients. As the COVID-19 pandemic continues, we anticipate an ongoing, though minimal, impact on our ability to maintain patient enrollment in our clinical trials. We could also see an impact on the ability to supply study drug, report trial results, or interact with regulators, ethics committees or other important agencies due to limitations in regulatory authority employee resources or otherwise. In addition, we rely on contract research organizations or other third parties to assist us with clinical trials, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic. If the COVID-19 pandemic continues, we could experience significant disruptions to our clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects.

Clinical Developments

Revumenib

- The pivotal Phase 2 portion of AUGMENT-101 is ongoing and we continue to expect completion of enrollment in one of the three pivotal cohorts by year-end. The trials are enrolling a total of 64 adult and up to 10 pediatric patients across each of

three distinct trial populations: patients with NPM1 mutant acute myeloid leukemia (AML), patients with MLLr AML, and patients with MLLr acute lymphocytic leukemia (ALL). Based on discussions with the U.S. Food and Drug Administration, AUGMENT-101 may serve as the basis for regulatory filings in each of the three distinct populations. We expect to report topline data from the trials starting in the first half of 2023, with the potential for the first New Drug Application filing later in 2023. We also anticipate announcing updated data from the Phase 1 portion of the AUGMENT-101 trial in the fourth quarter of 2022.

- Two trials, BEAT-AML and AUGMENT-102, are ongoing and will assess the safety, tolerability, and preliminary anti-leukemic efficacy of revumenib and establish an appropriate Phase 2 dose when used in combination with other approved agents. BEAT-AML is a front-line combination trial of revumenib with venetoclax and azacitidine being conducted as part of the Leukemia & Lymphoma Society's Beat AML® Master Clinical Trial. AUGMENT-102 is a trial assessing revumenib in combination with chemotherapy in patients with R/R mNPM1 or MLLr acute leukemias.
- We expect the Australasian Leukaemia and Lymphoma Group (ALLG) to initiate the INTERCEPT trial of revumenib as monotherapy in patients with AML who are minimal residual disease-positive (MRD+) following initial treatment, in the fourth quarter of 2022. The trial is a part of the INTERCEPT AML Master Clinical Trial, a collaborative clinical trial investigating novel therapies to target early relapse and clonal evolution as pre-emptive therapy in AML. Revumenib is the first menin inhibitor to be included in the INTERCEPT AML Master Clinical Trial.
- We previously announced that we intend to initiate a proof-of-concept clinical trial of revumenib in patients with unresectable metastatic microsatellite stable CRC in the fourth quarter of 2022.

Axatilimab

- Enrollment is ongoing in our global pivotal Phase 2 AGAVE-201 trial of axatilimab in patients with cGVHD. The trial is evaluating the safety and efficacy of three dosing regimens of axatilimab. The primary endpoint will assess objective response rate based on the 2014 NIH consensus criteria for cGVHD, with key secondary endpoints including duration of response and improvement in modified Lee Symptom Scale score. We remain on track to report topline data in the first half of 2023, with the potential for a Biologics License Application filing later in 2023.
- We plan to initiate a Phase 2b trial to assess the efficacy, safety and tolerability of axatilimab in patients with IPF in the fourth quarter of 2022. This 52-week, randomized, double-blind and placebo-controlled trial is expected to enroll approximately 170 patients. The primary endpoint will assess the change from baseline in forced vital capacity, which is the current registrational endpoint in IPF.
- We are working with our partner, Incyte Corporation, to plan additional trials of axatilimab in earlier lines of cGVHD, and expect that Incyte will initiate a Phase 1 trial of axatilimab in combination with Jakafi® in patients with steroid-refractory cGVHD in the fourth quarter of 2022.

Corporate Updates

- In June 2022, we announced the appointment of Keith A. Goldan as Chief Financial Officer. Mr. Goldan brings to Syndax nearly thirty years of leadership and operational experience at several pharmaceutical, biotechnology, and medical technology companies.

Financial Overview

Revenue

To date, we have not generated any product revenues. Our ability to generate revenue and become profitable depends upon our ability to obtain marketing approval of and successfully commercialize our product candidates. Our revenue for the three and six months ended June 30, 2021, had been solely derived from our license, development and commercialization agreement with Kyowa Kirin Co., Ltd., or KKC. In September 2021, KKC informed us that they discontinued the entinostat program and cancelled the license to develop and commercialize entinostat.

In September 2021, the Company entered into the Incyte License and Collaboration Agreement with Incyte covering the worldwide development and commercialization of SNDX-6352 (axatilimab). We granted Incyte an exclusive license to develop and commercialize axatilimab in the United States and the rest of the world. In 2021, we received $152.0 million in total consideration, of which $126.6 million was allocated to the license and recognized as license revenue as of December 31, 2021. As of June 30, 2022, no additional revenue has been recognized under the Incyte License and Collaboration Agreement.

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, or CROs, 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. Drug 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, clinical studies and clinical trials of our product candidates. The duration, costs and timing of clinical 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 sites;
- the countries in which the studies and 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 drug 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 product candidates may commence. Clinical development timelines, the probability of success and development costs can differ materially from expectations.

General and Administrative

General and administrative expenses consist primarily of employee-related expenses, including salaries, benefits, non-cash stock-based compensation and travel expenses, for our employees in executive, finance, business development and support functions. Other general and administrative expenses include facility-related costs not otherwise allocated to research and development expenses

and accounting, tax, legal and consulting services. We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. Additionally, if and when we believe a regulatory approval of the first product candidate appears likely, we anticipate an increase in payroll and related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

Interest Expense

Interest expense consists primarily of interest expense on our term loan, operational and capital leases.

Interest Income

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

Other Income (Expense)

Other income (expense) includes income recorded for the change in fair value of derivative liability established based on the terms of the Incyte License and Collaboration Agreement and Share Repurchase Agreement, or the Incyte Agreement.

New Accounting Standards

For a discussion of new accounting standards please read *Note 3 Summary of Significant Accounting Policies*, to our condensed consolidated financial statements included in this report.

Critical Accounting 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 of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. 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.

Results of Operations

Comparison of the three months ended June 30, 2022 and 2021:

	Three Months Ended June 30,		Increase (Decrease)	
	2022	2021	$	%
	(In thousands)			
Revenue:				
License fees	$ —	$ 379	$ (379)	-100%
Total revenues	—	379	(379)	-100%
Operating expenses:				
Research and development	29,734	16,871	12,863	76%
General and administrative	7,990	5,842	2,148	37%
Total operating expenses	37,724	22,713	15,011	66%
Loss from operations	(37,724)	(22,334)	15,390	69%
Other income (expense):				
Interest expense	(695)	(634)	(61)	10%
Interest income	878	108	770	713%
Other (expense) income, net	(31)	(50)	19	-38%
Total other income (expense)	152	(576)	728	-126%
Net loss	$ (37,572)	$ (22,910)	$ 14,662	64%

License Fees

For the three months ended June 30, 2022, we recognized no revenue under our current agreements, which are not revenue generating. For the three months ended June 30, 2021, we recognized $0.4 million, derived from the KKC license agreement which was terminated in Q3 2021.

Research and Development

For the three months ended June 30, 2022, our total research and development expenses increased approximately $12.9 million, or 76%, to $29.7 million from $16.9 million for the comparable quarter in the prior year. The increase in research and development expenses was primarily due to increases in clinical and manufacturing activities of $10.9 million, increases in employee related expenses of $1.4 million and increased professional fees of $0.6 million. Increased clinical and manufacturing expenses are primarily due to increased manufacturing activities related to axatilimab of $5.6 million and menin of $0.5 million. Clinical activities for menin increased by $5.1 million, for axatilimab by $5.1 million, for third party studies by $1.9 million, offset by collaboration cost reimbursement of $7.3 million. Employee related activities increased due to increased headcount expenses of $1.2 million and increased stock compensation of $0.2 million. We expect research and development expenses to fluctuate from quarter to quarter depending on the timing of clinical trial activities, clinical manufacturing and other development activities.

Research and development expenses consisted of the following:

	Three Months Ended June 30,		Increase (Decrease)	
	2022	2021	$	%
	(In thousands)			
External research and development expenses	$ 23,688	$ 12,063	$ 11,625	96%
Internal research and development expenses	6,046	4,808	1,238	26%
Total research and development expenses	$ 29,734	$ 16,871	$ 12,863	76%

General and Administrative

For the three months ended June 30, 2022, our total general and administrative expenses increased $2.1 million, or 37%, to $8.0 million from $5.8 million for the comparable period in the prior year. The increase in general and administrative expenses was primarily due to increased employee related expenses of $1.6 million and increased professional fees of $0.5 million.

Interest Income and Interest Expense

For the three months ended June 30, 2022, interest income increased from the comparable period in the prior year primarily due to increased interest rates partially offset by an increased average balance on cash equivalents and short-term and long-term investments.

For the three months ended June 30, 2022, interest expense increased from the comparable period in the prior year primarily due to the interest expense on the Amended Loan Agreement.

Comparison of the six months ended June 30, 2022 and 2021:

	Six Months Ended June 30,		Increase (Decrease)	
	2022	2021	$	%
	(In thousands)			
Revenue:				
License fees	$ —	$ 758	$ (758)	-100%
Total revenues	—	758	(758)	-100%
Operating expenses:				
Research and development	59,756	38,742	21,014	54%
General and administrative	14,827	11,513	3,314	29%
Total operating expenses	74,583	50,255	24,328	48%
Loss from operations	(74,583)	(49,497)	25,086	51%
Other (expense):				
Interest expense	(1,346)	(1,258)	(88)	7%
Interest income	1,103	229	874	382%
Other income (expense), net	85	(107)	192	-179%
Total other (expense)	(158)	(1,136)	978	-86%
Net loss	$ (74,741)	$ (50,633)	$ 24,108	48%

License Fees

For the six months ended June 30, 2022, we recognized no revenue under our current agreements, which are not revenue generating. For the six months ended June 30, 2021, we recognized $0.8 million respectively, derived from the KKC license agreement which was terminated in Q3 2021.

Research and Development

For the six months ended June 30, 2022, our total research and development expenses increased $21.0 million, or 54%, to $59.8 million from $38.7 million for the comparable period in the prior year. The increase in research and development expenses was primarily due to increased clinical and manufacturing activities of $16.5 million, increased employee related expenses of $3.5 million, and increased professional fees of $1.0 million. Increased clinical and manufacturing activities are primarily due to increased clinical activities for menin of $6.0 million, for axatilimab of $14.4 million, for third party studies of $3.3 million, offset by collaboration cost reimbursement of $13.1 million. Additionally, we recognized a $5.8 million milestone expense in connection with the axatilimab program. Employee related expenses primarily increased due to increased headcount and stock compensation. We expect research and development expenses to fluctuate from period to period depending on the timing of clinical trial activities, clinical manufacturing, and other development activities.

Research and development expenses consisted of the following:

	Six Months Ended June 30,		Increase (Decrease)	
	2022	2021	$	%
	(In thousands)			
External research and development expenses	$ 47,445	$ 29,669	$ 17,776	60%
Internal research and development expenses	12,311	9,073	3,238	36%
Total research and development expenses	$ 59,756	$ 38,742	$ 21,014	54%

General and Administrative

For the six months ended June 30, 2022, our total general and administrative expenses increased $3.3 million, 29%, to $14.8 million from $11.5 million for the comparable period in the prior year. The increase in general and administrative expenses was primarily due to increased employee related expenses of $2.5 million, increased professional fees of $0.6 million and increased insurance related expense of $0.2 million.

Interest Income and Interest Expense

For the six months ended June 30, 2022, interest income increased from the comparable period in the prior year primarily due to interest rates partially offset by an increased average balance on cash equivalents and short-term and long-term investments.

For the six months ended June 30, 2022, interest expense increased from the comparable period in the prior year primarily due to the interest expense on the Amended Loan Agreement.

Liquidity and Capital Resources

Overview

As of June 30, 2022, we had cash, cash equivalents and short-term and long-term investments totaling $378.9 million. Our operations have been primarily financed by net proceeds from public stock offerings, and revenue from our license agreements. We believe that our present cash, cash equivalents and short-term investments as of June 30, 2022, will fund our projected operating expenses and capital expenditure requirements for at least the next 12 months. In addition to our existing cash, cash equivalents and short-term investments, we are eligible to receive research and development funding and to earn milestone and other contingent payments for the achievement of defined collaboration objectives and certain development, regulatory and commercial milestones and royalty payments under our collaboration agreements. Our ability to earn these milestone and contingent payments and the timing of achieving these milestones is primarily dependent upon the outcome of our collaborators' research and development activities and is uncertain at this time.

Loan and Security Agreement

In December 2021, the Company entered into Amendment No. 1 to the Company's loan and security agreement (the "First Amendment" and the Loan Agreement, as amended, the "Amended Loan Agreement") with several banks and financial institutions or

entities from time-to-time party thereto (collectively, the "Lender") and Hercules, in its capacity as administrative agent for itself and the Lender (in such capacity, the "Agent").

The Amended Loan Agreement provides for an aggregate maximum borrowing of up to $80.0 million, consisting of (i) a term loan of up to $20 million (the "Initial Advance"), (ii) second tranche ("Tranche 2") of up to $30.0 million with $15.0 million being available at the Company's option through April 30, 2022 and the remaining $15.0 million being available at the Company's option through November 30, 2022, which availability period will be extended to April 30, 2023 if the first $15.0 million is drawn prior to April 30, 2022, and (iii) third tranche ("Tranche 3") of up to $30.0 million which is available, subject to the Agent's investment committee approval, through the Interest-Only Period. The Company did not draw the first $15.0 million from Tranche 2. For additional information, see *Note 11 Loan Payable* to our condensed consolidated financial statements elsewhere in this report.

At-the-Market Offering Program

In March 2021, we entered into a new sales agreement with Cowen, under which we may issue and sell shares of our common stock having aggregate sales proceeds of up to $75.0 million from time to time through Cowen, acting as agent, in a series of one or more ATM equity offerings (the "2021 ATM Program"). Cowen is not required to sell any specific amount but acts as our sales agent using commercially reasonable efforts consistent with its normal trading and sales practices. Shares sold pursuant to the sales agreement will be sold pursuant to a shelf registration statement on Form S-3ASR (Registration No. 333-254661), which became automatically effective upon filing on March 24, 2021. Our common stock will be sold at prevailing market prices at the time of the sale; and as a result, prices may vary. As of June 30, 2022, we had sold 1,111,111 shares of common stock under the 2021 ATM Program. As of August 5, 2022, the Company had $49.7 million available under the ATM.

Future Funding Requirements

We believe that our available cash, cash equivalents and short-term investments and continued access to our term loan are sufficient to fund existing and planned cash requirements for the next 12 months. 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, 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 drug candidates in clinical trials is costly, and the timing of progress in these trials is uncertain. We cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our drug candidates or whether, or when, we may achieve profitability. Our future capital requirements will depend on many factors, including:

- the initiation, progress, timing, costs and results of clinical trials for our product candidates;
- the outcome, timing and cost of seeking and obtaining 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 establishing sales, marketing and distribution capabilities for our drug candidates if either candidate receives regulatory approval and we determine to commercialize it ourselves;
- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the diversion of healthcare resources away from the conduct of clinical trials as a result of the ongoing COVID-19 pandemic, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- the interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel, quarantines or social distancing protocols imposed or recommended by federal or state governments, employers and others in connection with the ongoing COVID-19 pandemic;

- the cost of disruptions 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, to meet our requirements as a public company.

We have no products approved for commercial sale and have not generated any product revenues from product sales to date. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our 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 payments under our agreements with them, we will not have any committed external source of liquidity.

Our material contractual obligations and commitments as June 30, 2022, primarily relate to our maturities of principal obligations under our long-term debt, operating leases for office space and equipment and capital leases for office equipment. As of June 30, 2022, we have $7.6 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, CMOs 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 year ended 2021. As of June 30, 2022, we had an accumulated deficit of $618.4 million. We anticipate that we will continue to incur significant losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase. As a result, we will need additional capital to fund our operations, which we may raise through a combination of the sale of equity, debt financings, or other sources, including potential collaborations. 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 drug 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 drug candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following is a summary of cash flows:

	Six Months Ended June 30,	
	2022	2021
	(In thousands)	
Net cash used in operating activities	$ (82,237)	$ (46,634)
Net cash used in investing activities	(41,766)	(7,548)
Net cash provided by financing activities	22,277	6,980
Net (decrease) in cash, cash equivalents and restricted cash	$ (101,726)	$ (47,202)

Net Cash Used in Operating Activities

Net cash used in operating activities for six months ended June 30, 2022 was $82.2 million and primarily consisted of our net loss of $74.7 million adjusted for non-cash items, including stock-based compensation of $7.4 million, a net decrease in operating assets and liabilities of $14.9 million, an investment accretion of $0.3 million, a non-cash operating lease expense of $0.2 million and non-cash interest expense associated with the term loan of $0.3 million. The increase in net loss was primarily due to increased clinical trial activities and CMC expenses. The net decrease in operating assets and liabilities primarily consisted of increased accounts payable of $0.8 million, increased prepayments and deposits of $4.9 million, increased other receivables or $13.1 million, increased accrued expenses and other liabilities of $2.3 million.

Net cash used in operating activities for the six months ended June 30, 2021, was $46.6 million and primarily consisted of our net loss of $50.6 million adjusted for non-cash items, including stock-based compensation of $6.0 million, a net decrease in operating

assets and liabilities of $2.8 million, an investment accretion of $0.3 million, non-cash operating lease expense of $0.2 million and non-cash interest expense associated with the term loan of $0.2 million. The increased net loss is primarily due to increased pre-clinical trial activities and CMC expenses partially offset by decreased pre-commercialization activities. The net decrease in operating assets and liabilities primarily consisted of increased accounts payable of $0.1 million, increased prepayments and deposits of $2.4 million, increased accrued expenses and other liabilities of $0.2 million and decreased deferred revenue of $0.8 million.

Net Cash Used in Investing Activities

Net cash used in investing activities for the six months ended June 30, 2022, was $41.8 million and was primarily due to the purchase of $164.6 million of available-for-sale marketable securities partially offset by the $122.8 million of proceeds from the maturities of available-for-sale securities.

Net cash used in investing activities for the six months ended June 30, 2021, was $7.5 million and was primarily due to the purchase of $126.5 million of available-for-sale marketable securities partially offset by the $119.0 million of proceeds from the maturities of available-for-sale securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2022, of $22.3 million was primarily due to proceeds from sales under the 2021 ATM Program, net of discounts and commissions of $19.4 million, proceeds from the exercise of stock options of $2.7 million and employee participation in our Employee Stock Purchase Plan of $0.2 million.

Net cash provided by financing activities for the six months ended June 30, 2021, of $7.0 million was primarily due to proceeds from sales under the 2021 ATM Program, net of discounts and commissions of $5.1 million, proceeds from the exercise of stock options of $1.7 million and employee participation in our Employee Stock Purchase Plan of $0.1 million.

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 June 30, 2022 we had cash and cash equivalents of $120.2 million, consisting of overnight investments, interest-bearing money market funds, commercial papers and short-term corporate bonds, and short-term investments of $246.6 million, consisting of commercial paper, and highly rated corporate bonds. 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 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 short-term maturities of our cash equivalents and the low risk profile of our short-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-term investments.

We also have exposure to market risk on our Loan Agreement with Hercules. Our Loan Agreement accrues interest from its date of issue at a variable interest rate equal to greater of (y) 9.25% and (z) 6.00% plus the Wall Street Journal prime rate. As of June 30, 2022, $20.0 million was outstanding under the Loan Agreement. The effect of a 100 basis points adverse change in market interest rates on our 2021 Loan Agreement, in excess of applicable minimum floors, on our interest expense would be approximately $0.4 million.

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), as of June 30, 2022. 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 Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission’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 judgement 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 June 30, 2022, that have materially affected, or are 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 June 30, 2022, 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

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Quarterly Report on Form 10-Q, including our financial statements and related notes hereto, before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. In these circumstances, the market price of our common stock could decline; and you may lose all or part of your investment. We cannot assure you that any of the events discussed below will not occur.

Summary of Selected Risks

Our business is subject to numerous risks and uncertainties, of which you should be aware before making a decision to invest in our securities. These risks and uncertainties include, among others, the following:

- Public health threats could have an adverse effect on our clinical trials, operations and financial results.
- We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any of our product candidates.
- We are currently developing several product candidates. If we are unable to successfully complete clinical development of, obtain regulatory approval for and commercialize our product candidates, our business prospects will be significantly harmed.
- Revumenib, formerly SNDX-5613, has undergone limited clinical testing and we may fail to show that the drug candidate is well tolerated and provides sufficient clinical benefit for patients.
- Axatilimab has undergone limited clinical testing and we may fail to show that this drug candidate is well tolerated and provides a sufficient clinical benefit for patients.
- Interim top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- Incyte may fail to perform its obligations as expected under the collaboration or may deprioritize its investment to further develop and commercialize axatilimab.
- If we are or our collaborators are unable to enroll patients in clinical trials, these clinical trials may not be completed on a timely basis or at all.
- The regulatory approval processes of the FDA and foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates could harm our business.
- Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community to be commercially successful.
- We rely on third-party suppliers to manufacture and distribute our clinical drug supplies for our product candidates, we intend to rely on third parties for commercial manufacturing and distribution of our product candidates and we expect to rely on third parties for manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates.
- Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

- Our 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.
- We have incurred net losses since our inception, except 2021, and anticipate that we will continue to incur net losses for the foreseeable future.
- We currently have no source of product revenue and may never achieve or maintain profitability.
- We will require additional capital to finance our planned operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of, or obtain regulatory approval for our existing product candidates or develop new product candidates.
- If we are unable to obtain or protect intellectual property rights, we may not be able to compete effectively in our market.
- We may not be able to protect our intellectual property rights throughout the world.
- The market price of our stock may be volatile and stockholders could lose all or part of their investment.
- We may sell additional equity or debt securities or enter into other arrangements to fund our operations, which may result in dilution to our stockholders and impose restrictions or limitations on our business.

Risks Related to Our Business and Industry

Public health threats could have an adverse effect on our clinical trials, operations and financial results.

We face various risks related to epidemics, pandemics, and other outbreaks, including the ongoing COVID-19 pandemic, including newly discovered strains of the virus, which could adversely affect our ongoing or planned business operations. In particular, the ongoing COVID-19 pandemic has resulted in quarantines, restrictions on travel and other business and economic disruptions. We cannot presently predict the scope and severity of any future business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the partners and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and adversely impacted.

The ongoing COVID-19 pandemic could continue to disrupt supply chain and operations, including associated delays in the manufacturing and supply of our products, which may affect our operations, including the conduct of clinical studies, or the ability of regulatory bodies to grant approvals or supervise our candidates and products, may further divert the attention and efforts of the medical community to coping with the COVID-19 and disrupt the marketplace in which we operate and may have a material adverse effects on our operations. COVID-19 may also affect our employees and employees and operations at suppliers that may result in delays or disruptions in supply. Even after the COVID-19 pandemic has subsided, we may continue to experience an adverse impact to our business as a result of COVID-19's global economic impact, including any recession that has occurred or may occur in the future and the uncertainty of the timing of the broader economic recovery to pre-pandemic levels.

We are currently developing several product candidates. If we are unable to successfully complete clinical development of, obtain regulatory approval for and commercialize our product candidates, our business prospects will be significantly harmed.

Our financial success will depend substantially on our ability to effectively and profitably commercialize our product candidates. In order to commercialize our product candidates, we will be required to obtain regulatory approvals by establishing that each of them is sufficiently safe and effective. The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- direct and indirect effects of the ongoing COVID-19 pandemic on various aspects and stages of the clinical development process, including the impact to expected site initiation, enrollment and participation in our clinical trials;
- significant reprioritization and diversion of healthcare resources away from the conduct of clinical trials as a result of the ongoing COVID-19 pandemic, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- timely completion of one or more of the pivotal Phase 2 cohorts of the AUGMENT-101 trial of revumenib in patients with relapsed/refractory acute leukemias;
- the timing of the progress and receipt of data from the AUGMENT-102 trial of revumenib in combination with chemotherapy in patients with R/R mutant nucleophosmin, NPM1, or mixed lineage leukemia rearranged, MLLr, acute leukemias;

- the timing of the progress and receipt of data from the combination trial of revumenib as part of the Leukemia & Lymphoma Society's Beat® AML Master Trial® and as a monotherapy as part of the Australian Leukemia and Lymphoma Group (ALLG) INTERCEPT Master Clinical Trial, each of which is not a Company sponsored trial;
- timely completion of the pivotal Phase 2 trial, AGAVE-201, of axatilimab in patients with chronic Graft Versus Host Disease, or cGVHD;
- the timing of the progress and receipt of data from the Phase 2 trial of axatilimab in idiopathic pulmonary fibrosis;
- the timing of the progress and receipt of data from the Phase 1 trial of revumenib in patients with unresectable metastatic microsatellite stable colorectal cancer;
- timely completion of any future clinical trials of revumenib and axatilimab;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel, quarantines or social distancing protocols imposed or recommended by federal or state governments, employers and others in connection with the ongoing COVID-19 pandemic or geopolitical tensions, such as the Russia Ukraine war;
- whether we are required by the FDA or foreign regulatory authorities to conduct additional clinical trials;
- the prevalence and severity of adverse drug reactions in any of our clinical trials;
- the ability to demonstrate safety and efficacy of our product candidates for their proposed indications and the timely receipt of necessary marketing approvals from the FDA and foreign regulatory authorities;
- successfully meeting the endpoints in the clinical trials of our product candidates;
- achieving and maintaining compliance with all applicable regulatory requirements;
- the potential use of our product candidates to treat various cancers and fibrotic diseases;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- the effectiveness of our own or our potential strategic collaborators' marketing, sales and distribution strategy and operations in the United States and abroad;
- the ability of our third-party contract manufacturers to produce trial supplies and to develop, validate and maintain a commercially viable manufacturing process that is compliant with cGMP;
- our ability to successfully commercialize our product candidates in the United States and abroad, whether alone or in collaboration with others; and
- our ability to enforce our intellectual property rights with respect to our product candidates.

If we fail to obtain regulatory approval for our product candidates, we will not be able to generate product sales, which will have a material adverse effect on our business and our prospects.

Revumenib has undergone limited clinical testing and we may fail to show that the drug is well tolerated and provides sufficient clinical benefit for patients.

Research suggests that certain acute leukemias, such as mixed lineage leukemia-rearranged, or MLLr, leukemias and nucleophosmin 1, or NPM1, mutant acute myeloid leukemia, or AML, are driven by the interaction of menin, a nuclear protein involved in transcription, with the N-terminus of MLL1 protein, a histone methyl transferase. In NPM1 mutant AML the interaction with menin occurs via the wild type MLL1 protein, and in MLLr acute leukemias, the interaction occurs via a mutant form of MLL1, a fusion protein known as MLLr. MLLr results from a rare, spontaneous fusion between the N-terminus of the mixed lineage leukemia protein-1, or MLL1, and a host of signaling molecules and nuclear transcription factors. This fusion produces an aberrant transcription program that drives leukemic transformation. In pre-clinical animal models, small molecule inhibitors of the menin-MLLr interaction, such as revumenib, which bind to, and block the interaction of menin with either MLLr or MLL1, have demonstrated deep and durable single agent treatment effects in multiple leukemic xenograft models harboring MLL fusions or NPM1 mutations. Our strategy for developing revumenib is to conduct a Phase 1/2 clinical trial in relapsed/refractory, or r/r, patients with MLLr and NPM1 mutant acute leukemias and determine if the observed clinical efficacy supports further development. The Phase 1 portion of the trial is assessing the safety, tolerability and pharmacokinetics of revumenib, and seeks to establish a recommended Phase 2 dose. It is open label, and we have released and may in the future release results from time to time that reflect small numbers of patients which may not be accurately predictive of safety or efficacy results later in the trial or in subsequent trials. The Phase 2 portion is evaluating the efficacy of revumenib across three expansion cohorts enrolling pediatric and adult patients with r/r MLLr acute lymphoblastic leukemia, or

ALL, r/r MLLr acute myeloid leukemia, or AML, and r/r NPM1 mutant AML. While we believe that we have established sufficient efficacy to warrant continued development in these indications, we have not yet sufficiently demonstrated a favorable risk-benefit of revumenib in patients.

Axatilimab has undergone limited clinical testing and we may fail to show that this drug is well tolerated and provides a clinical benefit for patients.

Preclinical studies suggest that CSF-1/CSF-1R signaling may be the key regulatory pathway involved in the expansion and infiltration of donor derived macrophages that mediate the disease processes involved in cGVHD and other fibrotic or inflammatory diseases. Nonclinical studies and analysis of patient samples indicates that the cGVHD inflammatory disease process is a result of a complex interaction between host and donor immune cells including B cells, and regulatory T cells with M2 differentiated macrophages in target tissue appearing to represent the common distal mediator of fibrosis. Therefore, we hypothesize that a CSF-1R signal inhibitor such as axatilimab may play a meaningful role as a monotherapy agent in the treatment of cGVHD. Our approach is to conduct a Phase 1/2 clinical trial with axatilimab in subjects with active cGVHD who have failed at least two prior lines of therapy. Following our end of Phase 1 meeting with the FDA, we have aligned on a regulatory path for axatilimab for the treatment of cGVHD and commenced a pivotal Phase 2 clinical trial, AGAVE-201, to assess the safety and efficacy of different doses and schedules of axatilimab for the treatment of patients with cGVHD. While we believe that we have established sufficient efficacy to warrant continued development in this indication, we have not yet sufficiently demonstrated a favorable risk-benefit of axatilimab in patients.

Interim top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim top-line or preliminary data from our clinical trials. For example, in April and December 2021, we announced interim data from our Phase 1/2 clinical trial of revumenib. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Preliminary or top-line data may include, for example, data regarding a small percentage of the patients enrolled in a clinical trial, and such preliminary data should not be viewed as an indication, belief or guarantee that other patients enrolled in such clinical trial will achieve similar results or that the preliminary results from such patients will be maintained. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of any of our product candidates, we or our collaborators must conduct extensive trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive and difficult to design and implement, can take many years to complete and is inherently uncertain as to the outcome. A failure of one or more trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not accurately predict the success of later trials, and interim results of a trial do not necessarily predict final results. For example, in May 2020, we announced that ECOG-ACRIN advised us that the E2112 trial did not achieve the primary endpoint of demonstrating a statistically significant overall survival benefit over hormone therapy alone in the Phase 3 clinical trial and we decided to deprioritize the entinostat program to focus resources on advancing the remainder of our pipeline. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials.

We are dependent upon our collaboration with Incyte to further develop and commercialize axatilimab. If we or Incyte fail to perform as expected the potential for us to generate future revenues under the collaboration could be significantly reduced, the development and/or commercialization of axatilimab may be terminated or substantially delayed, and our business could be adversely affected.

We are subject to numerous risks related to the Incyte Agreement to collaborate on the development and commercialization of axatilimab.

For example, there is no assurance that the parties will achieve any of the regulatory development or sales milestones, that we will receive any future milestone or royalty payments under the collaboration agreement. Incyte's activities may be influenced by, among other things, the efforts and allocation of resources by Incyte, which we cannot control. If Incyte does not perform in the manner we expect or fulfill its responsibilities in a timely manner, or at all, the clinical development, manufacturing, regulatory approval, and commercialization efforts related to axatilimab could be delayed or terminated. In addition, our license with Incyte may be unsuccessful due to other factors, including, without limitation, the following:

- Incyte may terminate the agreement for convenience upon 90 or 180 days' notice depending on whether or not the parties have commercialized axatilimab in an indication in the respective territory;
- Incyte may change the focus of its development and commercialization efforts or prioritize other programs more highly and, accordingly, reduce the efforts and resources allocated to axatilimab
- Incyte may, within its commercially reasonable discretion, choose not to develop and commercialize axatilimab in all relevant markets or for one or more indications, if at all; and
- if Incyte is acquired during the term of our collaboration, the acquirer may have competing programs or different strategic priorities that could cause it to reduce its commitment to our collaboration or to terminate the collaboration.

We cannot ensure that the potential strategic benefits and opportunities expected from this collaboration with be realized on our anticipated timeline or at all.

If we or our collaborators are unable to enroll patients in clinical trials, these clinical trials may not be completed on a timely basis or at all.

The timely completion of clinical trials largely depends on patient enrollment. Many factors affect patient enrollment, including:

- the impact of public health epidemics, such as the COVID-19 pandemic, or geopolitical tensions, such as the Russia Ukraine war;
- perception about the relative efficacy of our product candidates versus other compounds in clinical development or commercially available;
- evolving standard of care in treating cancer patients;
- the size and nature of the patient population, especially in the case of any orphan indications, we are pursuing;
- the number and location of clinical trial sites enrolled;
- competition with other organizations or our own clinical trials for clinical trial sites or patients;
- the eligibility and exclusion criteria for the trial;
- the design of the trial;
- ability to obtain and maintain patient consent; and
- risk that enrolled subjects will drop out before completion.

As a result of the above factors, there is a risk that our or our collaborators' clinical trials may not be completed on a timely basis or at all.

We may be required to relinquish important rights to and control over the development and commercialization of our product candidates to our current or future collaborators.

Our collaborations, including any future strategic collaborations we enter into, could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to issue equity securities that would dilute our existing stockholders' percentage of ownership;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;
- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing, sales and distribution of our product candidates, limiting our potential revenues from these products;

- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic collaborator's business strategy may also adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing, our product candidates.

We may explore strategic collaborations that may never materialize or may fail.

We periodically explore a variety of possible strategic collaborations in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations can be complicated and time consuming to negotiate and document. We may enter into strategic collaborations that we subsequently no longer wish to pursue, and we may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the numerous risks and uncertainties associated with establishing them.

The regulatory approval processes of the FDA and foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would harm our business.

The FDA and comparable foreign regulatory authorities extensively and rigorously regulate and evaluate the manufacture, testing, distribution, advertising and marketing of drug products prior to granting marketing approvals with respect to such products. This approval process generally requires, at minimum, testing of any product candidate in preclinical studies and clinical trials to establish its safety and effectiveness, and confirmation by the FDA and comparable foreign regulatory authorities that any such product candidate, and any parties involved in its manufacturing, testing and development, complied with current Good Manufacturing Practices, or GMP, current Good Laboratory Practices, or GLP, and current Good Clinical Practices, or GCP, regulations, standards and guidelines during such manufacturing, testing and development. The time required to obtain approval by the FDA and foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any of our product candidates and it is possible that we will never obtain regulatory approval for our existing product candidates or any future product candidates.

Due to the ongoing COVID-19 pandemic, it is possible that we could experience delays in the timing of our interactions with regulatory authorities due to absenteeism by governmental employees, inability to conduct planned physical inspections related to regulatory approval, or the diversion of regulatory authority efforts and attention to approval of other therapeutics or other activities related to COVID-19, which could delay anticipated approval decisions and otherwise delay or limit our ability to make planned regulatory submissions or obtain new product approvals. In addition, our product candidates could fail to receive regulatory approval from the FDA or foreign regulatory authorities for other reasons, including but not limited to:

- failure to demonstrate that our product candidates are effective for their proposed indication and have an acceptable safety profile;
- failure of clinical trials to meet the primary endpoints or level of statistical significance required for approval;
- failure to demonstrate that the clinical and other benefits of a product candidate outweigh any of its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- disagreement with the design, size, conduct or implementation of our or our collaborators' trials;
- the insufficiency of data collected from trials of our product candidates to support the submission and filing of an NDA, BLA or other submission or to obtain regulatory approval;

- failure to obtain approval of the manufacturing and testing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial product supplies or preclinical or clinical testing;
- receipt of a negative opinion from an advisory committee due to a change in the standard of care regardless of the outcome of the clinical trials; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or foreign regulatory authorities may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or may cause us to decide to abandon our development program. Even if we were to obtain approval, regulatory authorities may approve one or more of our product candidates for a more limited patient population than we request, may grant approval contingent on the performance of costly post-marketing trials, may impose a risk evaluation and mitigation strategy ("REMS") or foreign regulatory authorities may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of one or more of our product candidates and impose burdensome implementation requirements on us, or may approve it with a label that does not include the labeling claims necessary or desirable for the successful commercialization of one or more of our product candidates, all of which could limit our ability to successfully commercialize our product candidates.

Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community to be commercially successful.

Even if our product candidates receive regulatory approval, they may not gain sufficient market acceptance among physicians, patients, healthcare payors and others in the medical community. Our commercial success also depends on coverage and adequate reimbursement by third-party payors, including government payors, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our product candidates. The degree of market acceptance will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in trials;
- the timing of market introduction as well as competitive products;
- the clinical indications for which the product candidate is approved;
- acceptance of the product candidate as a safe and effective treatment by physicians, clinics and patients;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- pricing and the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- our willingness or ability to pay adequate rebates to payors or pharmacy benefit managers;
- relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing; and
- unfavorable publicity relating to our product candidates.

If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue to become or remain profitable.

We rely on third-party suppliers to manufacture and distribute our clinical drug supplies for our product candidates, we intend to rely on third parties for commercial manufacturing and distribution of our product candidates and we expect to rely on third parties for manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to manufacture or distribute preclinical, clinical or commercial quantities of drug substance or drug product, including our existing product candidates. While we expect to continue to depend on third-party manufacturers for the foreseeable future, we do not have direct control over the ability of these manufacturers to maintain adequate manufacturing capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. In additional, public health epidemics, such as the COVID-19 pandemic, may impact the ability of our existing or future manufacturers to perform their obligations to us.

We are dependent on our third-party manufacturers for compliance with cGMPs and for manufacture of both active drug substances and finished drug products. Facilities used by our third-party manufacturers to manufacture drug substance and drug product for commercial sale must be approved by the FDA or other relevant foreign regulatory agencies pursuant to inspections that will be conducted after we submit our NDA or relevant foreign regulatory submission to the applicable regulatory agency. If our third-party manufacturers cannot successfully manufacture materials that conform to our specifications and/or the strict regulatory requirements of the FDA or foreign regulatory agencies, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. Furthermore, these third-party manufacturers are engaged with other companies to supply and/or manufacture materials or products for such companies, which also exposes our third-party manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a third-party manufacturers' facility. If the FDA or a foreign regulatory agency does not approve these facilities for the manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative manufacturing facilities, which would impede or delay our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for our product candidates, they would be subject to ongoing requirements by the FDA and foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The FDA and foreign regulatory authorities will continue to monitor closely the safety profile of any product even after approval. If the FDA or foreign regulatory authorities become aware of new safety information after approval of a product candidate, they may require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on its indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including withdrawal of the product from the market or suspension of manufacturing, or we may recall the product from distribution. If we, or our third-party manufacturers, fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or refuse to permit the import or export of products.

The occurrence of any event or penalty described above may inhibit our ability to commercialize and generate revenue from the sale of our product candidates.

Advertising and promotion of any product candidate that obtains approval in the United States will is heavily scrutinized by the FDA's Office of Prescription Drug Promotion , the Department of Justice, the Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, other government agencies and the public. While physicians may prescribe products for off-label uses as the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. Companies may only share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. Violations, including promotion of our products for unapproved (or off-label) uses, may be subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the government. Additionally, foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval in their respective jurisdictions.

In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to administrative, civil and criminal penalties, damages, monetary fines, disgorgement, individual imprisonment, exclusion from participation in Medicare, Medicaid and other federal healthcare programs, curtailment or restructuring of our operations and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include, but are not limited to, the federal civil False Claims Act, which allows any individual to bring a lawsuit against an individual or entity, including a pharmaceutical or biopharmaceutical company on behalf of the federal government alleging the knowing submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment or approval by a federal program such as Medicare or Medicaid. These False Claims Act lawsuits against pharmaceutical or biopharmaceutical companies have increased significantly in number and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices, including promoting off-label drug uses involving fines in excess of $1.0 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from participation in Medicare, Medicaid and other federal and state healthcare programs. If we, or any partner that we may engage, do not lawfully promote our approved products, we may become subject to such litigation, which may have a material adverse effect on our business, financial condition and results of operations.

Our 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 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. 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 REMS 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.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States.

In order to market and sell our product candidates in other jurisdictions, we must obtain separate marketing approvals for those jurisdictions and comply with their numerous and varying regulatory requirements. We may not obtain foreign regulatory approvals on a timely basis, or at all. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, product reimbursement approvals must be secured before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant

delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Our failure to obtain approval of our product candidates by foreign regulatory authorities may negatively impact the commercial prospects of such product candidates and our business prospects could decline. Also, if regulatory approval for our product candidates is granted, it may be later withdrawn. If we fail to comply with the regulatory requirements in international jurisdictions and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential for our product candidates will be harmed and our business may be adversely affected.

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

Even if any of our product candidates received regulatory approval, such product candidates would face competition from other therapies in the relevant indication. For example, chronic graft versus host disease has historically been managed by off-label treatments. However, in the past five 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 axatilimab in patients diagnosed with cGVHD.

Revumenib is being developed for the treatment of relapsed/refractory adult and pediatric patients with MLLr ALL, MLLr AML and NPM1 mutant AML. At this time, 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. While there are other agents in early development for similar populations, revumenib has the potential to be the first defined therapy for patients with MLLr ALL, MLLr AML and/or NPM1 mutant AML.

Many of our existing or potential competitors 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 products 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 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 our product candidates if they receive regulatory approval;
- the price of 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 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 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.

The actions of Eddingpharm Investment Company Limited, or Eddingpharm, and any other current or future sublicensees could adversely affect our business.

We currently exclusively sublicense entinostat to Eddingpharm for development and commercialization in China and select Asian countries. In December 2021, Eddingpharm announced that the results of its multi-center, randomized, double-blinded, placebo-controlled Phase III registration trial showed that entinostat plus exemestane improved progression free survival, overall response rate and disease control rate, compared with placebo plus exemestane in patients with advanced HR positive, HER2 negative breast cancer

who had progressed after previous endocrine therapy. Nonetheless, it is possible that any future clinical trials conducted by Eddingpharm, including the forthcoming overall survival data in its ongoing Phase III registration trial, and trials by other current or future sublicensees in their respective jurisdictions could have negative results.

We are dependent on UCB Biopharma Sprl, or UCB, to comply with the terms of our license agreement for axatilimab.

Our commercial success also depends upon our ability to develop, manufacture, market and sell axatilimab. We have a worldwide, sublicenseable, exclusive license to axatilimab, an IND-ready anti-CSF-1R monoclonal antibody pursuant to a license agreement with UCB. Certain of the rights licensed to us under the UCB license agreement are in-licensed by UCB from third parties. We are dependent on UCB maintaining the applicable third-party license agreements in full force and effect, which may include activities and performance obligations that are not within our control. If any of these third-party license agreements terminate, certain of our rights to develop, manufacture, commercialize or sell axatilimab may be terminated as well. The occurrence of any of these events could adversely affect the development and commercialization of axatilimab, and materially harm our business.

Our employees, consultants and collaborators may engage in misconduct or other improper activities, including insider trading and non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, consultants, distributors, and collaborators may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates the regulations of the FDA and non-U.S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and abroad or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of pharmaceuticals, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

We must attract and retain additional highly skilled employees in order to succeed.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical, commercial and management personnel and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the pharmaceutical and biopharmaceutical industries is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop product candidates and our business will be limited.

Even if we commercialize our product candidates, they or any other product candidates that we develop, may become subject to unfavorable pricing regulations or third-party coverage or reimbursement practices, which could harm our business.

Our ability to successfully commercialize our existing product candidates, or any other product candidates that we develop, will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government healthcare programs, private health insurers, pharmacy benefit managers, managed care plans and other organizations. Third-party payors determine which medications they will cover and establish reimbursement

levels. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined rebates and discounts from list prices and are challenging the prices charged for medical products.

We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Limitation on coverage and reimbursement may impact the demand for, or the price of, and our ability to successfully commercialize any product candidates that we develop.

There may be significant delays in obtaining adequate coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, marketing, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

Private payors often follow decisions by the Centers for Medicare & Medicaid Services (“CMS”) regarding coverage and reimbursement to a substantial degree. However, one payor’s determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have an adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

The regulations that govern marketing approvals, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we may obtain marketing approval for our product candidates in a particular country, but be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment even if our product candidates obtain marketing approval.

There can be no assurance that our product candidates, if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication, that it will be considered cost effective by third-party payors, that coverage and an adequate level of reimbursement will be available, or that third-party payors’ reimbursement policies will not adversely affect our ability to sell our product candidates profitably.

Current and future legislation may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate for which we obtain marketing approval. For example, then President Obama signed into law the Affordable Care Act. Among other cost containment measures, the Affordable Care Act established an annual, nondeductible fee on any entity that manufactures or imports branded prescription drugs and biologic agents, a Medicare Part D coverage gap discount program, and a formula that increased the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. Moreover, prior to the U.S. Supreme Court ruling, January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that

include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, then President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not agree upon a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective as of 2013. Further legislation has extended the 2% reduction to 2031 with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional congressional action is taken. In January 2013, then President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries, Presidential executive orders, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that sought to implement several of the administration's proposals. As a result, the FDA released a final rule and guidance in September 2020, providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health & Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed by the Biden administration until January 1, 2023. On November 20, 2020, the CMS issued an interim final rule implementing the Trump administration's Most Favored Nation, or MFN, executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. On December 27, 2021, CMS issued a final rule that rescinded the interim final rule implementing the Trump administration's Most Favored Nation executive order. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to President Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. Congress is also considering additional health reform measures. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

It is also possible that additional governmental action is taken in response to the COVID-19 pandemic. We cannot predict the likelihood, nature or extent of government regulations that may arise from future legislation, administrative or executive action. We expect that the Affordable Care Act, as well as other current or future healthcare reform measures may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. This could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

We do not currently have any sales, marketing or distribution experience or infrastructure.

In order to market any approved product candidate in the future, we must build our sales, marketing, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, as we do not presently have all of these capabilities. To develop our internal sales, distribution and marketing capabilities, we must invest significant amounts of financial and management resources in the future. For drugs where we decide to perform sales, marketing and distribution functions ourselves, we could face a number of challenges, including that:

- we may not be able to attract and build an effective marketing or sales organization;
- the cost of establishing, training and providing regulatory oversight for a marketing or sales force may not be justifiable in light of the revenues generated by any particular product;
- our direct or indirect sales and marketing efforts may not be successful; and
- there are significant legal and regulatory risks in drug marketing and sales that we have never faced, and any failure to comply with all legal and regulatory requirements for sales, marketing and distribution could result in enforcement action by the FDA or other authorities that could jeopardize our ability to market the product or could subject us to substantial liabilities.

Alternatively, we may rely on third parties to launch and market our product candidates, if approved. We may have limited or no control over the sales, marketing and distribution activities of these third parties and our future revenue may depend on the success of these third parties. Additionally, if these third parties fail to comply with all applicable legal or regulatory requirements, the FDA or another governmental agency could take enforcement action that could jeopardize their ability and our ability to market our product candidates.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of our product candidates.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or other products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

While we currently hold trial liability insurance coverage consistent with industry standards, this may not adequately cover all liabilities that we may incur. We also may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise in the future. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates, but we may be unable to obtain commercially reasonable product liability insurance. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business and financial condition.

Our relationships with healthcare providers, customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations as well as privacy and data security laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, fines, exclusion from participation in government healthcare programs, curtailments or restrictions of our operations, administrative burdens and diminished profits and future earnings.

Healthcare providers, including physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct clinical research and market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include, but are not limited to, the following:

- the federal Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or

arranging for or recommending purchase, lease or order, or any good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal false claims, including the federal civil False Claims Act, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, and civil monetary penalties laws, which prohibit knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, also imposes obligations on covered entities, including certain health care providers, health plans and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to CMS information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require manufacturers to report pricing information regarding certain drugs; state and local laws that require the registration of pharmaceutical sales representatives; state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and federal, state, and foreign laws that govern the privacy and security of other personal information, including federal and state consumer protection laws, state data security laws, and data breach notification laws (a data breach affecting sensitive personal information, including health information, could result in significant legal and financial exposure and reputational damages).

Efforts to ensure that our business arrangements with third parties and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any physician or other healthcare provider or entity with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third-party vendors who may or could have access to our computer networks, our confidential information or the confidential information of third parties that is in our possession. In addition, those third-party vendors may in turn subcontract or outsource some of their responsibilities to other parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious, internal and external attacks on our technology environment. In addition, due to the COVID-19 pandemic, we have enabled substantially all of our employees to work remotely, which may make us more vulnerable to cyberattacks. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. The prevalent use of mobile devices further increases the risk of data security incidents.

Significant disruptions of our, our third-party vendors’ and/or business partners’ information technology systems or other similar data security incidents could adversely affect our business operations and/or result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

There is no way of knowing with certainty whether we have experienced any data security incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the ways that they conceal access to systems. Many companies that have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use or disclosure of personal information, including but not limited to personal information regarding employees or clinical trial patients, could disrupt our business, harm our reputation, compel us to comply with applicable federal and/or state breach notification laws and foreign law equivalents, subject us to time consuming, distracting and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us and result in significant legal and financial exposure and/or reputational harm. Any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality or data security-related legal or other obligations to third parties, or any further security incidents or other inappropriate access events resulting in the unauthorized access, release or transfer of sensitive information, which could include personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators or current and potential partners, to lose trust in us or we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations, which could materially and adversely affect our business and prospects. Moreover, data security incidents and other inappropriate access can be difficult to detect. Any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or security incidents. Further, because of the work-from-home policies we implemented due to COVID-19, information that is normally protected, including company confidential information, may be less secure.

Risks Related to Our Financial Position and Capital Needs

We have incurred net losses since our inception, except 2021, and anticipate that we will continue to incur net losses for the foreseeable future.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety

profile, gain regulatory approval or be commercially viable. We are a clinical stage biopharmaceutical company with limited operating history. We have no products approved for commercial sale and have not generated any product revenues to date, and we continue to incur significant research and development and other expenses related to our ongoing operations and clinical development of our product candidates. As a result, we are not and have never been profitable and have incurred losses in each period since our inception in 2005, except in 2021.

For the quarter ended June 30, 2022, we reported a net loss attributable to stockholders of $37.6 million. As of June 30, 2022, we had an accumulated deficit of $618.4 million, which included non-cash charges for stock-based compensation, preferred stock accretion and extinguishment charges. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our pre-commercialization activities for, and our research and development of, and seek regulatory approvals for, our product candidates. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of growth of our expenses and our ability to generate revenues, if any. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We currently have no source of product revenue and may never achieve or maintain profitability.

Our ability to generate product revenue and become profitable depends upon our ability to successfully commercialize our product candidates. We do not anticipate generating revenue from the sale of our product candidates for the foreseeable future. Our ability to generate future product revenue also depends on a number of additional factors, including, but not limited to, our ability to:

- successfully complete the research and clinical development of, and receive regulatory approval for, our product candidates;
- launch, commercialize and achieve market acceptance of our product candidates, and if launched independently, successfully establish a sales, marketing and distribution infrastructure;
- continue to build a portfolio of product candidates through the acquisition or in-license of products, product candidates or technologies;
- initiate preclinical and clinical trials for any additional product candidates that we may pursue in the future;
- establish and maintain supplier and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- establish, maintain, expand and protect our intellectual property rights; and
- attract, hire and retain additional qualified personnel.

In addition, because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of increased expenses, and if or when we will achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide to or are required by the FDA or foreign regulatory authorities to perform studies or trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing our current product candidates and any other product candidates we may develop.

Even if we generate revenues from the sale of our product candidates, we may not become profitable and may need to obtain additional funding to continue operations or acquire additional products that will require additional funding to develop them. If we fail to become profitable or do not sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations or even shut down.

We will require additional capital to finance our planned operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of, or obtain regulatory approval for our existing product candidates or develop new product candidates.

Our operations have consumed substantial amounts of cash since our inception, primarily due to our research and development efforts. We expect our research and development expenses to increase substantially in connection with our ongoing and planned activities. We believe that our existing cash, cash equivalents and short-term investments will fund our projected operating expenses and capital expenditure requirements for at least the next 12 months. Unexpected circumstances may cause us to consume capital more rapidly than we currently anticipate, including as a result of COVID-19's global economic impact, including any recessions that has occurred or may occur in the future. In addition, we may discover that we need to conduct additional activities that exceed our current budget to achieve appropriate rates of patient enrollment, which would increase our development costs.

In any event, we will require additional capital to continue the development of, obtain regulatory approval for, and to commercialize our existing product candidates and any future product candidates. Any efforts to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. The COVID-19 pandemic has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we do not raise additional capital when required or on acceptable terms, we may need to:

- delay, scale back or discontinue the development or commercialization of our product candidates or cease operations altogether;
- seek strategic alliances for our existing product candidates on terms less favorable than might otherwise be available; or
- relinquish, or license on unfavorable terms, our rights to technologies or any future product candidates that we otherwise would seek to develop or commercialize ourselves.

If we need to conduct additional fundraising activities and we do not raise additional capital in sufficient amounts or on terms acceptable to us, we may be unable to pursue development and commercialization efforts, which will harm our business, operating results and prospects.

Our future funding requirements, both short- and long-term, will depend on many factors, including:

- the initiation, progress, timing, costs and results of clinical trials of our product candidates;
- the outcome, timing and cost of seeking and obtaining 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 coverage and reimbursement by third-party payors, which may require additional trials to address pharmacoeconomic benefit;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates if any candidate receives regulatory approval and we determine to commercialize it ourselves;
- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the effect of competing technological and market developments;
- our need to acquire and implement additional internal systems and infrastructure, including compliance and financial and reporting systems, as we grow our company; and
- business interruptions resulting from pandemics and public health emergencies, including those related to the ongoing COVID-19 pandemic, geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires.

If we cannot expand our operations or otherwise capitalize on our business opportunities because we cannot secure sufficient capital, our business, financial condition and results of operations could be materially adversely affected.

The terms of our loan and security agreements place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

Our loan and security agreement, or the Loan Agreement, with Hercules Capital, Inc., or Hercules, for aggregate maximum borrowings of up to $80.0 million, or the Credit Facility, is collateralized by substantially all of our and our subsidiaries personal property and other assets, other than our intellectual property. As of June 30, 2022, the outstanding principal balance under the Credit Facility was $20.0 million. The Credit Facility contains customary representations, warranties, affirmative and negative covenants and events of default applicable to us and our subsidiaries.

If we default under the Credit Facility, Hercules may accelerate all of our repayment obligations and exercise all of their rights and remedies under the Credit Facility and applicable law, potentially requiring us to renegotiate our agreement on terms less favorable to us. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Hercules could declare a default upon the occurrence of any event, among others, that they interpret as a material adverse effect or a change of control as delineated under the Credit Facility, payment defaults, or breaches of covenants thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Changes in tax laws or regulations could materially adversely affect our company.

New tax laws or regulations could be enacted at any time, and existing tax laws or regulations could be interpreted, modified or applied in a manner that is adverse to us, which could adversely affect our business and financial condition. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or the Tax Act, enacted many significant changes to the U.S. tax laws, including changes in corporate tax rates, which collectively may impact the utilization of our NOLs and other deferred tax assets, the deductibility of expenses, and the taxation of foreign earnings. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, or any newly enacted federal tax legislation. The impact of changes under the Tax Act, the CARES Act, or future reform legislation could increase our future U.S. tax expense and could have a material adverse impact on our business and financial condition.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history. We do not expect to become profitable in the near future, and we may never achieve profitability. Unused losses generally are available to be carried forward to offset future taxable income, if any. Under Sections 382 and 383 of the Code if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change taxable income or taxes may be limited. We last completed an analysis through December 31, 2020 and determined that on March 30, 2007, August 21, 2015, and May 4, 2020, ownership changes had occurred. We may also experience ownership changes in the future as a result of shifts in our stock ownership, some of which may be outside of our control. As a result, our ability to use our pre-change NOLs to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Risks Related to Intellectual Property

If we are unable to obtain or protect intellectual property rights, we may not be able to compete effectively in our market.

Our success depends in significant part on our and our licensors' and licensees' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others. We have filed patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have discovered. We have also licensed from third parties rights to patent portfolios. Some of these licenses give us the right to prepare, file and prosecute patent applications and maintain and enforce patents we have licensed, and other licenses may not give us such rights.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors or licensees will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors or licensees fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' or licensees' patent rights are highly uncertain. Our and our licensors'

or licensees' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors or licensees to narrow the scope of the claims of our or our licensors' or licensees' pending and future patent applications, which may limit the scope of patent protection that may be obtained. It is possible that third parties with products that are very similar to ours will circumvent our or our licensors' or licensees' patents by means of alternate designs or processes. We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidate, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidate or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our products. Our and our licensors' or licensees' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Entinostat composition of matter U.S. Patent RE39,754, which we licensed from Bayer, covers the chemical entity of entinostat and any crystalline or non-crystalline form of entinostat and expired in September 2017.

The portfolio we licensed from Bayer also includes U.S. Patent 7,973,166, or the '166 patent, which covers a crystalline polymorph of entinostat which is referred to as crystalline polymorph B, the crystalline polymorph used in the clinical development of entinostat. Many compounds can exist in different crystalline forms. A compound which in the solid state may exhibit multiple different crystalline forms is called polymorphic, and each crystalline form of the same chemical compound is termed a polymorph. A new crystalline form of a compound may arise, for example, due to a change in the chemical process or the introduction of an impurity. Such new crystalline forms may be patented. The '166 patent expires in 2029. On March 7, 2014, our licensor Bayer applied for reissue of the '166 patent. The reissue application seeks to add three inventors not originally listed on the '166 patent. The reissue application does not seek to amend the claims issued in the '166 patent. On April 28, 2015, the United States Patent and Trademark Office, or the USPTO, re-issued the '166 patent as U.S. patent RE45,499. RE45,499 reissued with the same claims originally issued in the '166 patent and the list of inventors on RE45,499 now lists the additional three inventors that were not included on the '166 patent. The '166 patent has now been surrendered in favor of RE45,499. RE45,499 has the same term as the initial term of the '166 patent, which expires in August 2029. After expiry of RE39,754, which occurred in September 2017, a competitor may develop a competing polymorphic form other than based on polymorph B, which could compete with polymorph B.

In spite of our efforts and efforts of our licensor, we may not be successful in defending the validity of the claims of the RE45,499 reissue patent or any of its foreign counterparts. If the claims of the '166 patent or any of its counterparts are found to be invalid by a competent court, we may not be able to effectively block entry of generic versions of our entinostat crystalline polymorph B candidate products into markets where the crystalline polymorph B patent claims are found to be invalid. Additionally, even if we submit an NDA before the expiration of U.S. Patent RE45,499 and are successful in obtaining an extension of the term of U.S. Patent RE45,499 based on FDA regulatory delays, such extension will only extend the term of RE45,499 for a few additional years (up to a maximum of five additional years for patent claims covering a new chemical entity).

The portfolio that we licensed from UCB includes granted patents and applications with pending claims directed to the composition of matter of axatilimab (a humanized, full-length IgG4 (kappa light chain) antibody with high affinity for the CSF-1R) as well as claims directed to methods of use of axatilimab. There is no guarantee that any further patents will be granted based on the pending applications we licensed from UCB or even if one or more patents are granted that the claims issued in those patents would cover axatilimab or methods of using axatilimab. Based on the priority date and filing date of the applications in the portfolio we licensed from UCB, we expect that additional patents, if any, granted based on the currently pending applications would expire in 2034. The actual term of any patents granted based on the pending applications we licensed from UCB can only be determined after such patents are actually granted.

The portfolio that we licensed from Vitae Pharmaceuticals, which is now a subsidiary of AbbVie Inc., or AbbVie, includes granted patents and applications with pending claims directed to inhibitors of the interaction of menin with MLL and MLL fusion proteins, pharmaceutical compositions containing the same, and their use in the treatment of cancer and other diseases mediated by the

menin-MLL interaction. There is no guarantee that any additional patents will be granted based on the pending applications that we licensed from AbbVie or even if one or more patents are granted that the claims issued in those patents would cover the desired lead compounds, compositions, and methods of use thereof. Based on the priority date and filing date of the applications in the portfolio that we licensed from AbbVie, we expect that a patent, if any, granted based on the currently pending applications would expire in 2037. The actual term of any patents granted based on the pending applications that we licensed from AbbVie can only be determined after such patents are actually granted.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world is prohibitively expensive, and our or our licensors' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors' inventions in countries outside the United States, or from selling or importing products made using our and our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our licensors to stop the infringement of our and our licensors' patents or marketing of competing products in violation of our and our licensors' proprietary rights generally. Proceedings to enforce our and our licensors' patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our and our licensors' patents at risk of being invalidated or interpreted narrowly and our and our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuits that we or our licensors initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for, and launch generic versions of our products. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

If we breach the UCB license agreement related to axatilimab or if the UCB license agreement is otherwise terminated, we could lose the ability to continue the development and commercialization of axatilimab.

Our commercial success depends upon our ability to develop, manufacture, market and sell axatilimab. Subject to the achievement of certain milestone events, we may be required to pay UCB up to $119.5 million in one-time development and regulatory milestone payments over the term of the UCB license agreement. If we or any of our affiliates or sublicensees commercializes axatilimab, we will also be obligated to pay UCB low double-digit royalties on sales, subject to reduction in certain circumstances, as well as up to an aggregate of $250 million in potential one-time sales-based milestone payments based on achievement of certain annual sales thresholds. Under certain circumstances, we may be required to share a percentage of non-royalty income from sublicensees, subject to certain deductions, with UCB.

Either party may terminate the UCB license agreement in its entirety or with respect to certain countries in the event of an uncured material breach by the other party. Either party may terminate the UCB license agreement if voluntary or involuntary bankruptcy proceedings are instituted against the other party, if the other party makes an assignment for the benefit of creditors, or upon the occurrence of other specific events relating to the insolvency or dissolution of the other party. UCB may terminate the UCB license agreement if we seek to revoke or challenge the validity of any patent licensed to us by UCB under the UCB license agreement or if we procure or assist a third party to take any such action.

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. We cannot determine the date on which our royalty payment obligations to UCB would expire because no commercial sales of axatilimab have occurred and the last-to-expire relevant patent covering axatilimab in a given country may change in the future.

If the UCB license agreement is terminated, we would not be able to develop, manufacture, market or sell axatilimab and would need to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all.

If we breach the license agreement related to revumenib or if the license agreement is otherwise terminated, we could lose the ability to continue the development and commercialization of revumenib.

Our commercial success depends upon our ability to develop, manufacture, market and sell revumenib. Subject to the achievement of certain milestone events, we may be required to pay Vitae, which is now a subsidiary of AbbVie, up to $99 million in one-time development and regulatory milestone payments over the term of the AbbVie license agreement. In the event that we or any of our affiliates or sublicensees commercializes revumenib, we will also be obligated to pay AbbVie low single to low double-digit royalties on sales, subject to reduction in certain circumstances, as well as up to an aggregate of $70 million in potential one-time sales-based milestone payments based on achievement of certain annual sales thresholds. Under certain circumstances, we may be required to share a percentage of non-royalty income from sublicensees, subject to certain deductions, with AbbVie.

Either party may terminate the license agreement in its entirety or with respect to certain countries in the event of an uncured material breach by the other party. Either party may terminate the license agreement if voluntary or involuntary bankruptcy proceedings are instituted against the other party, if the other party makes an assignment for the benefit of creditors, or upon the occurrence of other specific events relating to the insolvency or dissolution of the other party. AbbVie may terminate the license agreement if we seek to revoke or challenge the validity of any patent licensed to us by AbbVie under the license agreement or if we procure or assist a third party to take any such action.

Unless terminated earlier in accordance with its terms, the 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. We cannot determine the date on which our royalty payment obligations to AbbVie would expire because no commercial sales of revumenib have occurred and the last-to-expire relevant patent covering revumenib in a given country may change in the future.

If the license agreement is terminated, we would not be able to develop, manufacture, market or sell revumenib and would need to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all.

If we breach our license agreement with Bayer related to entinostat or if the license agreement is otherwise terminated, we could lose the ability to continue the development and commercialization of entinostat.

We have a license, development and commercialization agreement, or the Bayer license agreement, with Bayer pursuant to which we obtained a worldwide, exclusive license to develop and commercialize entinostat and any other products containing the same active ingredient. The Bayer license agreement, as amended, permits us to use entinostat or other licensed products under the Bayer license agreement for the treatment of any human disease, and we are obligated to use commercially reasonable efforts to develop, manufacture and commercialize licensed products for all commercially reasonable indications.

We are obligated to pay Bayer up to approximately $50 million in the aggregate upon obtaining certain milestones in the development and marketing approval of entinostat, assuming that we pursue at least two different indications for entinostat or any other licensed product under the Bayer license agreement. We are also obligated to pay Bayer up to $100 million in aggregate sales milestones, and a tiered, single-digit royalty on net sales by us, our affiliates and sublicensees of entinostat and any other licensed products under the Bayer license agreement. We are obligated to pay Bayer these royalties on a country-by-country basis for the life of the relevant licensed patents covering such product or 15 years after the first commercial sale of such product in such country, whichever is longer. We cannot determine the date on which our royalty payment obligations to Bayer would expire because no commercial sales of entinostat have occurred and the last-to-expire relevant patent covering entinostat in a given country may change in the future.

The Bayer license agreement will remain in effect until the expiration of our royalty obligations under the agreement in all countries. Either party may terminate the Bayer license agreement in its entirety or with respect to certain countries in the event of an uncured material breach by the other party. Either party may terminate the Bayer license agreement if voluntary or involuntary bankruptcy proceedings are instituted against the other party, if the other party makes an assignment for the benefit of creditors, or upon the occurrence of other specific events relating to the insolvency or dissolution of the other party. Bayer may terminate the Bayer

license agreement if we seek to revoke or challenge the validity of any patent licensed to us by Bayer under the Bayer license agreement or if we procure or assist a third party to take any such action.

If the Bayer license agreement is terminated, we would not be able to develop, manufacture, market or sell entinostat and would need to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents and patents we and our licensors or collaborators may obtain in the future. In view of recent developments in U.S. patent laws, in spite of our efforts and the efforts of our licensors, we may face difficulties in obtaining allowance of our biomarker based patient selection patent claims or if we are successful in obtaining allowance of our biomarker based patient selection claims, we or our licensor may be unsuccessful in defending the validity of such claims if challenged before a competent court.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the America Invents Act, was signed into law. The America Invents Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the American Invents Act, and many of the substantive changes to patent law associated with the America Invents Act and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the America Invents Act will have on the operation of our business. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could harm our business and financial condition.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would harm our business.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have an adverse effect on the success of our business and on our stock price.

Third parties may infringe our or our licensors' patents or misappropriate or otherwise violate our or our licensors' intellectual property rights. In the future, we or our licensors may initiate legal proceedings to enforce or defend our or our licensors' intellectual property rights, to protect our or our licensors' trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us or our licensors to challenge the validity or scope of intellectual property rights we own or control. The proceedings can be expensive and time-consuming and many of our or our licensors' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors can. Accordingly, despite our or our licensors' efforts, we or our licensors may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect our rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable or may refuse to stop the other party from using the technology at issue

on the grounds that our or our licensors' patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our or our licensors' patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Third-party preissuance submission of prior art to the USPTO, or opposition, derivation, reexamination, *inter partes* review or interference proceedings, or other preissuance or post-grant proceedings in the United States or other jurisdictions provoked by third parties or brought by us or our licensors or collaborators may be necessary to determine the priority of inventions with respect to our or our licensors' patents or patent applications. An unfavorable outcome could require us or our licensors to cease using the related technology and commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors a license on commercially reasonable terms or at all. Even if we or our licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors. In addition, if the breadth or strength of protection provided by our or our licensors' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this process. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a downward effect on the price of shares of our common stock.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain and could have an adverse effect on the success of our business.

Third parties may initiate legal proceedings against us or our licensors or collaborators alleging that we or our licensors or collaborators infringe their intellectual property rights or we or our licensors or collaborators may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, reexaminations, *inter partes* reviews or derivation proceedings before the United States or other jurisdictions. These proceedings can be expensive and time-consuming and many of our or our licensors' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can.

An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, for some of our in-licensed patents and patent applications, we do not have access to every patent assignments or employee agreements demonstrating that all inventors have assigned their rights to the inventions or related patents. As a result, we may be subject to claims of ownership by such inventors.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, third-party manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Risks Related to Ownership of Our Common Stock and Other General Matters

The market price of our stock may be volatile and you could lose all or part of your investment.

The trading price of our common stock is highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this report, these factors include:

- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- results of trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our product candidates or clinical development programs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry, political and market conditions, including, but not limited to the ongoing impact of the COVID-19 pandemic and the Russia Ukraine war.

In addition, the stock market in general, and the Nasdaq Global Select Market, or Nasdaq, and biopharmaceutical companies in particular, frequently experiences extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of such companies, including recently in connection with the ongoing COVID-19 pandemic, which resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the COVID-19 pandemic, may negatively affect the market price of our common stock, regardless of our

actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and negative impact on the market price of our common stock.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. Similarly, the current Russia Ukraine war has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Inflation can adversely affect us by increasing our costs, including personnel costs (wages). Any significant increases in inflation and related increase in interest rates could have a material adverse effect on our business, results of operations and financial condition

We may sell additional equity or debt securities or enter into other arrangements to fund our operations, which may result in dilution to our stockholders and impose restrictions or limitations on our business.

Until we can generate a sufficient amount of profit from our products, if ever, we expect to finance future cash needs through public or private equity or debt offerings. If we raise additional funds through the issuance of additional equity or debt securities, it may result in dilution to our existing stockholders and/or increased fixed payment obligations. For example, during 2021, we sold a total of 3,802,144 shares of our common stock and pre-funded warrants to purchase 1,142,856 shares of our common stock. The pre-funded warrants are exercisable into shares of common stock for $0.0001 per share. The shares of common stock into which the warrants may be exercised are considered outstanding for the purposes of computing earnings per share. As of June 30, 2022, we had 3,975,024 pre-funded warrants outstanding. Additionally, in April 2022, the Company sold 1,111,111 common shares under the 2021 ATM Program, with net proceeds of approximately $19.4 million. The issuance of these shares of our common stock resulted, and any future issuance pursuant to the exercise of the outstanding pre-funded warrants will result, in dilution to our stockholders.

We may also seek additional funding through government or other third-party funding and other collaborations, strategic alliances and licensing arrangements. These financing activities may have an adverse impact on our stockholders' rights as well as on our operations, and such additional funding may not be available on reasonable terms, if at all. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. For example, on December 22, 2021, we entered into Amendment No. 1 to our Loan Agreement with Hercules, which provided for increased aggregate maximum borrowings of up to $80.0 million in multiple tranches. Our only borrowings to date under the Loan Agreement are the first tranche of $20.0 million, which we drew upon on February 7, 2020. Borrowings under the Loan Agreement are collateralized by substantially all of our and our subsidiaries personal property and other assets, other than our intellectual property. In addition, the Loan Agreement includes customary affirmative and restrictive covenants and representations and warranties, including a covenant against the occurrence of a "change in control," financial reporting obligations, and certain limitations on indebtedness, liens (including a negative pledge on intellectual property and other assets), investments, distributions (including dividends), collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, and deposit accounts.

Additionally, if we seek funds through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us. Any of these events could significantly harm our business, financial condition and prospects.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If no or few securities or industry analysts continue coverage of us, the trading price for our stock could be negatively impacted. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our trials or operating results fail to meet the expectations of analysts, our stock price could decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant influence control over matters subject to stockholder approval.

As of June 30, 2022, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 33.8% of our outstanding voting stock and options. As a result, these stockholders will continue to have a significant influence over all matters requiring stockholder approval. For example, these stockholders may be able to influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile, and in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Commencing after the filing of our initial annual report on Form 10-K, we have been required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

Beginning with our annual report on Form 10-K for the year ending December 31, 2021, we were required to include an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. Our compliance with Section 404 requires that we incur substantial expense and expend significant management efforts. We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the Nasdaq Global Select Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would benefit our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders and the ability of our board of directors to issue preferred stock without stockholder approval. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by

making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under the DGCL, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change of control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Default upon Senior Securities

None.

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	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).
10.1†	Mutual Release and Settlement Agreement by and between the Company and UCB Biopharma SRL, dated as of June 6, 2022.
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	Financial statements from the Quarterly Report on Form 10-Q of Syndax Pharmaceuticals, Inc. for the quarter ended June 30, 2022, formatted in iXBRL (Inline eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets; (ii) the Condensed Consolidated Statements of Comprehensive Loss; (iii) the Condensed Consolidated Statements of Cash Flows; and (iv) Notes to Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

† Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601(b)(10)(iv). The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.
* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), 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: August 8, 2022

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)

Exhibit 10.1

Certain identified information marked with [***] has been excluded from the exhibit because it is both not material and is the type that the registrant treats as private or confidential.

EXECUTION COPY

MUTUAL RELEASE AND SETTLEMENT AGREEMENT

This Mutual Release and Settlement Agreement (the "**Settlement Agreement**"), effective as of the last date signed below (the "**Settlement Date**"), is made and entered into by and between:

(i) UCB Biopharma SRL, a Belgian corporation with offices located at Allée de la Recherche 60, B-1070 Brussels, Belgium ("**UCB**"); and

(ii) Syndax Pharmaceuticals, Inc., a Delaware corporation with offices located at 35 Gatehouse Drive, Building D, Floor 3, Waltham, Massachusetts 02451, USA ("**Syndax**").

Each of UCB and Syndax are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**", and any capitalized terms which are used but not expressly defined in this Settlement Agreement shall have their respective meanings as set forth in the License Agreement dated July 01, 2016, between UCB and Syndax, as amended (the "**License Agreement**").

Recitals

A. Under the terms of the License Agreement, Syndax is developing the Compound (which is a CSF1R specific antibody discovered and initially developed by UCB, and is referred to variously as UCB6352, SNDX-6352 and by the INN name axatilimab);

B. On [***], Syndax informed UCB that [***], and that Syndax believed [***] constituted achievement of Milestone Event #[***] under Section 4.2 of the License Agreement, identified as "[***]", and requested that UCB send an invoice to Syndax for the milestone payment triggered by achievement of Milestone Event #[***];

C. On [***], UCB sent to Syndax an invoice (identified as invoice no. [***]) in the amount of the milestone payment triggered by achievement of Milestone Event #[***], which amount was subsequently paid by Syndax to UCB (the "**March 2021 Payment**")];

D. Syndax and Incyte Corporation, a Delaware corporation with offices at 1801 Augustine Cut-Off, Wilmington, Delaware 19803, USA ("**Incyte**"), signed a Collaboration and License Agreement, dated September 24, 2021 (the "**Syndax-Incyte Agreement**"), to establish a global collaboration for the further worldwide development and commercialization of axatilimab, and which granted Incyte the exclusive commercialization rights for products containing axatilimab, but subject to certain co-commercialization rights which were retained by Syndax in the U.S.;

E. Upon the closing of the Syndax-Incyte Agreement, announced on December 09, 2021, Syndax received a one-time, non-creditable, non-refundable upfront license fee from Incyte in the

amount of $117,000,000 (the "**Upfront Payment**") and consummated the transactions contemplated by the Securities Purchase Agreement by and between Incyte and Syndax dated September 24, 2021 (the "**Equity Investment**"), pursuant to Sections 8.1(a) and 8.1(b), respectively, of the Syndax-Incyte Agreement (the Upfront Payment and Equity Investment being collectively referred to as, the "**Upfront Consideration"**);

F. Following the closing of the Syndax-Incyte Agreement, the Parties engaged in a series of communications with respect to [***] (the "**Dispute**"); and

G. The Parties have now agreed to finally resolve and settle the Dispute on the terms and conditions which are set forth in this Settlement Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. One-Time Payment to UCB

The Parties acknowledge that the licenses and other rights which were granted to Incyte under the terms of the Syndax-Incyte Agreement constitute a sublicense of the rights granted by UCB to Syndax under the terms of the License Agreement and that Incyte is a Sublicensee for all purposes of the License Agreement. Syndax shall make a one-time, non-refundable and non-creditable payment to UCB in the amount of $[***]; provided that Syndax shall be entitled to credit and offset against such payment the full amount [***] of the March 2021 Payment, such that the net amount which shall be due and payable to UCB under this Section 1 shall be $5,750,000. The payment of the net amount provided for in this Section 1 shall be due and payable to UCB under the terms of Sections 4.9 and 4.11 of the License Agreement and within [***] business days after Syndax's receipt of a written invoice from UCB for such amount, such payment representing further consideration for the licenses granted to Syndax under the terms of the License Agreement (and the sublicenses thereunder which were granted to Incyte under the terms of the Syndax-Incyte Agreement).

2. Amendment of License Agreement

2.1 Definition of Sublicense Consideration. Notwithstanding anything in Section [***] of the License Agreement to the contrary, the Parties hereby agree that [***].

2.2 Additional Defined Terms. Article 1 of the License Agreement is hereby amended to include: (i) the defined terms "[***]", "**Syndax-Incyte Agreement**" and "**Upfront Consideration**", each of which shall have their respective meanings as set forth in this Settlement Agreement; (ii) the defined term "**Incyte**", which shall mean Incyte Corporation, a Delaware corporation, or its successor-in-interest with respect to, or permitted assignee of, the Syndax-Incyte Agreement; (iii) the defined term "**Amendment Date**", which shall mean the Settlement Date; and (iv) the defined term "**cGVHD**", which shall mean chronic graft versus host disease.

2.3 Section 4.7. Section 4.7 of the License Agreement is hereby amended and restated to read in its entirety as follows:

"4.7 Sublicense Consideration.

(i) [***].

(ii) [***].

(iii) [***].

2.4 Section 12.5. Syndax's address for notices and other communications under Section 12.5 of the License Agreement shall be the address set forth in the introductory paragraph of this Settlement Agreement.

3. No Other Amendments

Except as expressly modified and amended by this Settlement Agreement, the License Agreement shall remain in full force and effect in accordance its terms and conditions. In case of any contradiction or conflict between the terms and conditions of this Settlement Agreement and the terms and conditions of the License Agreement, the terms of this Settlement Agreement shall prevail solely with respect any and all specific matters which are expressly set forth herein.

4. Releases

Effective immediately upon completion of the payment to UCB of the net amount described in Section 1 above, the Parties hereby fully release and forever discharge each other and their representatives, agents, Affiliates, partners, shareholders, officers, directors, successors, assigns, attorneys, and predecessors, from any and all actions, causes of action, claims, demands, costs, expenses, liability, attorney's fees and debts whatsoever, in law or in equity or otherwise, whether known, unknown, suspected or unsuspected, which they ever had, now have or hereafter can, shall or may have in any way relating to or arising out of facts, events, circumstances, acts or omissions existing or occurring from any time on or before the Effective Date relating in any way to or arising out of the Dispute or any of the facts or circumstances underlying the Dispute, including, in each case, any of the foregoing relating in any way to or arising out of the Upfront Consideration, but excluding any claims to enforce the express terms of this Settlement Agreement (including without limitation the amendments to the License Agreement provided for in Section 2 above).

5. No Admission of Liability

It is expressly understood and agreed among the Parties that this Settlement Agreement is made in compromise of disputed and controverted claims, and that nothing contained herein and no payment made pursuant to this Settlement Agreement shall constitute or be deemed to be an admission of any breach of the License Agreement, fault, liability or wrongdoing of any kind by either Party, or as an admission by either Party of the validity of any allegations, claims or contentions.

6. Confidentiality

Each of the Parties shall keep the details of the Dispute, the negotiations and other related communications (whether written or verbal) between the Parties (or their respect representatives) prior to the Effective Date with respect to this Settlement Agreement, and the terms of this Settlement Agreement itself, as confidential and shall not disclose any information or documents relating to the Dispute, these negotiations or the contents of this Settlement Agreement (or a copy of all or any portion of it) to any person without the express prior written consent of the other Party. Neither of the Parties shall make any public comment or comment to any Third Party (including the press) concerning this Settlement Agreement save to say in response to any question which may be asked that the Dispute between the Parties has been settled and finally resolved on terms satisfactory to both Parties. The foregoing notwithstanding, a Party shall be permitted to disclose the existence and terms of this Settlement Agreement (without such consent) solely in the following circumstances:

(i) in confidence to its auditors, group companies, insurers, financiers, accountants or legal or professional advisers;

(ii) if and only to the extent such disclosure is required in order to comply with the listing requirements of any securities or investment exchange on which the securities of such Party or its Affiliate are traded or to comply with the requirements of any regulatory or governmental body having jurisdiction over such Party (including the U.S. Securities and Exchange Commission, the Belgian Financial Services and Markets Authority or the Euronext Brussels Stock Exchange);

(iii) to a court or arbitrator solely to enable enforcement of this Settlement Agreement; or

(iv) if required by the U.S. Federal Trade Commission, U.S. Department of Justice, European Commission or any other competition authority of competent jurisdiction, or by law, rule or regulation of any relevant jurisdiction or a court of competent jurisdiction;

provided in each case that such Party shall, if legally permitted and reasonably possible to do so in the circumstances, promptly notify the other Party before any disclosure pursuant to subsection 6(ii) or subsection 6(iv) above and shall consult the other Party as to the possible steps to obtain confidential treatment and/or to avoid or limit the extent of the disclosure, or the terms on which the disclosure will be made, in each case to the extent permitted and reasonably possible under the circumstances.

The Parties acknowledge that either or both Parties may be obligated to file under applicable laws a copy of this Settlement Agreement with the SEC or other governmental authorities or otherwise to disclose the terms of this Settlement Agreement in securities filings as required by applicable law. Each Party shall be entitled to make such a required filing or disclosure; provided that, in the case of required filing of a copy of this Settlement Agreement, it requests confidential treatment of the commercial terms and sensitive technical terms hereof to the extent such confidential treatment is reasonably available to such Party. At least ten (10) business

days prior to such disclosure or filing (or such shorter period as may be required to permit timely filing or disclosure with the SEC or other governmental authority), the Party required to make such a filing of a copy of this Settlement Agreement will provide the other Party with a copy of this Settlement Agreement marked to show provisions for which such Party intends to seek confidential treatment, and shall reasonably consider any requests made by such other Party during such period to seek confidential treatment of any additional provisions.

7. Termination for Non-Payment

In the event that Syndax fails to make timely payment to UCB of the one-time payment which is provided for under Section 1 of this Settlement Agreement, then UCB shall have the unilateral right, exercisable in its sole discretion and with immediate effect upon written notice to Syndax, to terminate this Settlement Agreement, in which event: (i) this Settlement Agreement shall be automatically deemed rescinded and any amendments to the License Agreement which are described herein will never come into effect or otherwise be binding upon or enforceable by any Party; and (ii) all of the terms and conditions of the License Agreement as existing immediately prior to the Effective Date, and each Party's rights and obligations with respect thereto or arising thereunder, shall remain in effect and continue to apply to the same extent and in the same manner as if this Settlement Agreement had never existed. In such event, neither the existence of this Settlement Agreement nor anything contained herein (including any statements with respect to the Dispute, the facts and circumstances underlying the Dispute or the terms and conditions set forth herein with respect to settlement of the Dispute) shall be asserted or otherwise construed by or on behalf of one Party against the rights and interests of the other Party in respect of the Dispute.

8. Attorneys' Fees and Costs

Each Party to this Settlement Agreement will bear its own expenses and attorneys' fees, whether taxable or otherwise, incurred in or arising out of or in any way related to matters released herein.

9. Construction of Agreement

The headings of clauses contained in this Settlement Agreement preceding the text of the sections and subsections hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Settlement Agreement or have any effect on its interpretation or construction. It is further agreed and understood that both Parties are represented by counsel and have participated in the drafting of this Settlement Agreement and that the rule interpreting any ambiguity in a contract against the Party drafting the document shall be of no force and effect.

10. Binding Effect

This Settlement Agreement shall be binding on and inure to the benefit of the Parties and their respective Affiliates, shareholders, directors, employees, agents, successors, and assigns.

11. Entire Agreement

The Parties agree that no representation or promise not expressly contained in this Settlement Agreement has been made and further acknowledge that the Parties are not entering

into this Settlement Agreement on the basis of any promise or representation, express or implied, not otherwise contained herein. This Settlement Agreement, together with the License Agreement (as amended by this Settlement Agreement), sets forth the entire understanding and agreement between the Parties and supersedes all prior negotiations, representations, agreements and understandings (whether written or verbal) of the Parties. Each Party hereto has fully and personally investigated the subject matter of this Settlement Agreement and does not rely on any statement, fact or opinion of the other Party to this Settlement Agreement.

12. Modification of Agreement

Any proposed amendment or modification of this Settlement Agreement shall not be binding on the Parties unless expressly set out in writing and signed by authorized representatives of each of the Parties.

13. Governing Law and Other Provisions

This Settlement Agreement is subject to and governed by the terms of Sections 12.1, 12.2, 12.3, 12.5 (as modified by Section 2.4 of this Settlement Agreement), 12.8, 12.9, 12.10, 12.11 and 12.12 of the License Agreement.

14. Signatories' Authority

Each Party, on behalf of itself and its Affiliates, warrants and represents that, as of the date this Settlement Agreement is signed on behalf of such Party, (i) such Party is a corporation or other business entity duly organized and validly existing under the laws of the jurisdiction in which it is organized and has full corporate or other power and authority to enter into this Settlement Agreement and to perform its obligations hereunder and consummate the transactions contemplated herein, and (ii) the individual(s) executing this Settlement Agreement on behalf of such Party have been duly authorized to do so by all requisite corporate action.

15. Counterparts

This Settlement Agreement may be executed in two or more counterparts, including by an exchange (whether via email, fax, regular mail or courier) of PDF copies of signed documents (whether signed physically or using certified digital signatures), with the same effect as if all Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall together constitute one and the same instrument.

IN WITNESS WHEREOF, this Settlement Agreement has been executed by the duly authorized representatives of the Parties as of the respective dates set forth below.

SYNDAX PHARMACEUTICALS, INC.

By: /s/ Luke J. Albrecht

Name: Luke J. Albrecht

Title: General Counsel, Secretary

Date: 6/6/2022

UCB BIOPHARMA SRL

By: /s/ Bill Silbey

Name: Bill Silbey

Title: Head of Legal, IP and Compliance

Date: 26-May-2022

By: /s/ Sandrine Dufour

Name: Sandrine Dufour

Title: CFO

Date: 29-May-2022

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: August 8, 2022

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: August 8, 2022

By: /s/ Keith A. Goldan
Keith A. Goldan
Chief Financial Officer and Treasurer
(Principal Financial 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 June 30, 2022, 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: August 8, 2022

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

Date: August 8, 2022

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