

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2021

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  
(State or Other Jurisdiction of  
Incorporation or Organization)

32-0162505  
(IRS Employer  
Identification No.)

35 Gatehouse Drive, Building D, Floor 3  
Waltham, Massachusetts  
(Address of Principal Executive Offices)

02451  
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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 November 11, 2021, there were 49,392,123 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 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 Phase 1/2 clinical trial of SNDX-5613 in patients with relapsed/refractory (R/R) acute leukemia and the potential use of SNDX-5613 to treat acute leukemias;
- the timing of the progress and receipt of data from the expansion cohort from the Phase 1/2 clinical trial of axatilimab in chronic Graft Versus Host Disease (cGVHD);
- the timing of the progress and receipt of data from the pivotal Phase 2 trial, AGAVE-201, of axatilimab in 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.;
- our ability to close and the success of our collaboration with Incyte Corporation (“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
- political, social and economic instability, natural disasters or public health crisis, including but not limited to the COVID-19 pandemic, in countries where we or our collaborators do business.

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

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

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**Part I: FINANCIAL INFORMATION****Item 1: Financial Statements**

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

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 71,433	\$ 115,243
Restricted cash	115	115
Short-term investments	158,281	177,822
Prepaid expenses and other current assets	8,423	5,684
Total current assets	<u>238,252</u>	<u>298,864</u>
Property and equipment, net	158	192
Right-of-use asset, net	1,093	290
Other assets	—	1,267
Total assets	<u>\$ 239,503</u>	<u>\$ 300,613</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 5,122	\$ 3,508
Accrued expenses and other current liabilities	13,732	11,246
Current portion of deferred revenue	—	1,517
Current portion of right-of-use liability	369	316
Current portion of term loan	9,489	2,285
Total current liabilities	<u>28,712</u>	<u>18,872</u>
Long-term liabilities:		
Deferred revenue, less current portion	—	11,617
Right-of-use liability, less current portion	798	101
Term loan, less current portion	10,989	17,834
Other long-term liabilities	—	1
Total long-term liabilities	<u>11,787</u>	<u>29,553</u>
Total liabilities	<u>40,499</u>	<u>48,425</u>
Commitments		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized; 0 shares outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, \$0.0001 par value, 100,000,000 shares authorized; 48,850,539 and 47,881,223 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	5	5
Additional paid-in capital	838,888	820,815
Accumulated other comprehensive income (loss)	11	(4)
Accumulated deficit	(639,900)	(568,628)
Total stockholders' equity	<u>199,004</u>	<u>252,188</u>
Total liabilities and stockholders' equity	<u>\$ 239,503</u>	<u>\$ 300,613</u>

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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>Revenue:</b>				
License fees	\$ 12,375	\$ 379	\$ 13,133	\$ 1,138
<b>Total revenues</b>	<b>12,375</b>	<b>379</b>	<b>13,133</b>	<b>1,138</b>
<b>Operating expenses:</b>				
Research and development	25,606	14,408	64,348	34,913
General and administrative	6,801	5,824	18,314	17,787
<b>Total operating expenses</b>	<b>32,407</b>	<b>20,232</b>	<b>82,662</b>	<b>52,700</b>
Loss from operations	(20,032)	(19,853)	(69,529)	(51,562)
<b>Other (expense) income:</b>				
Interest expense	(649)	(635)	(1,906)	(1,722)
Interest income	83	177	312	735
Other expense, net	(41)	(126)	(149)	(186)
<b>Total other (expense) income</b>	<b>(607)</b>	<b>(584)</b>	<b>(1,743)</b>	<b>(1,173)</b>
Net loss	\$ (20,639)	\$ (20,437)	\$ (71,272)	\$ (52,735)
<b>Other comprehensive loss:</b>				
Unrealized (loss) gain on marketable securities	\$ (6)	\$ (64)	\$ 15	\$ 53
<b>Comprehensive loss</b>	<b>\$ (20,645)</b>	<b>\$ (20,501)</b>	<b>\$ (71,257)</b>	<b>\$ (52,682)</b>
Net loss attributable to common stockholders	\$ (20,639)	\$ (20,437)	\$ (71,272)	\$ (56,641)
Net loss per share attributable to common stockholders—basic and diluted	\$ (0.40)	\$ (0.46)	\$ (1.38)	\$ (1.43)
Weighted-average number of common shares used to compute net loss per share attributable to common stockholders—basic and diluted	51,962,320	44,156,808	51,690,173	39,714,490

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)**

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

	<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (71,272)	\$ (52,735)
Adjustments to reconcile net loss to net cash from operating activities:		
Depreciation	33	68
Amortization and accretion of investments	473	(195)
Non-cash operating lease expense	302	321
Non-cash interest expense	358	276
Stock-based compensation	9,388	7,022
Other	(1)	2
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,471)	(5,789)
Accounts payable	1,614	(2,342)
Deferred revenue	(13,133)	(1,138)
Accrued expenses and other liabilities	2,131	(1,119)
Net cash used in operating activities	<u>(71,578)</u>	<u>(55,629)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of short-term investments	(189,492)	(150,350)
Proceeds from sales and maturities of short-term investments	208,575	71,960
Net cash provided by (used) in investing activities	<u>19,083</u>	<u>(78,390)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock in at-the-market stock offering, net	5,131	—
Proceeds from direct stock offering, net	—	142,734
Proceeds from debt agreement, net	—	19,730
Proceeds from Employee Stock Purchase Plan	242	242
Proceeds from stock option exercises	3,312	3,060
Net cash provided by financing activities	<u>8,685</u>	<u>165,766</u>
<b>NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH</b>	<b>(43,810)</b>	<b>31,747</b>
CASH, CASH EQUIVALENTS AND RESTRICTED CASH—beginning of period	115,358	24,724
CASH, CASH EQUIVALENTS AND RESTRICTED CASH—end of period	<u>\$ 71,548</u>	<u>\$ 56,471</u>
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:</b>		
Cash paid for interest	\$ 1,499	\$ 1,133

**SYNDAX PHARMACEUTICALS, INC.**  
**(unaudited)**  
**NOTES TO 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 September 30, 2021, and the results of operations and comprehensive loss for the three and nine months ended September 30, 2021 and 2020, and cash flows for the nine months ended September 30, 2021 and 2020. The results for the three and nine months ended September 30, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021, 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, 2020, 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 12, 2021.

In 2011, the Company established a wholly owned subsidiary in the United Kingdom. There have been no activities for this entity to date. In 2014, the Company established a wholly owned U.S. subsidiary, Syndax Securities Corporation. In 2021, the Company established a wholly owned subsidiary in the Netherlands. There have been no activities for this entity to date. The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. 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, 2020 and the notes thereto are included in the Company’s Annual Report on Form 10-K that was filed with the SEC on March 12, 2021. Since the date of that filing, there have been no material changes to the Company’s significant accounting policies except as noted below.

*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 United States, Europe and other countries, the slow rollout of mass vaccinations for COVID-19 and any limitations to the efficacy of such vaccines and the effectiveness of other 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.

### *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. The Company's actual results may differ from these estimates under different assumptions or conditions.

We anticipate that the COVID-19 pandemic will have an impact on the clinical and pre-clinical development timelines for our clinical and pre-clinical programs. 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.

## **4. Revenue from Contracts with Customers**

### **Incyte Collaboration**

In September 2021, the Company entered into a collaboration and license agreement (the "Incyte Agreement") with Incyte Corporation ("Incyte") covering the worldwide development and commercialization of SNDX-6352 (axatilimab). Under the terms of the Incyte Agreement, Incyte will receive exclusive commercialization rights outside of the United States, subject to its royalty payment obligations set forth below. In the United States, Incyte and the Company will co-commercialize axatilimab, with the Company having the right to co-promote the product with Incyte, subject to the Company's exercise of its co-promotion option. Incyte will be responsible for leading all other aspects of commercialization, including booking all revenue from sales of axatilimab in the United States. The Company and Incyte will share equally the profits and losses from the co-commercialization efforts in the United States. The Company and Incyte have agreed to co-develop axatilimab and to share development costs associated with 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 independent development activities. All development costs related to the collaboration will be subject to a joint development plan. Incyte has agreed to pay the Company a non-refundable cash payment of \$117 million under the Incyte Agreement, in addition to a \$35 million equity investment in connection with a stock purchased agreement entered into simultaneously with the Incyte Agreement. 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 as well as tiered royalties ranging in the mid-teens percentage on net sales of the licensed product comprising axatilimab in Europe and Japan and low double digit percentage in the rest of the world outside of the United States. The Company's right to receive royalties in any particular country will expire upon the last to occur of (a) the expiration of licensed patent rights covering the licensed product in that particular country, (b) a specified period of time after the first post-marketing authorization sale of a licensed product in that country, and (c) the expiration of any regulatory exclusivity for that licensed product in that country. The effectiveness of the Incyte Agreement was conditioned on the early termination or expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. As of September 30, 2021, the Company has not received any cash or other consideration from Incyte and has not issued any shares under the stock repurchase agreement or transferred any licenses or other deliverables under the Incyte Agreement.

### **KKC Agreement**

On December 19, 2014 (the "Effective Date"), the Company entered into a license agreement with Kyowa Kirin, Co., Ltd. (the KKC License Agreement), under which the Company granted KKC an exclusive license to develop and commercialize entinostat in Japan and Korea. Under the terms of the KKC License Agreement, the Company will be responsible for the manufacture and supply of the products during the development activities. In addition to the license and manufacturing obligations, the Company is obligated to provide KKC access to know-how and regulatory information the Company may develop over the life of the entinostat patent. Lastly, to the extent additional intellectual property is developed during the term of the agreement, KKC will receive the right to the intellectual property when and if available. KKC will conduct the development, regulatory approval filings, and commercialization activities of entinostat in Japan and Korea. KKC paid the Company \$25.0 million upfront, which included a \$7.5 million equity investment and a \$17.5 million non-refundable cash payment. In addition, to the extent certain development and commercial milestones are achieved, KKC will be required to pay the Company up to \$75.0 million in milestone payments over the term of the license agreement. The term of the agreement commenced on the Effective Date and, unless earlier terminated in accordance with the terms of the agreement, will continue on a country-by-country and product-by-product basis, until the later of: (i) the date all valid



claims of the last effective patent among the Company's patents expires or is abandoned, withheld, or is otherwise invalidated in such country; and (ii) 15 years from the date of the first commercial sale of a product in the Japan or Korea.

The equity purchase and the up-front payment of the license fee were accounted for separately. The Company allocated the amount of consideration equal to the fair value of the shares on the Effective Date, which resulted in \$7.7 million of proceeds allocated to the equity purchase and the remaining consideration of \$17.3 million allocated to the up-front license fee.

In October 2017, the Company announced that KKC enrolled the first Japanese patient into a local pivotal study of entinostat for the treatment of hormone receptor positive, human epidermal growth factor receptor 2 negative breast cancer. In accordance with the terms of the license agreement, KKC paid the Company a \$5.0 million milestone payment which the Company received in December 2017.

The Company determined that the performance obligations associated with the KKC License Agreement include (i) the combined license, rights to access and use materials and data, and rights to additional intellectual property, and (ii) the clinical supply obligation. All other goods or services promised to KKC are immaterial in the context of the agreement. Under ASC 606, the identification of the clinical supply obligation as a distinct performance obligation separate and apart from the license performance obligation resulted in a change in the performance period. The start of the performance period under ASC 606 was determined to be the contract inception date, December 19, 2014. The clinical supply was identified as a separate performance obligation under ASC 606 as (i) the Company is not providing a significant service of integration whereby the clinical supply and other promises are inputs into a combined output, (ii) the clinical supply does not significantly modify or customize the other promises nor is it significantly modified or customized by them, and (iii) the clinical supply is not highly interdependent or highly interrelated with the other promises in the agreement as KKC could choose not to purchase the clinical supply from the Company without significantly affecting the other promised goods or services. The Company further concluded that the clinical supply represented an immaterial performance obligation and therefore the entire \$17.3 million allocated to the upfront payment was allocated to the combined license and will be recognized ratably over the performance period, representing contract inception through 2029. In 2017, KKC achieved a development milestone, and was required to pay the Company \$5.0 million. The Company is recognizing the development milestone consideration over the performance period coinciding with the license to intellectual property. As the Company determined that its performance obligations associated with the KKC Agreement at contract inception were not distinct and represented a single performance obligation, and that the obligations for goods and services provided would be completed over the performance period of the agreement, any payments received by the Company from KKC, including the upfront payment and progress-dependent development and regulatory milestone payments, are recognized as revenue using a time-based proportional performance model over the contract term (December 2014 through 2029) of the collaboration, within license fees. To date no commercial milestone payments or royalties have been achieved.

In September 2021, KKC informed the Company that it is discontinuing its development of entinostat in Japan and Korea and terminating the KKC License Agreement. As a result, the Company recognized all remaining deferred revenue of \$12.4 million, as of September 30, 2021.

## 5. Net Loss per Share Attributable to Common Stockholders

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(In thousands, except share and per share data)		(In thousands, except share and per share data)	
<b>Numerator—basic and diluted:</b>				
Net loss	\$ (20,639)	\$ (20,437)	\$ (71,272)	\$ (52,735)
Deemed dividend due to warrant reset	—	—	—	(3,906)
Net loss attributable to common stockholders—basic and diluted	<u>\$ (20,639)</u>	<u>\$ (20,437)</u>	<u>\$ (71,272)</u>	<u>\$ (56,641)</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (0.40)</u>	<u>\$ (0.46)</u>	<u>\$ (1.38)</u>	<u>\$ (1.43)</u>
<b>Denominator—basic and diluted:</b>				
Weighted-average number of common shares used to compute net loss per share attributable to common stockholders—basic and diluted	<u>51,962,320</u>	<u>44,156,808</u>	<u>51,690,173</u>	<u>39,714,490</u>

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

	September 30,	
	2021	2020
Options to purchase common stock	7,340,654	6,770,660
Warrants to purchase common stock	—	689,242
Employee Stock Purchase Plan	21,063	18,838
Non-vested restricted stock units (RSUs)	132,333	18,500

In June 2018, the Company signed an exchange agreement with an investor under which the investor exchanged 2,000,000 shares of common stock for 2,000,000 warrants. Further, as discussed in Note 12, in March 2019, the Company sold 2,095,039 shares of common stock as well as 2,500,000 pre-funded warrants and 4,595,039 Series 1 and Series 2 warrants. The pre-funded warrants are exercisable into shares of common stock for \$0.0001 per share. In January 2020, the Company sold 3,036,719 shares of common stock as well as 1,338,287 pre-funded warrants. The warrants are exercisable into shares of common stock for \$0.0001 per share. The shares of common stock into which the pre-funded warrants may be exercised are considered outstanding for the purposes of computing earnings per share. All Series 1 and Series 2 warrants were exercised in 2020.

During the first quarter of 2021, 250,000 pre-funded warrants were exchanged for shares of common stock in a cash exercise. As of September 30, 2021, 3,307,952 pre-funded warrants were outstanding.

## 6. Significant Agreements

### Vitae Pharmaceuticals, Inc.

In October 2017, the Company entered into a license agreement (the “AbbVie License Agreement”) with Vitae Pharmaceuticals, Inc., which is now a subsidiary of AbbVie, Inc. (“AbbVie”), under which AbbVie granted the Company an exclusive, sublicensable, worldwide license to a portfolio of preclinical, orally available, small molecule inhibitors of the interaction of Menin with the Mixed Lineage Leukemia (“MLL”) protein (the “Menin Assets”). The Company made a nonrefundable upfront payment of \$5.0 million to AbbVie in the fourth quarter of 2017. Additionally, subject to the achievement of certain milestone events, the Company may be required to pay AbbVie up to \$99.0 million in one-time development and regulatory milestone payments over the term of the AbbVie 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 AbbVie low single to low double-digit royalties on sales, subject to reduction in certain circumstances, as well as up to an aggregate of \$70.0 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 AbbVie. The Company is solely responsible for the development and commercialization of the Menin Assets. Each party may terminate the AbbVie License Agreement for the other party's uncured material breach or insolvency; and the Company may terminate the AbbVie License Agreement at will at any time upon advance written notice to AbbVie. AbbVie may terminate the AbbVie 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 AbbVie 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 AbbVie 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. As a result, in June 2019, the Company recorded \$4.0 million as research and development expense. The amount was paid in 2020.

### **UCB Biopharma Sprl**

In 2016, the Company entered into a license agreement (the "UCB License Agreement") 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. The Company made a nonrefundable upfront payment of \$5.0 million to UCB in 2016. Additionally, 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. In July 2020, the Company achieved certain development and regulatory milestones and the Company recorded \$2.0 million as a research and development expense, which has been fully paid. In March and September 2021, the Company recorded \$2.0 million, respectively, as research and development expenses for the achievement of certain development milestones. The Company fully paid the March 2021 milestone in the second quarter of 2021. The September 2021 milestone of \$2.0 million is recorded as an accrued expense as of September 30, 2021.

### **Eastern Cooperative Oncology Group**

In March 2014, the Company entered into the ECOG Agreement with Eastern Cooperative Oncology Group, a contracting entity for the Eastern Cooperative Oncology Group—American College of Radiology Imaging Network Cancer Research Group ("ECOG-ACRIN"), that describes the parties' obligations with respect to the NCI-sponsored pivotal Phase 3 clinical trial of entinostat. Under the terms of the ECOG Agreement, ECOG-ACRIN will perform this clinical trial in accordance with the clinical trial protocol and a mutually agreed scope of work. The Company is providing a fixed level of financial support for the clinical trial through an upfront payment of \$0.7 million and a series of payments of up to \$1.0 million each that are comprised of milestone payments through the completion of enrollment and time-based payments through the completion of patient monitoring post-enrollment. In addition, the Company is obligated to supply entinostat and placebo to ECOG-ACRIN for use in the clinical trial. From the second quarter of 2016 through the fourth quarter of 2018, the Company has entered into a number of amendments to the agreement to provide for additional study activities resulting in an increase of the contractual obligation of \$5.3 million. The Company has agreed to provide this additional financial support to fund the additional activities required to ensure that the E2112 clinical trial will satisfy FDA registration requirements.

In May 2020, the Company announced that the E2112 trial did not achieve the primary endpoint of demonstrating a statistically significant overall survival benefit over hormone therapy alone. As a result, the Company has decided to deprioritize the entinostat

program to focus resources on advancing the remainder of its pipeline. As of September 30, 2021, the Company's aggregate payment obligations under this agreement are approximately \$24.7 million; and its estimated remaining payment obligations are approximately \$3.2 million, which are estimated to be paid over a period of approximately one year. As of September 2021, the Company has accrued \$2.7 million related to the ECOG Agreement.

Data and inventions from the Phase 3 clinical trial are owned by ECOG-ACRIN. The Company has access to the data generated in the clinical trial, both directly from ECOG-ACRIN under the ECOG Agreement as well as from the NCI. Additionally, ECOG-ACRIN has granted the Company a non-exclusive royalty-free license to any inventions or discoveries that are derived from entinostat as a result of its use during the clinical trial, along with a first right to negotiate an exclusive license to any of these inventions or discoveries. Either party may terminate the ECOG Agreement in the event of an uncured material breach by the other party or if the U.S. Food and Drug Administration ("FDA") or National Cancer Institute ("NCI") withdraws the authorization to perform the clinical trial in the United States. The parties may jointly terminate the ECOG Agreement if the parties agree that safety-related issues support termination of the clinical trial. The Company records the appropriate clinical trial expenses in its financial statements by matching those expenses with the period in which the services and efforts are expended. The Company accounts for these expenses according to the progress of the clinical trial as measured by patient enrollment and the timing of various aspects of the clinical trial. The Company determines accrual estimates through financial models, taking into account discussion with applicable personnel and ECOG-ACRIN as to the progress or state of consummation of the clinical trial or the services completed.

#### **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. Under the terms of the Bayer Agreement, the Company paid a nonrefundable upfront license fee of \$2.0 million and is responsible for the development and marketing of entinostat. The Company recorded the \$2.0 million license fee as research and development expense during the year ended December 31, 2007, as it had no alternative future use. 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.

During the periods presented, the Company has not changed the manner in which it values assets and liabilities that are measured at fair value using Level 3 inputs. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy for any of periods presented.

A summary of the assets and liabilities carried at fair value in accordance with the hierarchy defined above is as follows:

	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)			
<b>September 30, 2021</b>				
Assets:				
Cash and cash equivalents	\$ 71,433	\$ 61,434	\$ 9,999	\$ —
Short-term investments	158,281	—	158,281	—
Total assets	<u>\$ 229,714</u>	<u>\$ 61,434</u>	<u>\$ 168,280</u>	<u>\$ —</u>
<b>December 31, 2020</b>				
Assets:				
Cash and cash equivalents	\$ 115,243	\$ 110,246	\$ 4,997	\$ —
Short-term investments	177,822	—	177,822	—
Total assets	<u>\$ 293,065</u>	<u>\$ 110,246</u>	<u>\$ 182,819</u>	<u>\$ —</u>

Cash and cash equivalents of \$61.4 million and \$110.2 million as of September 30, 2021 and December 31, 2020, respectively, consisted of overnight investments and money market funds and are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets. Cash equivalents of \$10.0 million and \$5.0 million as of September 30, 2021 and December 31, 2020 respectively, consisted of highly rated corporate bonds and commercial paper and are classified within Level 2 of the fair value hierarchy because pricing inputs are other than quoted prices in active markets, which are either directly or indirectly observable as of the reporting date, and fair value is determined through the use of models or other valuation methodologies.

Short-term investments of \$158.3 million and \$177.8 million as of September 30, 2021 and December 31, 2020, respectively, consisted of commercial paper, highly rated corporate bonds and U.S. Treasury and are classified within Level 2 of the fair value hierarchy because pricing inputs are other than quoted prices in active markets, which are either directly or indirectly observable as of the reporting date, and fair value is determined through the use of models or other valuation methodologies.

The short-term investments are classified as available-for-sale securities. As of September 30, 2021, the remaining contractual maturities of the available-for-sale securities were less than one year, 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 three and nine months ended September 30, 2021 and 2020. 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 September 30, 2021, 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)			
<b>September 30, 2021</b>				
Commercial paper	\$ 126,895	\$ 13	\$ —	\$ 126,908
Corporate bonds	27,080	—	(3)	27,077
Federal bonds	14,294	1	—	14,295
	<u>\$ 168,269</u>	<u>\$ 14</u>	<u>\$ (3)</u>	<u>\$ 168,280</u>
<b>December 31, 2020</b>				
Commercial paper	\$ 154,176	\$ 13	\$ (16)	\$ 154,173
Corporate bonds	22,617	2	(3)	22,616
U.S. Treasury	6,030	—	—	6,030
	<u>\$ 182,823</u>	<u>\$ 15</u>	<u>\$ (19)</u>	<u>\$ 182,819</u>

## 8. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
	(In thousands)	
Short-term deposits	\$ 6,499	\$ 4,683
Prepaid insurance	1,259	427
Interest receivable on investments	182	175
Prepaid subscriptions	242	203
Prepaid clinical supplies	—	58
Reimbursable costs	3	24
Other	238	114
Total prepaid expenses and other current assets	<u>\$ 8,423</u>	<u>\$ 5,684</u>

## 9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
	(In thousands)	
Accrued clinical costs	\$ 9,058	\$ 7,132
Accrued compensation and related costs	3,468	3,213
Accrued professional fees	854	373
Accrued interest payable	164	170
Other	188	358
Total accrued expenses and other current liabilities	<u>\$ 13,732</u>	<u>\$ 11,246</u>

## 10. Stock-Based Compensation

In January 2021, the number of shares of common stock available for issuance under the 2015 Omnibus Incentive Plan (“2015 Plan”) was increased by 1,915,248 shares due to the automatic annual provision to increase shares available under the 2015 Plan. As of September 30, 2021, the total number of shares of common stock available for issuance under the 2015 Plan was 1,001,470. 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:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
	(In thousands)			
Research and development	\$ 1,134	\$ 620	\$ 3,130	\$ 1,713
General and administrative	2,247	2,443	6,258	5,309
Total	<u>\$ 3,381</u>	<u>\$ 3,063</u>	<u>\$ 9,388</u>	<u>\$ 7,022</u>

Compensation expense by type of award in the three and nine months ended September 30, 2021 and 2020 was as follows:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
	(In thousands)			
Stock options	\$ 2,730	\$ 3,005	\$ 7,689	\$ 6,885
Restricted Stock Units	603	—	1,581	—
Employee Stock Purchase Plan	48	58	118	137
Total	<u>\$ 3,381</u>	<u>\$ 3,063</u>	<u>\$ 9,388</u>	<u>\$ 7,022</u>

During the nine months ended September 30, 2021, the Company granted 1,537,400 stock options to certain executives, consultants and employees having service-based vesting conditions. The grant date fair value of the options granted in the nine months ended September 30, 2021, was \$22.7 million, or \$14.74 per share on a weighted-average basis and will be recognized as compensation expense over the requisite service period of three to four years.

During the nine months ended September 30, 2021, 414,809 options were exercised for cash proceeds of \$3.3 million. During the nine months ended September 30, 2020, 311,871 options were exercised for cash proceeds of \$3.1 million.

As of September 30, 2021, there was \$28.7 million of unrecognized compensation cost 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 3.0 years. Stock-based compensation costs have not been capitalized by the Company.

#### **Restricted stock units**

During the nine months ended September 30, 2021, the Company granted 119,333 shares of the Company's restricted stock units. The shares vest on either i) one-year anniversary date of the related grant or ii) 25% on each anniversary for 4 years. The fair value of these shares totaled \$2.5 million at the grant date, representing a weighted-average grant date fair value per share of \$21.19.

### **11. Loan Payable**

In February 2020, the Company entered into a loan and security agreement (the "Loan Agreement") with Hercules Capital, Inc. ("Hercules"), which provided for aggregate maximum borrowings of up to \$30.0 million, consisting of (i) a term loan of up to \$20.0 million, which was funded on February 7, 2020 (the "Initial Advance"), and (ii) subject to Hercules' investment committee approval, an additional term loan of up to \$10.0 million, available for borrowing from February 7, 2020 to December 15, 2020 (the "Tranche 2 Advance"). Borrowings under the Loan Agreement bear interest at an annual rate equal to the greater of (i) 9.85% or (ii) 5.10% plus the Wall Street Journal prime rate. As of September 30, 2021, the Company's interest rate under the Loan Agreement was 9.85%.

Borrowings under the Loan Agreement were repayable in monthly interest-only payments through October 1, 2021. Borrowings under the Loan Agreement are now repayable in equal monthly payments of principal and accrued interest until the maturity date of the loan, which is September 1, 2023. 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 applicable loan being funded, (ii) 1.5% of the principal amount outstanding if the prepayment occurs during the second year following the applicable loan being funded, and (iii) 1.0% of the principal amount outstanding at any time thereafter but prior to the Maturity Date. In addition, the Company paid a \$100,000 facility charge upon closing, which is being expensed over the term of the debt. The Loan Agreement also provides for a final payment, payable upon maturity or the repayment in full of all obligations under the agreement, of up to 4.99% of the aggregate principal amount of the Term Loan Advances (as defined in the Loan Agreement). The final payment will be accrued over the term of the debt.

Borrowings under the 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 Loan Agreement includes a minimum cash covenant of \$12.5 million that applies commencing on October 1, 2020, subject to reduction upon satisfaction of certain conditions as set forth in the Loan Agreement. As of September 30, 2021, the conditions set forth in the Loan Agreement were met. The cash covenant of \$12.5 million was deferred. 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. The 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 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 Loan Agreement.

In connection with the 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 nine months ended September 30, 2021 and 2020, the Company recognized \$1.9 million and \$1.6 million, respectively, of interest expense related to the Initial Advance pursuant to the Loan Agreement.

As of September 30, 2021, the Company's maturities of principal obligations under its long-term debt are as follows:

	<b>Amount</b>
Remainder of 2021	\$ 2,285
2022	9,727
2023	7,988
Total principal outstanding	20,000
Amortized final fee	589
Unamortized debt issuance costs	(111)
Total	20,478
Term loan, current portion	9,489
Term loan, less current portion	\$ 10,989

## 12. Stockholders' Equity

The following table presents the changes in stockholders' equity for the three and nine months ended September 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
Pre-funded warrant exchange	250,000	—	—	—	—	—
Employee withholdings ESPP	—	—	79	—	—	79
Proceeds from exercise 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 of \$200 offering expenses	277,629	—	5,131	—	—	5,131
Proceeds from exercise 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
Stock-based compensation expense	—	—	3,381	—	—	3,381
Unrealized loss on short-term investments	—	—	—	(6)	—	(6)
Employee withholdings ESPP	—	—	99	—	—	99
Stock purchase under ESPP	10,496	—	—	—	—	—
Proceeds from exercise stock options	223,415	—	1,606	—	—	1,606
Net loss	—	—	—	—	(20,639)	(20,639)
Balance as of September 30, 2021	48,850,539	\$ 5	\$ 838,888	\$ 11	\$ (639,900)	\$ 199,004



The following table presents the changes in stockholders' equity for the three and nine months ended September 30, 2020:

(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, 2019	27,140,484	\$ 3	\$ 527,067	\$ —	\$ (495,470)	\$ 31,600
Stock purchase under ESPP	12,601	—	—	—	—	—
Stock-based compensation expense	—	—	1,829	—	—	1,829
Proceeds from direct offering, net of \$93 offering expenses	3,036,719	—	24,201	—	—	24,201
Proceeds from pre-funded common stock warrant from direct offering, net of \$41 offering expenses	—	—	10,665	—	—	10,665
Deemed dividend from repricing Series 1 and 2 warrants	—	—	3,906	—	—	3,906
Repricing Series 1 and 2 warrants	—	—	(3,906)	—	—	(3,906)
Proceeds from exercise of stock options	51,034	—	338	—	—	338
Unrealized gains on short-term investments	—	—	—	48	—	48
Employee withholdings ESPP	—	—	64	—	—	64
Net loss	—	—	—	—	(15,236)	(15,236)
Balance as of March 31, 2020	<u>30,240,838</u>	<u>\$ 3</u>	<u>\$ 564,164</u>	<u>\$ 48</u>	<u>\$ (510,706)</u>	<u>\$ 53,509</u>
Stock-based compensation expense	—	—	2,130	—	—	2,130
Issuance of common stock in exchange for pre-funded warrants	280,332	—	—	—	—	—
Exercise Series 1 and Series 2 warrants	1,512,229	—	—	—	—	—
Proceeds from direct offering, net of \$7,099 of offering expenses	6,388,889	1	107,900	—	—	107,901
Proceeds from exercise of stock options	90,456	—	1,015	—	—	1,015
Unrealized gains on short-term investments	—	—	—	69	—	69
Employee withholdings ESPP	—	—	85	—	—	85
Net loss	—	—	—	—	(17,062)	(17,062)
Balance as of June 30, 2020	<u>38,512,744</u>	<u>\$ 4</u>	<u>\$ 675,294</u>	<u>\$ 117</u>	<u>\$ (527,768)</u>	<u>\$ 147,647</u>
Stock-based compensation expense	—	—	3,063	—	—	3,063
Stock purchase under ESPP	21,105	—	—	—	—	—
Exercise Series 1 and Series 2 warrants	130,151	—	—	—	—	—
Offering expenses associated with direct offering	—	—	(33)	—	—	(33)
Proceeds from exercise of stock options	170,381	—	1,707	—	—	1,707
Unrealized loss on short-term investments	—	—	—	(64)	—	(64)
Employee withholdings ESPP	—	—	94	—	—	94
Net loss	—	—	—	—	(20,437)	(20,437)
Balance as of September 30, 2020	<u>38,834,381</u>	<u>\$ 4</u>	<u>\$ 680,125</u>	<u>\$ 53</u>	<u>\$ (548,205)</u>	<u>\$ 131,977</u>

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. In the nine months ended September 30, 2021, the Company sold 277,629 shares of common stock under the 2021 ATM Program, with net proceeds of approximately \$5.1 million.

In March 2019, the Company issued 2,095,039 shares of its common stock and pre-funded warrants to purchase 2,500,000 shares of common stock to certain investors in a registered direct offering. The pre-funded warrants are exercisable immediately upon

issuance at an exercise price of \$0.0001 per share and have a term of 20 years. The Company sold the shares of common stock and pre-funded warrants together with two series of warrants, Series 1 Warrants and Series 2 Warrants, to purchase an aggregate of 4,595,039 shares of the Company's common stock (collectively, the "Series Warrants"). The offering price for the securities was \$6.00 per share (or \$5.9999 for each Pre-Funded Warrant). The aggregate gross proceeds to the Company from this offering were \$27.6 million, excluding any proceeds the Company may receive upon exercise of the pre-funded warrants and Series Warrants and offering costs of \$0.2 million. No underwriter or placement agent participated in the offering.

The Series Warrants were immediately exercisable. Each Series 1 Warrant had an initial exercise price of \$12.00 per share of common stock and each Series 2 Warrant had an initial exercise price of \$18.00 per share of common stock, in each case subject to certain adjustments. All Series 1 and Series 2 warrants were exercised in 2020.

The Pre-Funded Warrants may not be exercised by the holder to the extent that the holder, together with its affiliates, would beneficially own, after such exercise more than 9.99% of the shares of the Company's common stock then outstanding (subject to the right of the holder to increase or decrease such beneficial ownership limitation upon notice to the Company, provided that such limitation cannot exceed 19.99%) and provided that any increase in the beneficial ownership limitation shall not be effective until 61 days after such notice is delivered.

The Series Warrants were classified as a component of permanent equity and were recorded at the issuance date using a relative fair value allocation method. The Series Warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of shares of common stock upon exercise. In addition, such warrants do not provide any guarantee of value or return. The Company valued the Series Warrants at issuance in March 2019 using the Black Scholes option pricing model and determined the fair value of the 4,595,039 Series Warrants at \$3.4 million. The key inputs to the valuation model included the weighted average volatility of 89.1% and the weighted-average expected term of 1.4 years.

In January 2020, the Company sold 3,036,719 shares of common stock and pre-funded warrants to purchase 1,338,287 shares of common stock. The offering price for the securities was \$8.00 per share of common stock or \$7.9999 for each pre-funded warrant. As a result of this offering, the exercise price of Series 1 Warrants and Series 2 Warrants outstanding reset from \$12.00 per share to \$10.00 per share and from \$18.00 per share to \$13.00, respectively. The Company recorded \$3.9 million as a deemed dividend which represents the value transferred to the warrant holders due to the Series Warrant adjustment mechanism being triggered. The deemed dividend was recorded as both an increase and a decrease in Additional Paid-in-Capital and reduced net income available to common stockholders by the same amount. The key inputs to the valuation model included the weighted average volatility of 96.74% and the weighted average expected term of 0.4 years.

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:

	<b>September 30, 2021</b>
Common stock issuable under pre-funded warrants	3,307,952
Options to purchase common stock	1,001,470
Employee Stock Purchase Plan	1,275,347

## 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 12, 2021.*

### Company Overview

We are a clinical-stage biopharmaceutical company developing an innovative pipeline of cancer therapies. Our two lead product candidates are, SNDX-5613 and SNDX-6352, or axatilimab. We are developing SNDX-5613, 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. As a result, we are not and have never been profitable and have incurred losses in each period since our inception in 2005. For the nine months ended September 30, 2021 and 2020, we reported a net loss of \$71.3 million and \$52.7 million, respectively. We reported a net loss attributable to stockholders of \$71.3 million and \$56.6 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of \$639.9 million, which included non-cash charges for stock-based compensation, preferred stock accretion and extinguishment charges. As of September 30, 2021, we had cash, cash equivalents and short-term investments of \$229.7 million.

We continue to monitor our daily operations and program timelines during the evolving coronavirus 2019 (COVID-19) pandemic. The health and safety of our employees as well as the patients and people participating in and operating our clinical trials are of paramount importance. COVID-19, including its variants, has not impacted our financial guidance or changed our timelines for clinical data in 2021, to date.

### Clinical Developments

#### SNDX-5613

- The Phase 2 portion of AUGMENT-101 is currently enrolling patients with NPM1c mutant and MLLr relapsed/refractory acute leukemias. A total of 64 adult and up to 10 pediatric patients will be enrolled across each of the following three distinct trial populations: patients with NPM1 mutant acute myeloid leukemia (AML), patients with MLLr AML, and patients with MLLr acute lymphocytic leukemia. Discussions with the FDA have confirmed that AUGMENT-101 may potentially serve as the basis for regulatory filings in each of the three distinct trials. The primary endpoint for each of the three trials will be efficacy as measured by complete remission rate (complete response [CR] + CR with partial hematologic recovery rate [CRh]), with key secondary endpoints including duration of response and overall survival.
- In November 2021, we announced that updated data from the Phase 1 portion of the ongoing AUGMENT-101 trial will be featured during an oral session at the 63rd ASH Annual Meeting being held December 11-14, 2021. Data included in the abstract demonstrated robust clinical activity with durable responses and no discontinuations due to treatment-related adverse events. The oral presentation will include updated Phase 1 data from additional patients as of a more recent cutoff date, as well as further details on durability and CR/CRh rate by mutational status.
- In November 2021, we also announced plans to initiate a new trial to assess the anti-leukemic efficacy of SNDX-5613 in NPM1 or MLLr patients with measurable residual disease (MRD) progression following initial treatment. The trial will be conducted as part of the Australian Leukemia and Lymphoma Group (ALLG) INTERCEPT Master Clinical Trial, a collaborative clinical trial investigating novel therapies to target early relapse and clonal evolution as pre-emptive therapy in AML. SNDX-5613 is the first menin inhibitor to be included in the INTERCEPT AML Master Clinical Trial. We expect ALLG to initiate the trial in the first half of 2022.
- In August 2021, we announced plans to initiate two additional trials to assess the safety, tolerability, and preliminary anti-leukemic efficacy of SNDX-5613 in combination with venetoclax and azacitidine as part of the Leukemia & Lymphoma Society's Beat® AML Master Clinical Trial, and in combination with chemotherapy in patients with R/R NPM1 or MLLr acute leukemias in the AUGMENT-102 trial. We expect both trials to initiate in the first half of 2022.

## **Axatilimab**

- In November 2021, we announced that updated data from its Phase 1/2 trial of axatilimab in patients with cGVHD will be featured during an oral session at the 63rd ASH Annual Meeting. Data included in the abstract demonstrated broad efficacy and tolerability for axatilimab in patients with relapsed or refractory cGVHD. The oral presentation will include additional follow up on all patients enrolled.

Enrollment is ongoing in our global pivotal Phase 2 AGAVE-201 trial of axatilimab in patients with cGVHD, with topline data expected in 2023. The trial will evaluate the safety and efficacy of three doses and schedules 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.

- In September 2021, together with Incyte we announced that we entered into an exclusive worldwide collaboration and license agreement to develop and commercialize axatilimab. The companies are seeking to develop axatilimab as a backbone therapy for patients with cGVHD as well as in additional immune-mediated diseases where CSF-1R-dependent monocytes and macrophages are believed to contribute to organ fibrosis. In addition to the ongoing global pivotal Phase 2 AGAVE-201 trial of axatilimab monotherapy in patients with cGVHD, the companies also plan to initiate additional trials of axatilimab in patients with cGVHD in 2022, including a Phase 2 trial in combination with a JAK inhibitor in patients with steroid-refractory cGVHD. Beyond cGVHD, we plan to commence a Phase 2 proof of concept trial of axatilimab mid next year in patients with IPF, a serious, life-limiting orphan disease for which axatilimab may represent a much-needed treatment option with a novel mechanism of action.

## **COVID-19 Business Update**

We have implemented business continuity plans designed 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, the remaining uncertainties with respect to the logistics of mass vaccinations for COVID-19 and any limitations to the efficacy of such vaccines, the evolution of multiple variants of the virus and the 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. In March 2020, our workforce transitioned to working remotely. We are gradually reopening our offices to allow employees to return to the office, while also supporting remote working options.

### **Supply Chain**

We are working closely 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 COVID-19 pandemic. We currently expect to have adequate supplies of SNDX-5613 and axatilimab. If the COVID-19 pandemic continues to persist for an extended period of time and begins to impact 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.

### **Clinical Development**

With respect to clinical development, we have taken 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 slight impact on our ability to maintain patient enrollment in the AUGMENT-101 and AGAVE 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 and persists for an extended period of time, we could experience significant disruptions to our clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects.

### **Corporate Development**

With our strong cash balance, we anticipate having sufficient liquidity to make planned investments in our business this year in support of our long-term growth strategy. We believe that our cash, cash equivalents and marketable securities as of September 30, 2021 will fund our current operating plans through at least the next 12 months. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity

or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. However, the COVID-19 pandemic continues to rapidly evolve and 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, which could in the future negatively affect our operations.

### ***Other Financial and Corporate Impacts***

While we continue to evaluate whether the COVID-19 pandemic will adversely affect our business operations and financial results, our clinical development 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 United States, Europe and other countries, and the effectiveness of actions taken globally to contain and treat the disease. For example, if remote work policies for certain portions of our business, or that of our business partners, are extended longer than we currently expect, we may need to reassess our priorities and our corporate objectives for the year.

## **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 revenues for the three and nine months ended September 30, 2021 and 2020 have been solely derived from our license, development and commercialization agreement with Kyowa Kirin Co., Ltd., or KKC, under which we granted KKC an exclusive license to develop and commercialize entinostat in Japan and Korea, or the KKC license agreement. In 2015, we received a \$25.0 million upfront payment from KKC, inclusive of an equity investment. We allocated \$17.3 million of the upfront payment to the license fee, and such fee is being recognized as revenue ratably over our expected performance period (currently expected to be through 2029). The balance of the upfront payment of \$7.7 million was allocated to KKC's purchase of shares of our convertible preferred stock.

In October 2017, KKC enrolled the first Japanese patient into a local pivotal study of entinostat for the treatment of hormone receptor positive, human epidermal growth factor 2 negative breast cancer. In accordance with the terms of the KKC License Agreement, in December 2017 we received a \$5.0 million milestone payment from KKC for achievement of the development milestone.

In September 2021, KKC informed us, that they have discontinued the entinostat program and have cancelled the license to develop and commercialize entinostat. As a result, we recognized \$12.4 million in revenue which was previously deferred.

### ***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.

#### ***Critical Accounting Policies and Use of 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 policies described in the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” contained in our Annual Report.

## Results of Operations

### Comparison of the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Increase (Decrease)	
	2021	2020	\$	%
(In thousands)				
<b>Revenue:</b>				
License fees	\$ 12,375	\$ 379	\$ 11,996	3165%
<b>Total revenues</b>	<b>12,375</b>	<b>379</b>	<b>11,996</b>	<b>3165%</b>
<b>Operating expenses:</b>				
Research and development	25,606	14,408	11,198	78%
General and administrative	6,801	5,824	977	17%
<b>Total operating expenses</b>	<b>32,407</b>	<b>20,232</b>	<b>12,175</b>	<b>60%</b>
Loss from operations	(20,032)	(19,853)	179	1%
<b>Other (expense) income:</b>				
Interest expense	(649)	(635)	(14)	2%
Interest income	83	177	(94)	-53%
Other (expense) income, net	(41)	(126)	85	-67%
<b>Total other (expense) income</b>	<b>(607)</b>	<b>(584)</b>	<b>(23)</b>	<b>4%</b>
<b>Net loss</b>	<b>\$ (20,639)</b>	<b>\$ (20,437)</b>	<b>\$ 202</b>	<b>1%</b>

### License Fees

For the three months ended September 30, 2021 and 2020, we recognized license fees of \$12.4 million and \$0.4 million respectively, derived from the KKC license agreement.

### Research and Development

For the three months ended September 30, 2021, our total research and development expenses increased approximately \$11.2 million, or 78%, to \$25.6 million from \$14.4 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 \$9.5 million, employee related expenses of \$1.0 million and professional fees of \$0.2 million and stock-based comp expense of \$0.5 million. Increases in clinical and manufacturing expenses were primarily due to manufacturing activities related tomenin research of \$4.2 million and CMC drug production costs of \$2.1 million. We also recognized a \$2.0 million expense upon the achievement of a certain milestone in connection with the SNDX-6352 program. Employee related expenses and stock-based compensation primarily increased due to an increase in headcount and new hire grants. 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 September 30,		Increase (Decrease)	
	2021	2020	\$	%
(In thousands)				
External research and development expenses	\$ 20,658	\$ 10,968	\$ 9,690	88%
Internal research and development expenses	4,948	3,440	1,508	44%
<b>Total research and development expenses</b>	<b>\$ 25,606</b>	<b>\$ 14,408</b>	<b>\$ 11,198</b>	<b>78%</b>

### General and Administrative

For the three months ended September 30, 2021, our total general and administrative expenses increased \$1 million, or 17%, to \$6.8 million from \$5.8 million for the comparable period in the prior year. The increase in general and administrative expenses was primarily due to an increase in professional service fees of \$0.9 million, and insurance expense of \$0.1 million.

### Interest expense

For the three months ended September 30, 2021, interest expense increased from the comparable period in the prior year primarily due to the interest expense on the loan payable.

### Interest income

For the three months ended September 30, 2021, interest income decreased from the comparable period in the prior year primarily due to a decrease on interest income related to the average balance of cash equivalents and short-term investments.

### Comparison of the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		Increase (Decrease)	
	2021	2020	\$	%
(In thousands)				
Revenue:				
License fees	\$ 13,133	\$ 1,138	\$ 11,995	1054%
Total revenues	13,133	1,138	11,995	1054%
Operating expenses:				
Research and development	64,348	34,913	29,435	84%
General and administrative	18,314	17,787	527	3%
Total operating expenses	82,662	52,700	29,962	57%
Loss from operations	(69,529)	(51,562)	17,967	35%
Other income (expense):				
Interest expense	(1,906)	(1,722)	(184)	11%
Interest income	312	735	(423)	-58%
Other expense (income), net	(149)	(186)	37	-20%
Total other income	(1,743)	(1,173)	(570)	49%
Net loss	\$ (71,272)	\$ (52,735)	\$ 18,537	35%

### License Fees

For the nine months ended September 30, 2021 and 2020, we recognized license fees of \$13.1 million and \$1.1 million respectively, derived from the KKC license agreement.

### Research and Development

For the nine months ended September 30, 2021, our total research and development expenses increased \$29.4 million, or 84%, to \$64.3 million from \$34.9 million for the comparable period in the prior year due to increases in clinical and manufacturing activities of \$25.3 million, employee related expenses of \$2.2 million, stock-based compensation of \$1.4 million and professional fees of \$0.5 million. Increases in clinical and manufacturing activities were primarily due to increased manufacturing activities related to menin and axatilimab of \$6.7 million, and \$5.7 million, respectively, and increases in clinical activities for menin and axatilimab of \$3.4 million and \$4.5 million, respectively. Employee related expenses and stock-based compensation primarily increased due to increased headcount and related new hire grants. 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:



	Nine Months Ended September 30,		Increase (Decrease)	
	2021	2020	\$	%
	(In thousands)			
External research and development expenses	\$ 50,327	\$ 24,564	\$ 25,763	105%
Internal research and development expenses	14,021	10,349	3,672	35%
Total research and development expenses	\$ 64,348	\$ 34,913	\$ 29,435	84%

### **General and Administrative**

For the nine months ended September 30, 2021, our total general and administrative expenses increased \$0.5 million, or 3%, to \$18.3 million from \$17.8 million for the comparable period in the prior year. The increases in general and administrative expenses were primarily due to increases in stock-based compensation \$0.9 million associated with increase related to Board RSU grants, \$0.3 million related to employee bonuses and \$0.2 million related to insurance expense, partially offset by decrease in professional services fees of \$0.9 million related to the termination of E2112 commercialization.

### **Interest Expense**

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

### **Interest Income**

For the nine months ended September 30, 2021, interest income decreased from the comparable period in the prior year primarily due to lower interest rates.

### **Liquidity and Capital Resources**

#### **Overview**

As of September 30, 2021, we had cash, cash equivalents and short-term investments totaling \$229.7 million, which includes \$5.1 million in net proceeds from the sale of 277,629 shares of common stock under our 2021 ATM Program (as described below). Our operations have been primarily financed by net proceeds from our initial public offering, our follow-on stock offerings, and proceeds from our license agreements. We believe that our present cash, cash equivalents and short-term investments 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.

The COVID-19 pandemic continues to rapidly evolve and 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, which could in the future negatively affect our operations.

#### **Loan and Security Agreement**

On February 7, 2020, we entered into a loan and security agreement, or the Loan Agreement, with Hercules Capital, Inc., or Hercules, which provides for aggregate maximum borrowings of up to \$30.0 million, consisting of (i) a term loan of up to \$20.0 million, which was funded on February 7, 2020, and (ii) subject to Hercules' investment committee approval, an additional term loan of up to \$10.0 million, available for borrowing from February 7, 2020 to December 15, 2020, which we refer to as the Tranche 2 Advance. We did not request the available additional borrowings by the due date. Borrowings under the Loan Agreement are repayable in monthly interest-only payments through October 1, 2021. After the interest-only payment period, borrowings under the Loan Agreement are repayable in equal monthly payments of principal and accrued interest until the maturity date of the loan, which is September 1, 2023. Borrowings under the Loan Agreement bear interest at an annual rate equal to the greater of (i) 9.85% or (ii) 5.10% plus the Wall Street Journal prime rate. The Wall Street Journal prime rate as of September 30, 2021, was 3.25%. At our option, we may prepay all, but not less than all, of the outstanding borrowings, subject to a prepayment premium. 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. For additional information regarding the Loan Agreement with Hercules, see Note 11 to our condensed consolidated financial statements located elsewhere in this report.

### ***At-the-Market Offering Program***

In March 2021, we entered into a sales agreement with Cowen and Company, LLC, or 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, or 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 September 30, 2021, we sold 277,629 shares of common stock under the 2021 ATM Program for net proceeds of approximately \$5.1 million.

### ***Future Funding Requirements***

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, clinical costs, 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 drug 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 drug 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 generate sales of and revenues from entinostat, if approved, and 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.

We have incurred losses and cumulative negative cash flows from operations since our inception; and as of September 30, 2021, we had an accumulated deficit of \$639.9 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. The ongoing COVID-19 pandemic has resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital, which could in the future negatively affect our operations. 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:

	<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
	<b>(In thousands)</b>	
Net cash used in operating activities	\$ (71,578)	\$ (55,629)
Net cash provided by / used in investing activities	19,083	(78,390)
Net cash provided by financing activities	8,685	165,766
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ (43,810)</u>	<u>\$ 31,747</u>

#### **Net Cash Used in Operating Activities**

Net cash used in operating activities for the nine months ended September 30, 2021, was \$71.6 million and primarily consisted of our net loss of \$71.3 million adjusted for non-cash items, including stock-based compensation of \$9.4 million, a net decrease in operating assets and liabilities of \$10.9 million, an investment accretion of \$0.5 million, a non-cash operating lease expense of \$0.3 million and non-cash interest expense associated with the term loan of \$0.4 million. The increase in net loss was primarily due to increased 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 \$1.6 million, increased prepayments and deposits of \$1.5 million and increased accrued expenses and other liabilities of \$2.1 million and decreased deferred revenue of \$13.1 million.

Net cash used in operating activities for the nine months ended September 30, 2020, was \$55.6 million and primarily consisted of our net loss of \$52.7 million adjusted for non-cash items, including stock-based compensation of \$7.0 million, a net decrease in operating assets and liabilities of \$10.4 million, an investment accretion of \$0.2 million and non-cash interest expense associated with the term loan of \$0.3 million. The increased net loss is primarily due to increased clinical activities in our axatilimab program, increased clinical and CMC activities in our SNDX-5613 program, increased pre-commercialization activities partially offset by reduced CMC expenses for axatilimab and decreased activities related to our entinostat program. The net decrease in operating assets and liabilities primarily consisted of decreased accounts payable of \$2.4 million, increased prepayments and deposits of \$5.8 million, and decreased accrued expenses and other liabilities of \$1.1 million and deferred revenue of \$1.1 million.

#### **Net Cash Provided by / Used in Investing Activities**

Net cash provided by investing activities for the nine months ended September 30, 2021, was \$19.1 million and was primarily due to the purchase of \$189.5 million of available-for-sale marketable securities partially offset by the \$208.6 million of proceeds from the maturities of available-for-sale securities.

Net cash used in investing activities for the nine months ended September 30, 2020, was \$78.4 million and was primarily due to the purchase of \$150.4 million of available-for-sale marketable securities from the proceeds of the January 2020 direct offering partially offset by \$72.0 million of proceeds from the maturities of available-for-sale securities, which will primarily be used to fund the next period's operating activities.

### ***Net Cash Provided by Financing Activities***

Net cash provided by financing activities for the nine months ended September 30, 2021, of \$8.7 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 \$3.3 million and employee participation in our Employee Stock Purchase Plan of \$0.2 million.

Net cash provided by financing activities for the nine months ended September 30, 2020, of \$165.8 million was primarily due to the proceeds from our direct placement and follow-on offering, net of fess, of \$142.7 million, net proceeds from our term loan of \$19.7 million, proceeds from stock option exercises of \$3.1 million and employee participation in our Employee Stock Purchase Plan of \$0.2 million.

### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

### **Emerging Growth Company and Smaller Reporting Company Status**

We are an “emerging growth company,” or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies. We will cease to be an “emerging growth company” on December 31, 2021.

As of June 30, 2021, we no longer qualify as a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended. We have historically taken and may continue through the filing of our Annual Report on Form 10-K for the year ending December 31, 2021 to take, advantage of certain scaled disclosures available to smaller reporting companies.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2021, we had cash and cash equivalents of \$71.4 million, consisting of overnight investments, interest-bearing money market funds, commercial papers and short-term corporate bonds, and short-term investments of \$158.3 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 (i) 9.85% and (ii) 5.10% plus the Wall Street Journal prime rate. As of September 30, 2021, \$20.0 million in loan principal was outstanding under the Loan Agreement. The effect of a 100 basis points adverse change in market interest rates on our 2020 Loan Payable, 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**

#### ***Management’s Evaluation of Our Disclosure Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities and Exchange Act of 1934 is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of September 30, 2021, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

***Changes in Internal Control over Financial Reporting***

There was no change in our internal control over financial reporting that occurred during our most recent fiscal quarter that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

In the ordinary course of business, we are from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters. While the outcome of these proceedings and claims cannot be predicted with certainty, as of September 30, 2021, 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:

- The ongoing COVID-19 pandemic could adversely impact our business, including our clinical trials.
- 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.
- SNDX-5613 has undergone limited clinical testing and we may fail to show that the drug 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 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.
- Our dependency upon our pending collaboration with Incyte 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.
- 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 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 you could lose all or part of your 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**

#### ***The ongoing COVID-19 pandemic could adversely impact our business, including our clinical trials.***

The ongoing COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease, including state and local orders across the United States and other countries worldwide, which, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, and order cessation of non-essential travel. In response to these public health directives and orders, we have implemented work-from-home policies for our employees. The effects of executive orders may disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

While COVID-19 has not yet had a material impact on our business operations, quarantines and various government orders related to COVID-19, including its variants, may adversely impact our business operations and the business operations of our contract research organizations conducting our clinical trials and our third-party manufacturing facilities in the United States and other countries. In particular, if the COVID-19 pandemic continues to persist for an extended period of time and begins to impact 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, which would adversely impact our ability to continue our clinical trial operations.

In addition, our clinical trials may be affected by the COVID-19 pandemic. For example, we have experienced delays in clinical site initiation and patient enrollment due to prioritization of hospital resources toward the COVID-19 pandemic. Patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, could be limited, which in turn could adversely impact our clinical trial operations. As a result, we may face delays in meeting our anticipated timelines for our ongoing and planned clinical trials.

The spread of COVID-19, including its variants, which has caused a broad impact globally, may materially affect us economically. While the full extent of the economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, the pandemic has resulted in uncertainty in macroeconomic conditions and result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the pandemic could materially affect our business and the value of our common stock.

COVID-19 continues to evolve rapidly, and multiple variants of the virus that cause COVID-19 are circulating globally. The extent to which the COVID-19 pandemic impacts our business, our clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, travel restrictions, quarantines, social distancing requirements, business closures in the United States and other countries, the rollout of mass vaccinations for COVID-19 and any limitations to the efficacy of such vaccines and the effectiveness of other actions taken in the United States and other countries to contain and treat the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

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 described in this “Risk Factors” section.

***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 the Phase 1/2 clinical trial, AUGMENT-101, of SNDX-5613 in patients with relapsed/refractory MLLr and NPM1c acute leukemia;
- timely completion of the pivotal Phase 2 clinical trial, AGAVE-201, of axatilimab in patients with chronic Graft Versus Host Disease, or cGVHD;
- timely completion of any future clinical trials of SNDX-5613 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;
- 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 cancer indications 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 in and 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.

***SNDX-5613 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 SNDX-5613, 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 SNDX-5613 is to conduct a Phase 1/2 clinical trial in relapsed/refractory 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 SNDX-5613, 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 will evaluate efficacy of SNDX-5613 across three expansion cohorts enrolling pediatric and adult patients with MLLr acute lymphoblastic leukemia, or ALL, MLLr acute myeloid leukemia, or AML, and 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 SNDX-5613 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. 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 2021, we announced interim data from our Phase 1/2 clinical trial of SNDX-5613. 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.

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

- direct and indirect effects of the ongoing COVID-19 pandemic;
- 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 an orphan indication such as MLLr acute leukemia;
- 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 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 may 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 could harm our business.***

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 safe and effective;
- 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 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 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 supplies;
- 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, or 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;
- 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 addition, public health epidemics, such as the worldwide 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 be heavily scrutinized by the FDA, 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 and 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*®), belomosalidil (*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.

SNDX-5613 is being developed for the treatment of 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, SNDX-5613 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; and
- our ability to manufacture commercial quantities of our product candidates if they receive regulatory approval.

Even if we obtain regulatory approval of our product candidates, the availability 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.

***We are dependent upon our pending 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.***

In September 2021, we entered into a collaboration and license agreement (the "Incyte Agreement") with Incyte to collaborate on the development and commercialization of axatilimab. Pursuant to the Incyte Agreement, Incyte has agreed to pay an upfront, non-refundable payment of \$117 million, in addition to a \$35 million equity investment. We are eligible to receive up to \$450 million in aggregate regulatory, development and commercial milestone payments plus the tiered royalties. The parties have agreed to co-develop axatilimab and to share development costs associated with global and U.S.-specific clinical trials, with Incyte responsible for 55% of such costs and we are 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. If the Incyte Agreement becomes effective, there can be no assurance that the parties will achieve any of the regulatory, development or sales milestones, or 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.

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

We currently sublicense entinostat to Eddingpharm under which we granted Eddingpharm an exclusive sublicense to develop and commercialize entinostat in China and select Asian countries. It is possible that any clinical trials conducted by Eddingpharm and other current or future sublicensees in their respective jurisdictions could have negative results, which in turn could have a material adverse effect on the development of entinostat for development and commercialization in the United States and the rest of the world.

***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. In July 2016, we entered into the UCB license agreement pursuant to which we obtained a worldwide, sublicenseable, exclusive license to axatilimab, an IND-ready anti-CSF-1R monoclonal antibody. 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 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 industry 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, 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 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 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, 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, or 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, which began on February 15, 2021 and will remain open through August 15, 2021. 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, including the BBA, has extended the 2% reduction to 2030 with the exception of a temporary suspension from May 1, 2020 through December 31, 2021 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 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 on September 24, 2020, effective November 30, 2020, providing guidance 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 Centers for Medicare & Medicaid Services, or 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. The MFN regulations mandate participation by identified Medicare Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021 and ending December 31, 2027. On December 28, 2020, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction against implementation of the interim final rule. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District Court of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN model interim final rule shall not commence earlier than sixty (60) days after publication of that regulation in the Federal Register. Additionally, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. 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, 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 would have to 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 force;
- 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) 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. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse-midwives; 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 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 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.

For the nine months ended September 30, 2021, we reported a net loss attributable to stockholders of \$71.3 million. As of September 30, 2021, we had an accumulated deficit of \$639.9 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 future 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 the COVID-19 pandemic. For example, 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 implement additional internal systems and infrastructure, including 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 \$30.0 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 September 30, 2021, 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, 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 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 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. ("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 SNDX-5613 or if the license agreement is otherwise terminated, we could lose the ability to continue the development and commercialization of SNDX-5613.***

Our commercial success depends upon our ability to develop, manufacture, market and sell SNDX-5613. 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 SNDX-5613, 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. In June 2019, we achieved certain development and regulatory milestones. As a result, in June 2019, we recorded \$4.0 million as research and development expense. The amount was paid in 2020.

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 SNDX-5613 have occurred and the last-to-expire relevant patent covering SNDX-5613 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 SNDX-5613 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.***

In March 2007, we entered into 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 U.S. Patent and Trademark Office, or 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.

In addition, the stock market in general, and the Nasdaq Global Select Market 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 very recently in connection with the ongoing COVID-19 pandemic, which has 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 ongoing 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.

***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 revenue 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 2020, we sold a total of 15,675,608 shares of our common stock and pre-funded warrants to purchase 1,338,287 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 September 30, 2021, we had 3,307,952 pre-funded warrants outstanding. 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 February 7, 2020, we entered into the Loan Agreement with Hercules, which provided for aggregate maximum borrowings of up to \$30.0 million, consisting of (i) a term loan of up to \$20.0 million, which was funded on February 7, 2020, and (ii) subject to Hercules' investment committee approval, an additional term loan of up to \$10.0 million, available for borrowing from February 7, 2020 to December 15, 2020. We did not request the available additional borrowing by the due date. 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 September 30, 2021, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 36.4% 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 are an “emerging growth company” as defined in the JOBS Act and a “smaller reporting company” and may avail ourselves of reduced disclosure requirements applicable to such companies, which could make our common stock less attractive to investors and adversely affect the market price of our common stock.***

For so long as we remain an “emerging growth company” as defined in the JOBS Act, we may take advantage of certain exemptions from various requirements applicable to public companies that are not “emerging growth companies” including:

- the provisions of Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- the “say on pay” provisions (requiring a non-binding stockholder vote to approve compensation of certain executive officers) and the “say on golden parachute” provisions (requiring a non-binding stockholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Act and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our chief executive officer;
- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and instead provide a reduced level of disclosure concerning executive compensation; and
- any rules that the Public Company Accounting Oversight Board may adopt requiring mandatory audit firm rotation or a supplement to the auditor’s report on the financial statements.

We may take advantage of these exemptions until we are no longer an “emerging growth company.” We will cease to be an “emerging growth company” on December 31, 2021.

We currently take advantage of some, but not all, of the reduced regulatory and reporting requirements that are available to us so long as we qualify as an “emerging growth company.” For example, we have irrevocably elected not to take advantage of the extension of time to comply with new or revised financial accounting standards available under Section 102(b) of the JOBS Act. Our independent registered public accounting firm is not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an “emerging growth company,” which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as an “emerging growth company,” we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the Securities and Exchange Commission, or SEC, which may make it more difficult for investors and securities analysts to evaluate our company. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile and may decline.

As of June 30, 2021, we no qualify as a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We have historically taken, and may continue through the filing of our Annual Report on Form 10-K for the year ending December 31, 2021 to take, advantage of certain scaled disclosures available to smaller reporting companies.

***Effective as of December 31, 2021, we will be a large accelerated filer, which will increase our costs and demands on management.***

As a result of the market value of our common stock held by non-affiliates as of June 30, 2021, we will be a large accelerated filer as of December 31, 2021, and we will therefore no longer qualify as an EGC. Additionally, due to our public float as of June 30, 2021, we will no longer qualify as a smaller reporting company as defined in the Exchange Act. However, we are not required to reflect the change in our smaller reporting company status, and comply with the associated increased disclosure obligations, until our quarterly report for the three-month period ended March 31, 2022.

As a large accelerated filer, we will be subject to certain disclosure and compliance requirements that apply to other public companies that did not previously apply to us due to our status as an emerging growth company. These requirements include, but are not limited to:

- the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002;
- compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- the requirement that we provide full and more detailed disclosures regarding executive compensation; and



- the requirement that we hold a non-binding advisory vote on executive compensation and obtain shareholder approval of any golden parachute payments not previously approved.

We expect that compliance with the additional requirements of being a large accelerated filer will increase our legal and financial compliance costs and may cause management and other personnel to divert attention from operational and other business matters to devote increased time to public company reporting requirements. In addition, if we are not able to comply with changing requirements in a timely manner, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources. We are also a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by nonaffiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than \$100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

***Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of 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.

While we have been EGC, our independent registered public accounting firm has not been required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. This exemption will no longer apply to us as of December 31, 2021. Accordingly, beginning with our annual report on Form 10-K for the year ending December 31, 2021, we will be 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 will 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 begins 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 6. Exhibits**

Exhibit No.	Description
3.1	<a href="#"><u>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).</u></a>
3.2	<a href="#"><u>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).</u></a>
10.1**	<a href="#"><u>Collaboration and License Agreement by and between the Company and Incyte Corporation, dated as of September 24, 2021.</u></a>
10.2	<a href="#"><u>Stock Purchase Agreement by and between the Company and Incyte Corporation, dated as of September 24, 2021.</u></a>
31.1	<a href="#"><u>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.</u></a>
31.2	<a href="#"><u>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.</u></a>
32.1*	<a href="#"><u>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.</u></a>
101	Financial statements from the Quarterly Report on Form 10-Q of Syndax Pharmaceuticals, Inc. for the quarter ended September 30, 2021, 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).

\* 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.

\*\* Certain portions of this exhibit (indicated by asterisks) have been excluded pursuant to Item 601(b)(10) of Regulation S-K because they are both not material and are the type of information that the Registrant treats as private or confidential.

## SIGNATURES

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

Date: November 15, 2021

By: /s/ Briggs W. Morrison, M.D.  
Briggs W. Morrison, M.D.  
Chief Executive Officer  
(Principal Executive Officer)

By: /s/ Alexander Nolte  
Alexander Nolte  
Chief Accounting Officer  
(Principal Accounting Officer, Interim Principal  
Financial Officer)

## COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement ("**Agreement**") is made and entered into effective as of **September 24, 2021** (the "**Execution Date**"), by and between

**Syndax Pharmaceuticals, Inc.**, a Delaware corporation having a place of business at 35 Gatehouse Drive, Building D, Floor 3, Waltham, Massachusetts 02451 ("**Syndax**")

and

**Incyte Corporation**, a Delaware corporation with its principal place of business at 1801 Augustine Cut-Off, Wilmington, Delaware 19803, USA ("**Incyte**").

Syndax and Incyte each may be referred to herein individually as a "**Party**," or collectively as the "**Parties**."

### RECITALS

- A.** Syndax has in-licensed from UCB Biopharma and further developed a humanized monoclonal antibody specifically binding to CSF-1R (as defined below) called axatilimab or SNDX-6352 (as defined herein). Syndax controls certain patents and other intellectual property rights pertaining to SNDX-6352 and methods and uses relating thereto;
- B.** Syndax and Incyte desire to establish a global collaboration for the further worldwide development and commercialization of SNDX-6352; and
- C.** Under such global collaboration Incyte will have the exclusive commercialization rights outside of the US and, subject to certain co-commercialization rights held by Syndax, in the US.

In consideration of the foregoing premises, the mutual promises and covenants set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Syndax and Incyte hereby agree as follows:

### **1. DEFINITIONS**

When used in this Agreement, capitalized terms shall have the meanings as defined below and throughout the Agreement. Unless the context indicates otherwise, the singular shall include the plural and the plural shall include the singular.

- 1.1** [\*\*\*]
- 1.2** [\*\*\*]
- 1.3** "**Acquired Party**" has the meaning set forth in Section 12.2.
- 1.4** "**Acquired Product**" has the meaning set forth in Section 12.2.
- 1.5** "**Acquirer**" has the meaning set forth in Section 12.2.
- 1.6** "**Acquirer Program**" has the meaning set forth in Section 12.2.

- 1.7** "Acquiring Party" has the meaning set forth in Section 12.2.
- 1.8** "Affiliate" means with respect to a Party, any entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the ownership of fifty percent (50%) or more of the voting securities entitled to elect the directors or management of the entity, or the power to, directly or indirectly, elect or direct or cause the direction of the management or policies of the entity, whether by law, contract or otherwise.
- 1.9** "AGAVE-201 Trial" means the Phase 2 Trial for Product for chronic Graft Versus Host Disease having the study identification number SNDX-6352-504 (NCT04710576).
- 1.10** "Anti-Bribery Laws" has the meaning set forth in Section 18.12.
- 1.11** "Antibody" means whether in nucleic acid or protein form, individually and collectively, any antibody, whether naturally occurring, artificially produced, raised in an artificial system, designed de novo, or created through modification of another antibody or otherwise; any fragment or fusion of any of the foregoing; and any chemically modified versions of the foregoing antibodies (including versions that are conjugated with another chemical entity, such as a drug or toxin; pegylated versions (regardless of whether containing amino acid substitutions in order to achieve pegylation or otherwise modified versions to enable half-life extension or other desirable properties), including versions that are chemically or genetically fused to another molecular entity, such as multispecific antibodies, and cytokine fusions; and other chemically or biologically modified versions).
- 1.12** "Antitrust Filings" has the meaning set forth in Section 18.16.
- 1.13** "Bankruptcy Code" has the meaning set forth in Section 17.2(b).
- 1.14** "Bankruptcy Laws" has the meaning set forth in Section 17.2(b).
- 1.15** "BLA" means a (i) Biologic License Application (as defined in the Public Health Service Act ("PHSA")), (ii) a Marketing Authorization Application ("MAA") in the EU, or (iii) any equivalent or comparable application registration or certification in any other country or region.
- 1.16** "Breaching Party" has the meaning described in Section 17.2(a).
- 1.17** "Budget" has the meaning set forth in Section 7.3.
- 1.18** "Business Day" means any day other than (i) Saturday or Sunday, (ii) a public holiday in New York City, New York, or (iii) any other day on which banks in New York City, New York, are permitted or required to be closed.
- 1.19** "Change of Control" means with respect to a Party: (i) the sale of all or substantially all of such Party's assets or business relating to this Agreement to a Third Party, through one transaction or more than one related transactions; (ii) a merger, reorganization or consolidation involving such Party in which the voting securities of such Party outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity as a consequence of such merger, reorganization or consolidation; or (iii) a person or entity, or group of persons or entities, acting in concert (other than financial investment groups that do not have as a primary business the

development and/or commercialization of pharmaceutical products or companion diagnostics) acquires direct or indirect ownership of fifty percent (50%) or more of the voting securities entitled to elect the directors or appoint the management of such Party.

**1.20** "cGVHD Phase 1/2 Trial" means the phase 1/2 Trial for Product for chronic Graft Versus Host Disease having the study identification number SNDX-6352-503 (NCT03604692).

**1.21** "Clearance" means with respect to this Agreement, the expiration or termination of all applicable waiting periods (and any extensions thereof), and any required approvals, under the HSR Act and any other antitrust laws and regulations applicable to this Agreement.

**1.22** "Co-Commercialization" means the performance of the Commercialization activities by Incyte (or by Incyte and Syndax, following Syndax's exercise of the Co-Commercialization Option and/or as otherwise provided in the Co-Commercialization Plan) with respect to the Licensed Antibody(ies) or Product(s) in the Co-Commercialization Territory, as further detailed in Section 5.2.

**1.23**"Co-Commercialization Budget" means the annual budget for Co-Commercialization in the Co-Commercialization Territory, agreed upon by the Parties and approved by the JSC, which budget may be amended and/or supplemented from time to time by the JSC. The initial Co-Commercialization Budget shall be approved by the JSC at least [\*\*\*] prior to the anticipated first launch of the Product in the Co-Commercialization Territory.

**1.24**"Co-Commercialization Costs" means the sum of the following items, in each case to the extent directly attributable to Commercialization of Product in the Field in the Co-Commercialization Territory in accordance with the Co-Commercialization Plan and Co-Commercialization Budget, whether or not occurring prior to or after First Commercial Sale of a Product, and to the extent that such items do not include any costs included in Collaboration Costs: [\*\*\*]. In calculating Co-Commercialization Costs, the costs of internal personnel of a Party engaged in Commercialization efforts shall be based on the FTE Cost applicable to such efforts, unless another basis is otherwise agreed by the Parties in writing.

**1.25**"Co-Commercialization Plan" means the plan for the Co-Commercialization activities, agreed upon by the Parties through the JCC and approved by the JSC, which plan may be amended and/or supplemented from time to time by the JCC and approved by the JSC and shall cover at least the upcoming [\*\*\*] at all times. The initial Co-Commercialization Plan shall be approved by the JSC at least [\*\*\*] prior to the anticipated first launch of the Product in the US.

**1.26**"Co-Commercialization Territory" means the US.

**1.27**"Collaboration Budget" means the annual budget for all Collaboration Costs, in the applicable Development Plan as agreed through the JDC and approved by the JSC, which budget may be amended and/or supplemented from time to time by the JDC and approved by the JSC and shall cover at least the upcoming [\*\*\*] at all times. The initial Collaboration Budget is provided in Schedule 1.27.

**1.28**"Collaboration Costs" means the costs incurred by a Party or its Affiliates that are directly attributable, or reasonably allocable, to the conduct of the Collaboration Trials, provided that such costs are consistent with the applicable Development Plan (including the Collaboration Development Budget contained therein), including costs directly attributable to

the Manufacture, distribution and clinical supply of Licensed Antibody and Product for Collaboration Trials, as well as any combination and comparator products and devices therefor.

**1.29 "Collaboration Development Activities"** means (i) any Collaboration Trial, including Development Activities directly attributable, or reasonably allocable, to the performance of a Collaboration Trial, and (ii) establishment and maintenance of the global safety database (or safety databases, as applicable) and, until obtaining the first Regulatory Approval for Product in Territory, pharmacovigilance activities for the Product; in each case undertaken by or on behalf of a Party or its Affiliates (or their Sublicensee(s) or subcontractors) with respect to the Licensed Antibody or Product in the Field and consistent with the Development Plan.

**1.30 "Collaboration Trial"** means any of the Trials listed on **Schedule 1.30** or any other Trial that the Parties determine to conduct jointly pursuant to Section 3.5.

**1.31 "Combination Product"** means any Product which contains one or more active ingredients (which are not the Licensed Antibody) (each, an **"Other Component"**) in addition to the Licensed Antibody, whether coformulated, copackaged, or otherwise sold at a single invoiced price.

**1.32** [\*\*\*]

**1.33 "Commercialize" or "Commercialization"** means all activities directed to the Pre-Launch, launch, market access, patient support, booking sales, marketing, promotion, advertising, performing Detailing Activities, selling and distribution of a Product in a country or region, including planning, forecasting, market research, market insight, importing, exporting, and post-marketing safety surveillance and reporting and Pricing Activities, including Government Price Calculations and Reporting obligations. For clarity, "Commercialization" shall not include any activities covering Manufacturing or Development or Regulatory Activities.

**1.34 "Commercially Reasonable Efforts"** means, with respect to a Party, the level of efforts required in order to carry out a task in a diligent manner, which level is at least commensurate with the level of efforts that such Party would normally devote to carrying out a similar task for a product of similar potential and having similar commercial and scientific advantages and disadvantages and at a similar stage in its development, taking into account the Product's safety and efficacy; anticipated costs, risks and economic prospects for the Product; the competitiveness of alternative products; the Product's proprietary position; pricing and reimbursement with respect to the Product; financial encumbrances associated with the Product; market-specific factors; technical, scientific and regulatory matters including estimated probabilities of success for future development stages of the Product; and all other relevant factors.

**1.35** [\*\*\*]

**1.36 "Competitive Infringement"** has the meaning set forth in Section 11.7(b).

**1.37 "Confidential Information"** of a Party means (i) all confidential or proprietary information relating to the Licensed Antibody or Products, and (ii) all other Know-How, information and data, and all other scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial or commercial information or data (including Personal Data), whether communicated in writing or orally or by any other method, which is provided by one Party to



the other Party in connection with the exercise of such Party's rights or performance of such Party's obligations under this Agreement or otherwise by a Party under the Prior Confidentiality Agreement.

**1.38** "Controlled" or "Control" means, with respect to any Know-How, Patent, Invention or other intellectual property right, possession (by means of ownership, license (other than pursuant to this Agreement), or otherwise) by a Party, directly or through an Affiliate, of the right to assign or grant a license or sublicense or other right as provided for in this Agreement without violating the terms of any agreement with any Third Party.

**1.39** "Cost of Goods Sold" means, with respect to Drug Substance, Drug Product, Finished Drug Product or Placebo, as the case may be, Manufactured under this Agreement, the reasonable FTE Costs and External Costs of a Party or any of its Affiliates or sublicensees (including Sublicensees, with respect to Incyte) incurred in Manufacturing such Drug Substance, Drug Product, Finished Drug Product or Placebo, including: [\*\*\*].

**1.40** "Cover" means, with respect to a Licensed Antibody or Product and a particular Patent, that such Patent, in the absence of a (sub)license under, or ownership of, such Patent, the making, using, offering for sale, selling or importing of such Licensed Antibody or Product would infringe such Patent as issued or, with respect to a pending claim included in such Patent, as if such pending claim were to issue without modification.

**1.41** "CSF-1R" means colony stimulating factor 1 receptor.

**1.42** "Cure Period" has the meaning set forth in Section 17.2(a).

**1.43** "Data Protection Laws" means all data protection and privacy legislation in force from time to time including but not limited to the EU General Data Protection Regulation 2016/679, as nationally implemented and supplemented in the countries of the European Economic Area, the Health Insurance Portability and Accountability Act of 1996, and any other federal, state, national or local legislation relating to Personal Data and privacy, which is applicable to a Party relating to the processing of Personal Data.

**1.44** "Detail" or "Detailing Activities" means the communication (including face-to-face, video, teledetailing, and e-detail contact) by a Sales Representative to a Healthcare Professional who is within the target audience, during which visit approved uses, safety, effectiveness, contraindications, side effects, warnings, or other relevant characteristics of a pharmaceutical or biological product are discussed in an effort to increase prescribing preferences of a pharmaceutical or biological product for its approved uses. Details shall not include: [\*\*\*].

**1.45** "Detailing Costs" means the costs (including FTE Costs for FTEs performing Detailing Activities in the Co-Commercialization Territory and External Costs) incurred by a Party, its Affiliates or sublicensees in accordance with the Co-Commercialization Plan and the Co-Commercialization Budget.

**1.46** "Develop" or "Development" means all activities covering research (including drug discovery, identification or synthesis), investigator initiated studies, non-clinical, preclinical and Trials (including Trial recruitment and Trial site engagement), toxicology testing, companion diagnostics development, statistical analysis and reporting, all the aforementioned regarding the Licensed Antibody and/or the Product in any country or jurisdiction in the world in the Field and being necessary or reasonably useful or requested

or required by a Regulatory Authority or as a condition or in support of obtaining or maintaining any or all Regulatory Approvals for the Licensed Antibody and/or Product in any country or jurisdiction in the world in the Field. For clarity, "Develop" and "Development" shall include Post-Marketing Authorization Trials that are required by or committed to Regulatory Authorities but shall not include any activities covering Commercialization or Manufacture or other Regulatory Activities.

**1.47** "Development Activities" means activities by or on behalf of the Parties or their Affiliates (or their sublicensees (including Sublicensee(s), with respect to Incyte) or subcontractor(s)) with respect to the Development of the Licensed Antibody or Product in the Field, which include (i) Collaboration Development Activities, (ii) Incyte Independent Trial Activities or (iii) Syndax Independent Trial Activities, as applicable.

**1.48** "Development Data" means all non-clinical, clinical, technical, biochemical, safety, and scientific data and information and other results, including relevant laboratory notebook information, screening data, Regulatory Data and synthesis schemes, including descriptions in any form, data and other information, including GMP and GCP-related quality information, generated by or resulting from or in connection with the conduct of Collaboration Development Activities ("Joint Development Data") or in connection with the conduct of any Independent Trial ("Independent Trial Data").

**1.49** [\*\*\*]

**1.50** "Development Plan" means the plan for the Development of the Product in the Field in the Territory agreed upon by the Parties through the JDC and approved by the JSC, which plan may be amended and/or supplemented from time to time in accordance with Section 3.4 and Article 9. The Development Plan will include a description of the specific activities to be performed by Syndax and Incyte in support of the Development Program and the projected timelines for completion of such activities. The initial Development Plan is provided in **Exhibit 3.3** ("Initial Development Plan").

**1.51** "Development Program" has the meaning set forth in Section 3.2.

**1.52** "Disclosing Party" has the meaning set forth in Section 16.1.

**1.53** "Dispute" has the meaning set forth in Section 18.3(a).

**1.54** "Distribution Costs" means the costs (including FTE Costs and External Costs) incurred by a Party or any of its Affiliates or sublicensees (including Sublicensees, with respect to Incyte), or for its account, specifically identifiable to the distribution of a Product to a Third Party intended for commercial sale in the Co-Commercialization Territory, including [\*\*\*].

**1.55** "Distributor" means any Third Party that (i) has been granted the right to distribute or resell any quantities of Product; and (ii) has not been granted a sublicense to Develop and Commercialize Product.

**1.56** "Divest" means, with respect to any Competing Product: the sale, exclusive license or other transfer of all of the right, title and interest in and to such Competing Product, including all technology, intellectual property and other assets relating solely thereto, to an independent Third Party, without the retention or reservation of any rights, license or interest

(other than solely an economic interest and, in the event of a termination, customary residual rights) in such Competing Product.

- 1.57** "Drug Product" means the Product in its final dosage form filled in its designated primary containers (e.g., vials) but which is not finally labelled and packaged for end-user use, as required for a Trial or for Commercialization, as applicable.
- 1.58** "Drug Substance" means an active pharmaceutical ingredient manufactured for the Drug Product.
- 1.59** "Early Access Program" means a program that gives patients access to the Product in a certain country or territory prior to a Marketing Authorization grant, or where applicable, prior to Pricing Approval, of the Product in such country or territory and outside the framework of a Trial.
- 1.60** "Effective Date" shall mean the first (1<sup>st</sup>) Business Day following the date on which any required Clearance occurs.
- 1.61** "EMA" means the European Medicines Agency or any successor agency thereto in the EU.
- 1.62** [\*\*\*]
- 1.63** [\*\*\*]
- 1.64** "Excess Amount" has the meaning set forth in Section 7.3.
- 1.65** "Execution Date" shall mean the date set forth in the Introductory Clause of this Agreement.
- 1.66** "Executive Officers" has the meaning set forth in Section 9.1(d).
- 1.67** "Existing Supply" has the meaning set forth in Section 6.3(d).
- 1.68** "External Costs" means solely external expenses (including travel expenses), in all cases excluding value added taxes, paid by a Party or its Affiliates or sublicensees (including Sublicensees, with respect to Incyte) to Third Parties for goods or services, to the extent directly attributable or reasonably allocable to the Development Activities, Medical Affairs Activities, Regulatory Activities, Pricing Activities, Commercialization, or other activities specified herein, as applicable. To the extent such goods or services are not attributable solely to the Product, then only the respective pro rata amount allocable to the Product, which shall be agreed between the Parties in good faith, shall be regarded as External Cost. External Costs excludes any costs or expense included or otherwise accounted for in FTE Costs.
- 1.69** "FDA" means the US Food and Drug Administration or any successor agency thereto.
- 1.70** "Field" means all human and non-human diagnostic, prophylactic, therapeutic and palliative uses other than non-oncological diseases of the nervous system.
- 1.71** "Finished Drug Product" means the Drug Product finally labelled and packaged for end-user use, as required for a Trial or for Commercialization, as applicable.

**1.72** "First Commercial Sale" means, with respect to any Product and country, the first sale of such Product in a country by Incyte or its Affiliates or Sublicensees to any Third Party (other than a Sublicensee), as applicable, following applicable Regulatory Approval of such Product in such country.

**1.73** "Force Majeure Event" means an event, act, occurrence, condition or state of facts, in each case outside the reasonable control of a Party, including: acts of God; acts of any government; any rules, regulations or orders issued by any governmental authority or by any officer, department, agency or instrumentality thereof; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; pandemic; epidemic; terrorism and invasion; in each case that interfere with the normal business operations of such Party. The Parties agree the effects of the COVID-19 pandemic that is ongoing as of the Effective Date (including related government orders) may be invoked as a Force Majeure Event for the purposes of this Agreement to the extent such effects otherwise qualify as a Force Majeure Event under this Section 1.73, even though the pandemic is ongoing and those effects may be foreseeable. In addition, a Force Majeure Event may include reasonable measures affirmatively taken by a Party or its Affiliates to respond to the COVID-19 pandemic (or other Force Majeure Event), such as requiring employees to stay home, closures of facilities, delays of clinical trials, or cessation of activities in response to the pandemic.

**1.74** "FTE" means the equivalent of [\*\*\*], or such other number as may be agreed by the Parties (taking account of normal vacations, sick days and holidays not being considered working days), and performing scientific, clinical, technical or operational work, directly related to Development activities, Manufacturing activities, Regulatory Activities or Commercialization activities related to the Product or otherwise performing activities hereunder, but for the avoidance of doubt excluding managerial, financial, human resources, legal or business development, and other support functions; ***provided, however***, that any hours worked by a person in excess of [\*\*\*] hours per calendar quarter shall not be included in the calculation of the hours worked by such person.

**1.75** "FTE Costs" means the cost for a Party's FTEs, which shall be calculated by multiplying (i) the then-current Development FTE Rate, Manufacturing FTE Rate, or Commercial FTE Rate, as applicable by (ii) the applicable number of FTEs performing the applicable activities for the applicable period.

**1.76** "GAAP" means U.S. Generally Accepted Accounting Principles.

**1.77** "GCP" means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable, (i) as set forth in European Commission Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, and brought into Law by European Commission Directive 2005/28/EC laying down the principles and detailed guidelines for good clinical practice for investigational medicinal products, (ii) regulation 536/2014 of the European Parliament and of the council of 16 April 2014 on clinical trials on medicinal products for human use, (iii) the International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any further addenda thereto and any other guidelines for good clinical practice for trials on medicinal products in the EU, (iv) the Declaration of Helsinki (2004) as last amended at the 64th World Medical Association in October 2013 and any further amendments or clarifications thereto, (v) US Code of Federal Regulations Title 21,

Parts 11 (Electronic Records), 50 (Protection of Human Subjects), 54 (Financial Disclosure by Clinical Investigators), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time, and (vi) the equivalent Laws in any relevant country, each as may be amended and applicable from time to time and in each case that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

**1.78** "Global Branding" has the meaning set forth in Section 5.5(a)(i).

**1.79** "Global Brand Strategy" has the meaning set forth in Section 5.5(a)(ii).

**1.80** "Global Product Mark" has the meaning set forth in Section 5.5(b).

**1.81** "GLP" means all applicable Good Laboratory Practice standards, including, as applicable, (i) as set forth in European Commission Directive 2004/10/EC relating to the application of the principles of good laboratory practices, as may be amended from time to time, as well as the OECD Series on Principles of Good Laboratory Practice, (ii) the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and (iii) the equivalent Laws in any relevant country, each as may be amended and applicable from time to time.

**1.82** "GMP" means all applicable Good Manufacturing Practices including, as applicable, (i) the applicable part of quality assurance to ensure that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use, as defined in European Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice, (ii) the principles detailed in the US Current Good Manufacturing Practices, 21 C.F.R. Parts 11, 210, 211, 600, 601 and 610, (iii) the Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products, (iv) the principles detailed in the ICH Q7A guidelines, and (v) the equivalent Laws in any relevant country, each as may be amended and applicable from time to time.

**1.83** "Government Price Calculations and Reporting" has the meaning set forth in Section 4.4.

**1.84** "Governmental Authority" means any multinational, supra-national, federal, state, local, municipal or other governmental authority of any nature (including any Regulatory Authority and any governmental association, division, prefecture, subdivision, department, agency, bureau, branch, office, commission, committee, council, court or other tribunal, such as statutory health insurance funds and their associations), in each case having jurisdiction over the applicable subject matter.

**1.85** "Government Official" means (a) any officer, employee of a government or any department, agency or instrument of a government; (b) any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government, including, for example, a Healthcare Professional employed by a public hospital or healthcare system; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a public international organization such as the World Bank or United Nations; (e) any political party, officer or employee of a political party, or any person acting in an official capacity on behalf of a political party; and/or (f) any candidate or relative of any candidate for political office.

- 1.86** "GVHD" means Graft versus Host Disease.
- 1.87** "Healthcare Professional" means any member of the medical, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, purchase, supply or administer a medicinal product.
- 1.88** "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules promulgated thereunder.
- 1.89** "Incyte Annual Development Report" means, for each calendar year, the written report that describes Incyte's past and planned Development Activities for the Licensed Antibody or Product in the Field for that year, and covers other subject matter as called for in Section 3.10(a).
- 1.90** "Incyte Foreground Patents" means any Patent claiming an Incyte Invention or Incyte Know-How arising as a result of Incyte's exercise of its rights or performance of its obligations under this Agreement.
- 1.91** "Incyte Indemnitees" has the meaning set forth in Section 14.1.
- 1.92** "Incyte Independent Trial" means an Independent Trial sponsored by Incyte.
- 1.93** "Incyte Independent Trial Activities" means (i) Development Activities of Incyte or its Affiliates (or Sublicensee(s) or subcontractor(s)) in the Field that are not specifically related to the performance of a Syndax Trial or Collaboration Trial, including any Trial that is solely designed or required to obtain and maintain Regulatory Approval in a certain jurisdiction of the Incyte Territory, and (ii) Independent Trials-related activities performed by or on behalf of Incyte or its Affiliates (or Sublicensee(s) or subcontractor(s)) in the Field.
- 1.94** "Incyte Invention" means an Invention that is created, discovered, reduced to practice, made, conceived or otherwise generated solely by Incyte or any of its Affiliates or their respective employees, independent contractors or consultants in the performance of activities under this Agreement.
- 1.95** "Incyte Know-How" means all Know-How that Incyte or its Affiliate Controls during the Term that relates to any Product, Licensed Antibody or to Developing, Manufacturing, using (including methods of administration and dosing regimens) or testing of (or in the case of testing, of or for the presence of) any of the foregoing (or any article necessary or useful to practice or use (including those present during the practice or use of)) any such Product, Licensed Antibody or method.
- 1.96** "Incyte Territory" means the whole world except the Co-Commercialization Territory.
- 1.97** "IND" means an Investigational New Drug Application (as defined in the US Federal Food, Drug and Cosmetics Act and the regulations promulgated thereunder (21 C.F.R. §312) in the US), a clinical trial application in Europe, or a comparable application or filing in any other jurisdiction (i.e., a filing with a Regulatory Authority or Ethics Committee that must be made prior to commencing clinical testing in humans).
- 1.98** "Indemnification Claim Notice" has the meaning set forth in Section 14.4(a).
- 1.99** "Indemnified Party" has the meaning set forth in Section 14.4(a).

- 1.100** "Indemnifying Party" has the meaning set forth in Section 14.4(a).
- 1.101** "Indemnitees" has the meaning set forth in Section 14.4(a).
- 1.102** "Independent Trial" means the Trials set forth on **Schedule 1.102** and any Trial deemed to be an Independent Trial in accordance with Section 3.5. For clarity, an Independent Trial may be conducted in countries in either or both the Co-Commercialization Territory and the Incyte Territory, **provided that** (a) such Independent Trial has been reviewed and discussed in the JDC, and (b) such Independent Trial has been included in the Development Plan.
- 1.103** "Indication" means, with respect to a Product, a separate and distinct disease or medical condition that such Product is intended to treat, cure, mitigate, control, prevent, diagnose, monitor or ameliorate, as set forth in the BLA or label for such Product, as applicable, for which such Product has received Regulatory Approval from the applicable Regulatory Authority. The use of a Product to treat an expanded set of patients or a sub population of patients for a disease or medical condition shall not constitute a separate Indication with respect to such Product. For example, first line treatment of IPF and second line treatment of IPF shall be considered the same Indication.
- 1.104** "Initial Know-How Transfer" has the meaning set forth in Section 3.1.
- 1.105** "Invention" means any invention, discovery, improvement, technology or other Know-How (in each case, whether patentable or not) that is not existing as of the Execution Date and is created, conceived, discovered, made, reduced to practice or otherwise generated by or on behalf of a Party (acting solely, jointly with the other Party or jointly with a Third Party) under this Agreement during the Term, including all rights, title and interest in and to the intellectual property rights therein.
- 1.106** "IPF" means idiopathic pulmonary fibrosis.
- 1.107** "IPF Product" has the meaning set forth in Section 7.5(c)(iii).
- 1.108** "JCC" has the meaning set forth in Section 9.2.
- 1.109** "JDC" has the meaning set forth in Section 9.2.
- 1.110** "Joint Foreground Patents" means all Patents claiming Joint Inventions.
- 1.111** "Joint Invention" means an Invention that is first created, reduced to practice, discovered, made, conceived or otherwise generated jointly by the Parties or any of their respective Affiliates or their respective employees, independent contractors or consultants in the performance of activities under this Agreement.
- 1.112** "JSC" or "Joint Steering Committee" shall have the meaning set forth in Section 9.1(a).
- 1.113** "Know-How" means, whether or not patentable, any and all information and materials, including techniques, data (including Development Data), inventions, practices, methods, processes, knowledge, know-how, trade secrets, skill, experience, technical data, test results (including pharmacological, toxicological, clinical, analytical and quality control data, regulatory submissions, correspondence and communications, and marketing,

distribution, pricing, cost, manufacturing, patent and legal data or descriptions), or compositions of matter, assays, cell lines, vectors, plasmids and other materials.

**1.114** "Knowledge" means, when referring to the knowledge of Syndax, the [\*\*\*] knowledge of Syndax personnel [\*\*\*] with the following titles: [\*\*\*].

**1.115** "Labelling and Packaging" means labelling and packaging of the Drug Product, including insertion of materials such as patient inserts, patient medication guides, professional inserts and any other written, printed or graphic materials accompanying the Product considered to be part of the Finished Drug Product, and its handling, storage, quality control, quality assurance, serialization, anti-counterfeiting measures, testing and related activities of the Product in connection with the foregoing.

**1.116** "Laws" means all laws, statutes, rules, regulations, directives, orders, ordinances, guidelines and other pronouncements of any Governmental Authority.

**1.117** "Licensed Antibody" means (a) the humanized monoclonal Antibody designated as "SNDX-6352" or "axatilimab" or "UCB-6352" the amino acid sequence of which is disclosed in **Schedule 1.117**, (b) all derivatives of axatilimab (including any multi-specific constructs that include axatilimab or portions thereof) Controlled by Syndax as of the Execution Date or during the Term that [\*\*\*], and (c) any other [\*\*\*] Antibodies Controlled by Syndax as of the Execution Date or during the Term that [\*\*\*]. "Licensed Antibody" excludes the [\*\*\*].

**1.118** "Losses" has the meaning set forth in Section 14.1.

**1.119** "Major Market" means the [\*\*\*].

**1.120** "Manufacturing" or "Manufacture" means all activities related to the production or manufacturing of the Licensed Antibody or a Product (both whether finished or not, including Drug Substance thereof) or a Placebo thereof, or a combination or comparator product, or any ingredient thereof, including manufacturing for clinical use or commercial sale, in-process and lot release testing, release, certification, filling, Labelling and Packaging, quality assurance activities, handling and storage related to such aforementioned manufacturing of the Licensed Antibody, Product, Placebo thereof, combination or comparator product.

**1.121** "Manufacturing FTE Rate" means, with respect to FTE costs, [\*\*\*].

**1.122** "Marketing Authorization" means, with respect to a Product, the possession of all approvals (including supplemental approvals and approval of any amendment to any BLA), Pricing Approvals, licenses, registrations and authorizations of any national (e.g., the FDA), supra-national (e.g., the European Commission), regional, state or local regulatory agency, department, bureau, commission, council or other governmental authority, necessary for the manufacture, distribution, use and sale of such Product in a regulatory jurisdiction.

**1.123** "Material Breach" has the meaning set forth in Section 17.2(a).

**1.124** "Medical Affairs Activities" means non-promotional and non-Detailing Activities designed to provide scientific information regarding, to ensure or improve appropriate medical use of, conduct medical education regarding, or conduct further research regarding, Licensed Antibody(ies) or Product(s), including by way of example: [\*\*\*].

**1.125** "Medical Affairs Activities Costs" means costs and expenses directly or reasonably allocable to the Medical Affairs Activities conducted pursuant to the Agreement and the



Development Plan and Co-Commercialization Plan (as applicable) then in effect, incurred by a Party or its Affiliates or sublicensees (including Sublicensees, with respect to Incyte) in support of Medical Affairs Activities in the Co-Commercialization Territory in accordance with the Collaboration Budget and Co-Commercialization Budget (as applicable), whether prior to or after receipt of Regulatory Approvals, including FTE costs at the Commercial FTE Rate and External Costs incurred in connection with the foregoing and costs associated with named patient supply, compassionate use programs or Early Access Programs.

**1.126** "NDA" means a New Drug Application submitted to the FDA, or any successor application or procedure in the Co-Commercialization Territory, as more fully defined in 21 C.F.R. § 314.50 et. seq.

**1.127** "Net Sales" means the gross amount invoiced by Incyte or its Affiliates or any Sublicensee(s) for the sale of Product in the Territory, less any of the following applicable deductions related to such sale:

[\*\*\*].

In the event that there is overlap among any of those deductions (a)-(f), each individual item shall only be deducted once in each Net Sales calculation.

In the event that a Product is sold as part of a Combination Product, Net Sales of the Product, for the purpose of determining royalty payments, shall be determined by multiplying Net Sales (as defined above) of the Combination Product by the fraction  $A/(A+B)$ , where A is the public or list price in such country of the Product sold separately in the same formulation and dosage, and B is the (sum of the) public or list price(s) in such country of the Other Component(s) sold separately in the same formulation and dosage, during the applicable calendar year. If the individual prices for the Product or the Other Component(s) in a Combination Product or both are not available, then the Net Sales of a Product in a Combination Product shall be determined by [\*\*\*].

Net Sales will not include sales between or among Incyte and its Affiliates and/or Sublicensees; ***provided that*** any resale to Third Parties shall be included in Net Sales. Net Sales excludes any [\*\*\*]. All other dispositions are treated as sales for purposes of this definition (whether or not the transaction is overtly characterized as a sale), including sales generated through named patient supply, compassionate use programs or Early Access Programs.

Net Sales amounts shall be accounted for by Incyte or its Affiliates or any Sublicensee(s), as applicable, in accordance with GAAP consistently applied and standard practices in the relevant country in the Territory.

**1.128** "Non-Breaching Party" has the meaning described in Section 17.2(a).

**1.129** "Non-Proposing Party" has the meaning set forth in Section 3.5(a).

**1.130** "Opposition" has the meaning set forth in Section 11.11.

**1.131** "Patent" means any pending patent application or issued or granted patent anywhere in the world, including all of the following kinds: provisional, utility, divisional, continuation, continuation-in-part, and substitution applications; and utility, re-issue, re-examination,

renewal and extended patents, and patents of addition, and any supplementary protection certificates, restoration of patent terms and other similar rights.

**1.132** "Personal Data" means any information relating to an identified or identifiable natural person as established by applicable Data Protection Laws in the applicable country or jurisdiction.

**1.133** "Pharmacovigilance Agreement" has the meaning set forth in Section 4.5(c).

**1.134** "Phase 1 Trial" means, with respect to a Product, a Trial (or -- in case of a multi-phase clinical trial -- those parts of a clinical trial) in line with the provisions of 21 C.F.R. Part 312.21(a) (or the non-US equivalent thereof).

**1.135** "Phase 2 Trial" means, with respect to a Product, a Trial (or – in case of a multi-phase clinical trial – those parts of a clinical trial) in line with the provisions of 21 C.F.R. Part 312.21(b) (or the non-US equivalent thereof).

**1.136** "Phase 3 Trial" means, with respect to a Product, a Trial (or -- in case of a multi-phase clinical trial -- those parts of a clinical trial) in line with the provisions of 21 C.F.R. Part 312.21(c) (or the non-US equivalent thereof).

**1.137** "Pivotal Trial" means, with respect to a Product, a Trial (or – in case of a multiphase clinical trial – those parts of a clinical trial), whether or not designated a Phase 3 Trial, that FDA has agreed would form the basis for Regulatory Approval of such Product, based on an explicit written statement from FDA (which may include a special protocol assessment or meeting minutes issued by FDA). For the avoidance of doubt, a Trial or portion thereof may be a Pivotal Trial regardless of whether the protocol for such Trial describes it as a "Phase 1 Trial," "Phase 2 Trial," or "Phase 3 Trial," or any variation thereof.

**1.138** "Placebo" means a substance or mixture of substances lacking presence of an active pharmaceutical ingredient, manufactured for purposes of control treatment in blinded clinical trials with Product.

**1.139** "Post-Marketing Authorization Trial" means with respect to Product, a Trial occurring after Marketing Authorization in a given Indication, including post-market requirement and commitment studies that are required of or agreed to by the Sponsor and that gather additional information about the Product's safety, efficacy, or optimal use within the Indication covered by the Marketing Authorization, including Phase 4 Trials and confirmatory Trials.

**1.140** "Potential Collaboration Trial" has the meaning set forth in Section 3.5(a).

**1.141** "Pre-Existing Affiliates" has the meaning set forth in Section 12.2.

**1.142** "Pre-Launch" means all activities undertaken prior to and in preparation for the launch of the Product in a given country or region. Pre-Launch shall include all activities directed to market research, advisory boards, medical education, disease-related public relations, sales force training and other pre-launch activities prior to the First Commercial Sale of the Product in a given country or region.

**1.143** "Pre-Tax Profit (Loss)" means, for the purposes of this Agreement, for a given period of time, all Net Sales of the Product in the Co-Commercialization Territory during such period, less the sum of both Parties' [\*\*\*]. For sake of clarity, Pre-Tax Profit (Loss) shall be

determined in accordance with GAAP consistently applied for all costs other than FTE costs, which costs shall be determined as set forth in this Agreement, prior to application of any income taxes. In the event that there is overlap among any of the deductions (i)-(iv) of this Section 1.143 and the deductions (a)-(f) under the Net Sales definition, each individual item shall only be deducted once in each Pre-Tax Profit (Loss) calculation.

**1.144** "Pre-Tax Profit (Loss) Share" has the meaning set forth in Section 7.6.

**1.145** "Pricing Activities" means activities by or on behalf of Incyte or its Affiliates (or its or their Sublicensee(s) or subcontractor(s)) with respect to [\*\*\*].

**1.146** "Pricing Approval" means the approval, agreement, determination or decision from a Governmental Authority or a private payer establishing the final net price and reimbursement for the Product for sale in a given country or regulatory jurisdiction, in such country or other regulatory jurisdiction prior to or subsequent to the marketing and sale of the Product in such country or regulatory jurisdiction.

**1.147** "Pricing Materials" means applications, submissions, notifications, communications, correspondence, registrations and/or other filings submitted to, made to, received from or otherwise conducted with a Governmental Authority that are necessary in order to obtain and maintain Pricing Approvals in a particular country or regulatory jurisdiction.

**1.148** "Prior Confidentiality Agreement" means the Mutual Confidential Disclosure Agreement by and between Incyte and Syndax, dated [\*\*\*].

**1.149** "Pro Rata Percentage" means, in the context of costs, expenses, fees and payments shared between the Parties under this Agreement, the following proportionate allocation:(i) with respect to Incyte, fifty-five percent (55%), and (ii) with respect to Syndax, forty-five percent (45%). [\*\*\*].

**1.150** "Product" means any product for use in the Field comprising or containing a Licensed Antibody, alone or in combination with one or more other active ingredients, in all forms, in current and future formulations, dosage forms and strengths, and delivery modes, including any improvements to any of the foregoing.

**1.151** "Product Liability Expenses" means the costs and expenses incurred by a Party or its Affiliates directly attributable, or reasonably allocable, to any product liability claim or matter (including costs and expenses described in Section 14.3), and product liability insurance premiums for policies covering the Development, Manufacture or Commercialization of the Product in the Field in the Co-Commercialization Territory.

**1.152** "Product Marks" means the trademarks for use in connection with the Commercialization of the Product, including the trade dress, style of packaging, logos, internet domain names, trade names and other proprietary names for the Product used in connection with the Commercialization of the Product. For clarity, Product Marks shall not include the corporate names and logos of Incyte or Syndax.

**1.153** "Proposing Party" has the meaning set forth in Section 3.5(a).

**1.154** "Recovery" has the meaning set forth in Section 11.9.

**1.155** "Receiving Party" has the meaning set forth in Section 16.1.

- 1.156** "Regulatory Activities" means activities by or on behalf of the Parties or their Affiliates (or their sublicensees (including Sublicensee(s), with respect to Incyte) or subcontractor(s)) with respect to (i) preparation, filing, obtaining and maintaining Regulatory Approvals (ii) Regulatory Materials, (iii) calls and meetings with Regulatory Authorities, all with respect to Licensed Antibody(ies) and/or Product(s).
- 1.157** "Regulatory Approvals" means all necessary approvals (including INDs, Marketing Authorizations and, in each case any supplements and amendments thereto), licenses, registrations or authorizations of any Governmental Authority, necessary for the Development, Manufacture, distribution, use, promotion, importing, sale and Commercialization of the Product in a given country or regulatory jurisdiction, including Pricing Approvals.
- 1.158** "Regulatory Authority" means any Governmental Authority in any jurisdiction of the world involved in the granting of any Regulatory Approvals.
- 1.159** "Regulatory Costs" means, with respect to a Product, the costs (including FTE Costs and reasonable External Costs) incurred by a Party or its Affiliates (or their sublicensees (including Sublicensee(s), with respect to Incyte) or subcontractor(s)) directly attributable to Regulatory Activities incurred by a Party in the applicable Indication and jurisdiction.
- 1.160** "Regulatory Data" means any and all research data, pharmacology data, chemistry, manufacturing and control data, preclinical data, clinical data and all other documentation submitted, or required to be submitted, to Regulatory Authorities in association with obtaining or maintaining all Regulatory Approvals for the Product in the Territory (including relevant parts of any applicable Drug Master Files ("DMFs"), Chemistry, Manufacturing and Control ("CMC") data, Common Technical Document ("CTD") or similar documentation).
- 1.161** "Regulatory Exclusivity" means, with respect to a particular country, the ability to exclude Third Parties from Commercializing a Product in such country, either through data exclusivity rights, orphan drug designation, or such other rights conferred by a Regulatory Authority in such country, other than through enforcement of Patent rights.
- 1.162** "Regulatory Materials" means regulatory applications, submissions, notifications, communications, correspondence, registrations and/or other filings submitted to, made to, received from or otherwise conducted with a Regulatory Authority that are necessary in order to Develop, Manufacture, obtain and maintain Regulatory Approvals, market, sell or otherwise Commercialize the Product in a particular country or regulatory jurisdiction. Regulatory Materials include materials relating to pre-IND meetings, INDs, pre-BLA meetings, BLAs, presentations, responses, and applications for other Regulatory Approvals, excluding Pricing Materials.
- 1.163** "Regulatory Transfer" has the meaning set forth in Section 4.1(c).
- 1.164** "Recovery" has the meaning set forth in Section 11.9.
- 1.165** "Representatives" has the meaning set forth in Section 18.12.
- 1.166** "ROW Territory" means the Incyte Territory excluding the European Region and Japan.

- 1.167** "Royalty Term" has the meaning set forth in Section 8.3(c).
- 1.168** "Sales Representative" means an authorized salesperson or agent who has been qualified by either Party under the Party's respective policies and procedures to promote or Detail a Product, whether employed or otherwise contracted by a Party.
- 1.169** "SEC" has the meaning set forth in Section 16.7.
- 1.170** "Securities Purchase Agreement" means the Securities Purchase Agreement, dated as of the Effective Date, by and between Incyte and Syndax.
- 1.171** "Shared Claims" has the meaning set forth in Section 14.3.
- 1.172** "Shared Losses" has the meaning set forth in Section 14.3.
- 1.173** [\*\*\*]
- 1.174** "Sponsor" means the Party (or such Party's Affiliate or sublicensee (including any Sublicensee, with respect to Incyte)) taking responsibility for the initiation and management, and/or financing of a Trial in accordance with applicable Laws. For the avoidance of doubt, the allocation of costs for Development Activities in the internal relationship between the Parties under this Agreement shall not be decisive to determine which Party is the Sponsor of a Trial under this definition.
- 1.175** "Sublicense Agreement" means a written sublicense agreement (including any option for a sublicense) pursuant to which a sublicense to a Licensed Antibody or Product is granted to a Sublicensee pursuant to Section 2.4, specifically excluding any agreement with a Distributor.
- 1.176** "Sublicensee" means a Third Party to whom Incyte (or its Affiliate) has granted a (sub)license under Section 2.4 of the rights granted to Incyte hereunder, specifically excluding Distributors of Incyte (or of its Affiliates or Sublicensees), contract manufacturing organizations solely Manufacturing on behalf of a Party (or on behalf of its Affiliates or Sublicensees) and permitted contractors who provide services to a Party (or to its Affiliates or Sublicensees).
- 1.177** "Supply Agreement" has the meaning set forth in Section 6.2.
- 1.178** "Syndax Annual Development Report" means, for each calendar year, the written report that describes Syndax's past and planned Development Activities for Licensed Antibody or Product in the Field for that year, and covers other subject matter as called for in Section 3.10(b).
- 1.179** "Syndax Background Patent" means, subject to Section 12.2(c) and Section 18.1, all Patents and Patent applications Controlled by Syndax or its Affiliates as of the Execution Date or during the Term that claim (i) Syndax Know-How, or (ii) the Development, Manufacture, Commercialization or other exploitation of the Licensed Antibody or Product, and that are necessary or reasonably useful to Develop, Manufacture or Commercialize or otherwise exploit the Licensed Antibody or the Product in the Field, other than Syndax's rights in the Syndax Foreground Patents and Joint Foreground Patents. The Syndax Background Patents include the Patents listed on **Schedule 1.179**. For the avoidance of doubt, the Syndax Background Patents include the UCB Biopharma Background Patents. At the reasonable request of Incyte, but no more than [\*\*\*] per calendar quarter, Syndax shall

provide Incyte with an updated list of Syndax Background Patents and correct any typographical errors; ***provided that***, with respect to any Syndax Background Patents which constitute UCB Biopharma Background Patents, Syndax shall only be obligated to include in such updates the list of updated UCB Biopharma Background Patents in the then-current form provided by UCB Biopharma to Syndax.

**1.180** "Syndax Foreground Patent" means any Patent claiming a Syndax Invention or Syndax Know-How arising as a result of Syndax's exercise of its rights or performance of its obligations under this Agreement that claims the Development, Manufacture, Commercialization or other exploitation of the Licensed Antibody or Product, and that are necessary or reasonably useful to Develop, Manufacture or Commercialize or otherwise exploit the Licensed Antibody or the Product in the Field.

**1.181** "Syndax Indemnitees" has the meaning set forth in Section 14.2.

**1.182** "Syndax Independent Trial" means any Independent Trial conducted by Syndax in accordance with the terms of this Agreement and excludes the Syndax Ongoing Trials.

**1.183** "Syndax Independent Trial Activities" means Independent Trials related activities performed by or on behalf of Syndax or its Affiliates (or sublicensee(s) or subcontractor(s)) for Product.

**1.184** "Syndax Invention" means an Invention that is created, discovered, reduced to practice, made, conceived or otherwise generated solely by Syndax or any of its Affiliates or their respective employees, independent contractors or consultants in the performance of activities under this Agreement during the Term.

**1.185** "Syndax IPF Trial" means the Phase 2 Trial in IPF as outlined in **Schedule 1.185**.

**1.186** "Syndax Know-How" means, subject to Section 12.2(c) and Section 18.1, all Know-How that Syndax or its Affiliates Control during the Term that relates to any Product, Licensed Antibody or a method of Developing, Manufacturing, using (including methods of administration and dosing regimens) or testing of (or in the case of testing, of or for the presence of) any of the foregoing (or any article necessary or reasonably useful to practice or use (including those present during the practice or use of)) any such Product, Licensed Antibody or method. The Syndax Know-How includes all clinical data generated in clinical trials of the Product by or for Syndax or its Affiliates.

**1.187** "Syndax Ongoing Trials" means the cGVHD Phase 1/2 Trial and the AGAVE-201 Trial. The Syndax Ongoing Trials shall be regarded as Collaboration Trials and are subject to cost sharing as set forth in Section 7.1, in each case as outlined in **Schedule 1.187**.

**1.188** "Syndax Patent" means any Syndax Background Patent, Syndax Foreground Patent and Syndax's interest in any Joint Foreground Patents.

**1.189** "Syndax Trials" means the Syndax Ongoing Trials, the **Syndax IPF Trial**, and the Syndax Independent Trials.

**1.190** "Target" means CSF-1R.

**1.191** "Technology Transfer" has the meaning assigned to it in Section 6.1(a).

**1.192** "Term" has the meaning assigned to it in Section 17.1(a).

- 1.193** "Termination Notice" has the meaning set forth in Section 17.2(a).
- 1.194** "Territory" means, collectively, the Co-Commercialization Territory and the Incyte Territory.
- 1.195** "Third Party" means any person or entity other than a Party or an Affiliate of a Party.
- 1.196** "Third Party Acquisition" has the meaning set forth in Section 12.2.
- 1.197** "Third Party IP" means (i) Know-How owned or controlled by a Third Party that relates to, or (ii) Patents that are owned or controlled by a Third Party that cover, the composition of matter (including any formulation) or method of use of a Licensed Antibody or Product or that is necessary for the research, Development, Manufacture (whether for Development or Commercialization activities), use or Commercialization of any Licensed Antibody or Product in a particular country or region (other than pursuant to the UCB Biopharma Agreement).
- 1.198** "Trial" means any clinical study or clinical trial (including interventional clinical trials) in which the Product is administered or otherwise evaluated in humans (including any Post-Marketing Authorization Trial, or pediatric trials) or any non-interventional, retrospective or observational studies related to the Product.
- 1.199** "[\*\*\*]" has the meaning set forth in Section 11.1(a).
- 1.200** "UCB Biopharma" means UCB Biopharma SPrl., a Belgian corporation with its principal offices at Allee de la Recherche 60, 1070 Brussels, Belgium.
- 1.201** "UCB Biopharma Agreement" means the license agreement entered into by and between Syndax and UCB Biopharma on July 1, 2016, under which Syndax obtained an exclusive license to further develop and commercialize the Licensed Antibody worldwide.
- 1.202** "UCB Biopharma Agreement Effective Date" means July 1, 2016.
- 1.203** "UCB Biopharma Agreement Term" shall mean the term of the UCB Biopharma Agreement.
- 1.204** "UCB Biopharma Background Patent" means, subject to Section 18.1, any Syndax Patent that is Controlled by Syndax pursuant to the UCB Biopharma Agreement. The UCB Biopharma Background Patents include the Patents listed on Schedule 1.204.
- 1.205** "UCB Biopharma Consent" has the meaning set forth in Section 13.2(a).
- 1.206** "UCB Biopharma Effective Royalty Rate" means, with respect to Net Sales of Product Covered by a UCB Biopharma Background Patent in a given period, a royalty rate equal to [\*\*\*].
- 1.207** "UCB Biopharma Know-How" means, subject to Section 18.1, all Syndax Know-How that is Controlled by Syndax pursuant to the UCB Biopharma Agreement.
- 1.208** "UCB Biopharma Payments" means the [\*\*\*] due by Syndax to UCB Biopharma under the UCB Biopharma Agreement.

**1.209** "UCB Biopharma US Royalties" means all royalties due to UCB Biopharma in a given period under the UCB Biopharma Agreement for Net Sales of Products in the Co-Commercialization Territory. For clarity, "UCB Biopharma US Royalties" [\*\*\*].

**1.210** "US" means the United States of America and its respective territories, districts, commonwealths and possessions (including Guam and Puerto Rico).

**1.211** "US Dollar" means U.S. Dollars and all references to "dollars" or "\$" herein shall mean U.S. Dollars.

**1.212** "Valid Claim" means (i) a claim of an issued and unexpired Patent that has not been found to be unpatentable, invalid or unenforceable by a court or other authority having jurisdiction, from which decision no appeal is taken or can be taken; or (ii) a claim of a pending patent application, (a) which pending patent application has not been pending for more than [\*\*\*] from its earliest priority date, and (b) which claim has not been finally abandoned. For the avoidance of doubt, any claim that ceases to be a Valid Claim under the foregoing clause (ii) shall not be a Valid Claim unless and until such claim becomes the claim of an issued and unexpired patent falling within clause (a) of this Section.

## **2. LICENSES AND SUBLICENSES**

**2.1 License Grant from Syndax.** Subject to the terms and conditions of this Agreement, Syndax hereby grants to Incyte:

**(a)** an exclusive, non-transferable (except in accordance with Section 2.2(b)), sublicensable (in accordance with Section 2.4 through one (1) or more tiers), royalty-bearing (in accordance with Section 8.3), license and sublicense, as applicable, under the Syndax Patents and Syndax Know-How to research, have researched, Develop, have Developed, make, have made, Manufacture, have Manufactured, use, have used, sell, have sold, offer for sale, have offered for sale, Commercialize, have Commercialized, import, have imported, export and have exported any Licensed Antibody and the Product(s) in the Field in the Incyte Territory;

**(b)** an exclusive (subject to Syndax's and its Affiliates' rights (i) to conduct Syndax Trials, and Collaboration Trials and (ii) under the Co-Commercialization Option), chargeable (subject to the Pre-Tax Profit (Loss) Share in accordance with Section 7.6), non-transferable (except in accordance with Section 2.2(b)), sublicensable (in accordance with Section 2.4 through one (1) or more tiers), license and sublicense under the Syndax Patents and Syndax Know-How, to research, have researched, Develop, have Developed, make, have made, Manufacture, have Manufactured, use, have used, sell, have sold, offer for sale, have offered for sale, Commercialize, have Commercialized, import, have imported, export and have exported any Licensed Antibody and/or the Product(s) in the Field in the Co-Commercialization Territory in accordance with the Development Plan and the Co-Commercialization Plan; and

**(c)** during the Term, a non-exclusive, non-transferable (except in accordance with Section 2.2(b)), sublicensable (in accordance with Section 2.4) through one (1) or more tiers, license under the Syndax Patents and Syndax Know-How to make, have made, Manufacture, have Manufactured, use, have used, import, have imported, export and have exported the [\*\*\*] solely for Incyte's, and its Affiliates', Sublicensees' and subcontractors' internal research and Development,



## 2.2 Limitations.

(a) The license grants under Section 2.1 are exclusive in the Incyte Territory, even as to Syndax and its Affiliates, to Commercialize the Product(s) in the Field in the Incyte Territory; ***provided, however,*** that Syndax retains the right to perform Development Activities worldwide pursuant to the Development Plan and otherwise as set forth in this Agreement, including the continuation of Syndax Ongoing Trials and the performance of Syndax Independent Trials and Collaboration Trials.

(b) The licenses and sublicenses granted to Incyte in Section 2.1 shall be sublicensable solely as provided in Section 2.4, but shall otherwise be non-assignable and non-transferable (except as explicitly permitted by Article 17 or Section 18.1)

(c) Certain of the rights, licenses and sublicenses granted to Licensee under this Article 2 are subject to the rights and obligations of Syndax under the UCB Biopharma Agreement. Incyte, its Affiliates and their respective Sublicensees will comply with applicable provisions of the UCB Biopharma Agreement to the extent both (i) applicable to Incyte's rights or obligations under this Agreement and (ii) set forth in **Exhibit 2.2(c)**. Without limiting the foregoing, Incyte will prepare and deliver to Syndax any additional reports required under the UCB Biopharma Agreement and reasonably requested by Syndax, in each case, sufficiently in advance to enable Syndax to comply with its obligations under the UCB Biopharma Agreement.

**2.3 License Grant from Incyte.** As consideration for all the rights granted by Syndax to Incyte hereunder, subject to the terms and conditions of this Agreement, Incyte hereby grants to Syndax a non-exclusive, royalty-free, sublicensable (through one (1) or more tiers) license under the Incyte Foreground Patents and the Incyte Know-How and Incyte's interest in any Joint Foreground Patents solely for the purpose of Syndax's exercise of its rights under the Co-Commercialization Option in the Co-Commercialization Territory and to conduct the approved Development Activities in the Territory in accordance with the Development Plan.

**2.4 Sublicenses.** If a Party is entitled to grant sublicenses under its licenses and sublicenses granted under Section 2.1, and does grant such a sublicense, then such Party shall be subject to the following:

(a) **Notification to Syndax.** With respect to the Incyte Territory and subject to Section 2.4(b), Incyte shall have the right to grant sublicenses under the Syndax Patents and Syndax Know-How [\*\*\*], ***provided, however,*** that Incyte shall promptly notify Syndax after granting a Sublicense to any Third Party and shall provide Syndax with a copy of each Sublicense Agreement with a Third Party within [\*\*\*] for [\*\*\*]. Such copy may be redacted as Incyte may reasonably determine with respect to sensitive financial information and confidential information solely to the extent such information is not necessary to monitor compliance with this Agreement. Such Sublicense Agreement(s) will be Confidential Information of Incyte. With respect to the Co-Commercialization Territory only and subject to Section 2.4(b), any grant of a Sublicense by Incyte or its Affiliates under the Syndax Patents and Syndax Know-

How to sell Products and book sales shall require the prior written approval of Syndax, not to be unreasonably withheld, conditioned or delayed.

**(b) UCB Biopharma Intellectual Property.** Incyte may not grant sublicenses under the UCB Biopharma Background Patents and UCB Biopharma Know-How except as permitted pursuant to the UCB Biopharma Consent.

**(c) Consistency Requirement.** Each Party and its sublicensees may only sublicense or further sublicense if the sublicense is granted under a written agreement that is subject and subordinate to, and consistent with the applicable terms of, this Agreement, including this Section 2.4, and that requires each such sublicensee to comply with all applicable terms of this Agreement and applicable obligations of such Party hereunder, including obligations relating to confidentiality, reporting and access to data and information obligations.

**(d) Performance by Sublicensee(s).** The activities and achievements of any sublicensee (including any Sublicensee(s), with respect to Incyte) shall be counted towards each Party's performance under this Agreement. Each Party shall continue to be responsible for full performance of its obligations under this Agreement and shall be responsible for all acts and omissions of any sublicensee (including a Sublicensee, with respect to Incyte) in connection with this Agreement.

**(e)** For clarity, this Section 2.4 shall not apply to any sublicense granted to a Third Party (sub)contractor pursuant to Section 2.7.

**2.5 Reservation of Rights; No Implied Licenses.** No right, title or interest is granted by either Party whether expressly or by implication to or under any Patents or Know-How or other intellectual property, other than those rights and licenses expressly granted in this Agreement. Each Party reserves to itself all rights not expressly granted under this Agreement. Subject to the covenants agreed by the Parties hereunder, this Agreement shall not be deemed to restrict a Party from exploiting any of its rights not expressly granted to the other Party under this Agreement.

**2.6 Additional Restrictions on Sublicensing.** Notwithstanding each Party's sublicensing rights in this Article 2, neither Party shall be permitted to sublicense, except to Affiliates, [\*\*\*]; in each case ((i) and (ii)) without the other Party's prior written consent, not to be unreasonably withheld, conditioned or delayed, ***provided, however,*** that [\*\*\*].

**2.7** Each Party may subcontract with a Third Party to perform obligations of such Party under this Agreement; ***provided, however,*** that [\*\*\*]. All subcontracts shall be in writing and consistent with the applicable terms and conditions of this Agreement, including confidentiality obligations that are at least as restrictive as the terms and conditions of this Agreement (but of shorter duration if customary). The subcontracting Party shall continue to be responsible for full performance of its obligations under this Agreement and shall be responsible for all acts and omissions of any (sub)contractor in connection with this Agreement.

### **3. TRANSFER AND DEVELOPMENT OF PRODUCTS**

#### **3.1 Transfer of Licensed Know How.**

- (a) Within [\*\*\*] after the Effective Date (or such longer period specified in **Exhibit 3.1(a)**), Syndax shall provide Incyte with the Syndax Know-How then in its possession and Control, in accordance with the initial information transfer plan set forth in **Exhibit 3.1(a)** (the “**Initial Know-How Transfer**”) and, in any event, shall use Commercially Reasonable Efforts to provide such Syndax Know-How to Incyte as soon as reasonably practicable.
- (b) From the Effective Date through the earlier of (i) the completion of the Development Plan, as may be amended (or at such other frequency as determined by the JSC) and (ii) the dissolution of the JDC, Syndax shall make its relevant scientific and technical personnel reasonably available to Incyte to answer any questions or provide instruction as reasonably requested by Incyte concerning the information delivered pursuant to Section 3.1(a).
- (c) **Continuing Information Transfer.** At least [\*\*\*] during the Term until the earlier of (i) the completion of the Development Plan, as may be amended (or at such other frequency as determined by the JSC) or (ii) the dissolution of the JDC, in either case, (A) Syndax shall make available to Incyte and to the JDC, in a mutually agreed-upon format, material data generated under the Development Plan (and any other material information related thereto as may be reasonably requested by Incyte); and (B) Incyte shall make available to Syndax and to the JDC, in a mutually agreed-upon format, material data generated with respect to Collaboration Development Activities conducted by Incyte (and any other material information related thereto as may be reasonably requested by Syndax).
- (d) Each Party shall [\*\*\*] in conducting and receiving the Initial Know-How Transfer and/or conducting the activities in subsection (b).

**3.2 Overview of Development; General Responsibilities.** Subject to the terms and conditions of this Agreement, the Parties shall collaborate with respect to the Development of the Licensed Antibody and the Product in the Field, as provided under this Agreement and as set forth in the Development Plan (the “**Development Program**”). The Development Program and each Party’s performance of its activities under this Agreement will be conducted in accordance with Section 3.12. Syndax shall be operationally responsible for the Syndax Trials, and Incyte shall be operationally responsible for the Incyte Independent Trials, all as further set forth in the Development Plan. [\*\*\*].

**3.3 Development Plan.** The Parties shall conduct the Development Activities in accordance with the Development Plan and Collaboration Budget, as each may be updated from time to time by the JDC in accordance with Section 9.3.

**3.4 Updating and Amending Development Plan and Collaboration Budget.** The Development Plan and Development Budget will be reviewed and updated as necessary by the JDC on at least [\*\*\*], and in any event as necessary to reflect any changes, any current or forecast budget overruns, reprioritizations of, or additions to the Development Plan (“**Development Changes**”). Once reviewed by the JDC pursuant to Section 9.3(c) and approved by the JDC or JSC (as applicable), the amended Development Plan and Collaboration Budget shall become effective and supersede the previous Development Plan and Collaboration Budget as of the date of such approval or at such other time as decided by the JDC or JSC (as applicable). Notwithstanding anything to the contrary herein, the Parties shall report to the JSC on [\*\*\*], and in any event reasonably in advance of any

scheduled JSC meeting, any then-contemplated Development Changes for discussion by the JSC, including applicable documentation relating thereto.

### 3.5 New Trials.

- (a) If, during the Term, a Party (the “**Proposing Party**”) desires to conduct a Trial with respect to the Product in the Territory in the Field (other than territory-specific Trials conducted in the Incyte Territory solely by a bona fide Development and commercial licensing partner of Incyte without material involvement by Incyte) that is not included in the then current Development Plan (a “**Potential Collaboration Trial**”), the Proposing Party shall provide to the other Party (the “**Non-Proposing Party**”) through the JDC a detailed proposal for such Potential Collaboration Trial, including the rationale and protocol synopsis for such Potential Collaboration Trial and the proposed budget for such Potential Collaboration Trial, so that the Non-Proposing Party may determine whether to participate in such Potential Collaboration Trial. The JDC shall discuss such Proposed Collaboration Trial at its next meeting, and the Proposing Party shall provide, within [\*\*\*] after such JDC meeting (or such longer period of time as agreed upon in writing by the Parties), any additional information reasonably requested by the Non-Proposing Party’s JDC representatives prior to or during such JDC meeting. In the event the Non-Proposing Party desires to elect to participate in a Potential Collaboration Trial and so notifies the Proposing Party in writing within [\*\*\*] after presentation of such Potential Collaboration Trial to the Non-Proposing Party through the JDC, then the Parties will seek to align on a study design, allocation of operational responsibilities and budget for such Potential Collaboration Trial. In the event that the Parties agree on a final protocol for such Potential Collaboration Trial, then such Potential Collaboration Trial will be deemed a Collaboration Trial. For each Collaboration Trial, the JDC shall review and approve an amendment to the Development Plan that allocates Development responsibilities for the Collaboration Trial between the Parties in accordance with the protocol and budget agreed upon by the Parties.
- (b) In the event the Non-Proposing Party does not elect to participate in a Potential Collaboration Trial within [\*\*\*] after presentation of such Potential Collaboration Trial to the JDC or the Parties do not agree on a final protocol for the Potential Collaboration Trial, the Proposing Party shall have the right to conduct, fund and support such Potential Collaboration Trial as an Independent Trial, at its discretion, subject to Section 7.5, and at its sole expense, in which case such Potential Collaboration Trial shall be an Independent Trial; ***provided, however***, that the Proposing Party shall [\*\*\*]. In addition, notwithstanding anything to the contrary contained in this Agreement, (A) Incyte shall furnish Syndax with copies of, and coordinate with Syndax regarding, all substantive correspondence that Incyte receives from (i) FDA in connection with the Incyte Independent Trials that relate to the Co-Commercialization Territory, (ii) FDA in connection with Collaboration Trials conducted by Incyte that relate to the Co-Commercialization Territory and (iii) any Regulatory Authority in connection with any Syndax Independent Trials or Collaboration Trials conducted by Syndax and (B) Syndax shall furnish Incyte with copies of all substantive correspondence that Syndax receives from any Regulatory Authority with respect to any Trial. Incyte shall provide Syndax with reasonably detailed minutes of any meetings or substantive telephone conferences it receives from the FDA relating to an Incyte Independent Trial conducted in the Co-

### 3.6 Syndax Obligations regarding Syndax Trials.

**(a) Syndax Obligations regarding Syndax Ongoing Trials.** Syndax shall use Commercially Reasonable Efforts to continue to conduct each of the Syndax Ongoing Trials in accordance with applicable Laws, GCP, the Development Plan, and the protocols therefor. Syndax shall [\*\*\*], subject to the final decision making authority provisions as set forth in Section 9.3(e) and Section 9.1(d) and applicable Law. In addition to the obligations under Section 9.3, Syndax shall inform Incyte regarding the status of the Syndax Ongoing Trials through progress reports submitted to the JDC [\*\*\*] in writing. Such reports shall provide the same level of information outlined in Section 3.10(b) and shall include copies of any preliminary reports and final reports and other information or data reasonably requested by Incyte if available at the time. [\*\*\*]. Prior to the Regulatory Transfer, Syndax shall provide Incyte with reasonable advance notice and a copy of briefing material and application dossiers of any meeting or substantive telephone conference with any Regulatory Authority relating to such Syndax Ongoing Trial, and shall, upon Incyte's request, permit Incyte to participate in any such meeting or telephone conference, to the extent legally permitted. In addition, Syndax shall [\*\*\*].

**(b) Syndax Obligations regarding Syndax IPF Trial.** Syndax shall use Commercially Reasonable Efforts to conduct the Syndax IPF Trial in accordance with applicable Laws, GCP, the Development Plan, and the protocol therefor. Syndax shall [\*\*\*], subject to the final decision making authority provisions as set forth in Section 9.3(e), Section 9.1(d) and applicable Law. In addition to the obligations under Section 9.3, Syndax shall inform Incyte regarding the status of the Syndax IPF Trial through progress reports submitted to the JDC [\*\*\*] in writing. Such reports shall include copies of any preliminary reports and final reports and other information or data reasonably requested by Incyte if available at the time. Syndax's conduct of the Syndax IPF Trial shall be regarded as an Independent Trial for which, notwithstanding anything to the contrary in Section 7.5, [\*\*\*] and as to Syndax's Independent Trial Data generated therein, notwithstanding anything to the contrary in Section 3.8 or 7.5, Incyte shall have the same use rights it has to Collaboration Trial Data under this Agreement. Prior to the Regulatory Transfer, Syndax shall provide Incyte with reasonable advance notice and a copy of briefing material and application dossiers of any meeting or substantive telephone conference with any Regulatory Authority relating to the Syndax IPF Trial, and shall, upon Incyte's request, permit Incyte to participate in any such meeting or telephone conference, to the extent legally permitted. In addition, Syndax shall [\*\*\*].

**(c) Syndax Obligations regarding Syndax Independent Trials.** Syndax shall [\*\*\*], subject to the final decision making authority provisions as set forth in Section 9.3(e), Section 9.1(d) and applicable Law. In addition to the obligations under Section 9.3, Syndax shall inform Incyte regarding the status of the Syndax Independent Trials through progress reports submitted to the JDC [\*\*\*] in writing. Such reports shall include copies of any preliminary reports and final reports and other information or data reasonably requested by Incyte if available at the time. For the avoidance of doubt and subject to Section 3.5, [\*\*\*]. Prior to the Regulatory Transfer, Syndax shall provide Incyte with reasonable advance notice and a copy of

briefing material and application dossiers of any meeting or substantive telephone conference with any Regulatory Authority relating to any Syndax Independent Trial, and shall, upon Incyte's request, permit Incyte to participate in any such meeting or telephone conference, to the extent legally permitted. In addition, Syndax shall [\*\*\*].

**3.7 Diligence.** Incyte shall use Commercially Reasonable Efforts to Develop the Licensed Antibody and the Product(s) and to seek to obtain Regulatory Approval (other than Pricing Approval) for at least [\*\*\*] in the Field in the Major Markets. The Parties shall use Commercially Reasonable Efforts to collaborate with respect to the Development of the Licensed Antibody and the Product(s) in the Field in the Territory as set forth in the Development Plan, and carry out such Party's obligations and responsibilities set forth in the Development Plan in accordance with the Collaboration Budget and on the time frames set forth in the Development Plan. The Parties shall conduct the Development based on [\*\*\*] and as agreed to in the Development Plan. Each Party shall utilize adequately skilled personnel to perform or oversee, as applicable, the Development and Manufacturing of the Product, in accordance with the terms of this Agreement. Neither Party shall be relieved of its diligence obligations under this Agreement by entering into Sublicense Agreements.

**3.8 Development Data.** Subject to the licenses granted herein, all Development Data shall be owned and shared by the Parties as set forth in this Section 3.8:

(a) Joint Development Data shall be jointly owned by both Parties and shall be regarded as Incyte Know-How and Syndax Know-How for all purposes under this Agreement and shall be regarded as the Confidential Information of both Parties. With respect to the data relating to a Party's proprietary molecule not otherwise subject to the licenses under this Agreement but included in Joint Development Data, the other Party may use such data solely in connection with the Development and Commercialization of the Product, and such data related to the proprietary molecule shall be considered the Confidential Information of the Party which owns such molecule, ***provided that*** the portion of such data that relates specifically to the proprietary molecule (and not the combination of the Product and the proprietary molecule) will be solely owned by the Party which owns such molecule.

(b) Independent Trial Data shall be owned solely and exclusively by the Party generating such data, which shall be Confidential Information of such Party.

(c) With respect to Joint Development Data generated by or on behalf of a Party, its Affiliates or sublicensees (including Sublicensees, with respect to Incyte), as applicable, such Party shall promptly provide the other Party with copies of reports and summaries thereof, in each case as such reports and summaries become available to such Party, its Affiliates or sublicensees (including Sublicensees, with respect to Incyte). Each Party will share all Joint Development Data generated by it or on its behalf, its Affiliates or sublicensees (including Sublicensees, with respect to Incyte) with the other Party [\*\*\*], and the Party receiving such Joint Development Data is entitled to disclose such Joint Development Data to its Affiliates and sublicensees (including Sublicensees, with respect to Incyte) only for use in accordance with the terms of this Agreement. Each Party shall ensure that its Affiliates and sublicensees (including Sublicensees, with respect to Incyte), as applicable, agree to disclose Joint Development Data to the other Party, its Affiliates and sublicensees (including Sublicensees, with respect to Incyte), as applicable.

(d) Each Party shall provide the other Party with copies of relevant Independent Trial Data reasonably promptly after such data becomes available to such Party, its Affiliates or sublicensees (including Sublicensees, with respect to Incyte); ***provided, however***, that such [\*\*\*]. Notwithstanding the foregoing, either Party shall be free to use any such Independent Trial Data that is in the public domain.

(e) Notwithstanding the foregoing, in the event Development Data contains Personal Data, to the extent required by applicable Data Protection Laws, the respective Party acting as data controller shall ensure that data subjects have been notified (and have consented, where applicable) with respect to the processing of their Personal Data, including the transfer and sharing of such Personal Data with the other Party.

**3.9 Records.** Each Party shall maintain current and accurate records of all work conducted by or on behalf of a Party and its Affiliates under the Development Plan, and all data and other information resulting from such work, which records shall include, as applicable, books, records, reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, computer programs and documentation thereof (e.g., samples of materials and other graphic or written data generated in connection with such Development Activities). Such records shall properly reflect all work done and results achieved in the performance of such Development Activities in sufficient detail and in good scientific manner appropriate for regulatory and patent purposes. Such records shall be properly retained and archived according to applicable good pharmacovigilance practice, GLP, GCP and/or GMP standards. Each Party shall document such Development Activities, including Trials conducted pursuant to the Development Plan, in formal written study reports upon completion of such activity according to applicable national and international (e.g., ICH, GCP and GLP) guidelines and Manufacturing. All Trial activities and Development Activities shall be documented by setting up, maintaining and controlling a trial master file according to ICH-GCP and subject to an audit plan to be agreed to by the Parties.

### **3.10 Annual Development Reports.**

(a) **Incyte Annual Development Report.** No later than [\*\*\*] after the end of each calendar year, Incyte shall provide to Syndax the Incyte Annual Development Report. The Incyte Annual Development Report shall summarize in reasonable detail Incyte's and its Affiliates' and Sublicensees' activities and progress related to the Development of the Licensed Antibody and Products in the Territory in accordance with the Development Plan, including information concerning the conduct of non-clinical activities and Trials, and applications for and securing of Regulatory Approvals of such Product in the Territory. Each Incyte Annual Development Report will [\*\*\*]. Syndax shall treat such Incyte Annual Development Reports as Incyte's Confidential Information and shall not distribute such report(s) to any Third Party without Incyte's prior written consent; ***provided that***, notwithstanding the foregoing, Syndax shall have the right to distribute such report(s) to [\*\*\*] to the extent necessary for Syndax to [\*\*\*] without such prior written consent.

(b) **Syndax Annual Development Report.** No later than [\*\*\*] after the end of each calendar year, Syndax shall provide to Incyte the Syndax Annual Development Report. The Syndax Annual Development Report shall summarize in reasonable detail Syndax's and its Affiliates' activities and progress related to the Development of the Licensed Antibody and Products in the Territory in accordance with the

Development Plan, including information concerning the conduct of non-clinical activities and Trials, and applications for and securing of Regulatory Approvals of such Product in the Territory. Incyte shall treat such Syndax Annual Development Reports as Syndax's Confidential Information and shall not distribute such report(s) to any Third Party without Syndax's prior written consent; **provided, however**, that Incyte may provide such report to any (i) [\*\*\*] and (ii) [\*\*\*], in each case ((i) and (ii)) without Syndax's prior written consent.

**3.11 Status Updates in the Territory by Both Parties.** Without limiting the foregoing obligations of each Party under Section 3.10, each Party shall provide the JDC with reports detailing its respective Development Activities under the Development Plan and the results thereof at least [\*\*\*] prior to any JDC meeting, but in any event, on at least a [\*\*\*] basis. Each Party shall promptly, but in any event within [\*\*\*] after receipt thereof, provide the other Party with copies of any material documents or correspondence received from any Regulatory Authority related to such Development Activities.

**3.12 Compliance.** In conducting any activities under this Agreement for the Development Program, each Party's performance will be in good scientific manner, and in compliance with applicable Law. Each of Incyte and Syndax shall use, and shall cause their respective Affiliates and sublicensee(s) (and Sublicensee(s) in the case of Incyte) to use, Commercially Reasonable Efforts to ensure that its employees, agents, clinical institutions and clinical investigators as well as any further entities actively involved in the conduct of development work (such as contract research organizations, contract manufacturing organizations, vendors, laboratories, or any other subcontractor, etc.) comply with all applicable Laws with respect to the performance of any activities under the Development Program, Licensed Antibody or Products, including (as applicable): the United States Federal Food, Drug and Cosmetic Act, as amended, the PHSA, the rules governing medicinal products in the European Union and including Directive 2001/83/EC and Regulation 726/2004/EC and applicable national legislation regulatory provisions regarding protection of human subjects, and, except to the extent contrary to applicable Law, the spirit and principles of the self-regulatory codes of The Pharmaceutical Research and Manufacturers of America and the European Federation of Pharmaceutical Industry and Associates, the rules relating to financial disclosure by clinical investigators, Institutional Review Boards (IRB) and independent ethics committees, GCP, GLP, GMP and Good Distribution Practices, IND regulations, and any conditions imposed by a reviewing Governmental Authority or Ethics Committee/IRB, and comparable statutes and regulatory requirements in other jurisdictions. Each Party will maintain any of its facilities at its own cost and expense and risk necessary to carry out its responsibilities under the Development Program pursuant to the Development Plan. Each Party agrees to make its employees reasonably available at their respective places of employment to consult with the other Party on issues arising relating to the performance of the Development Program pursuant to the Development Plan.

#### **4. REGULATORY ACTIVITIES AND PRICING ACTIVITIES**

##### **4.1 Ownership of Regulatory Approvals.**

**(a) General Regulatory Activities and Pricing Activities in the Incyte Territory.** Subject to Section 4.1(c), Incyte shall be responsible for all Regulatory Activities and Pricing Activities in the Incyte Territory in the Field (including in connection with Labelling and Packaging for the Product in the Incyte Territory). Syndax shall have the right to attend meetings and scheduled calls with the relevant



Governmental Authorities in the European Region (other than with respect to pricing reimbursement) to the extent permitted by applicable Laws. Syndax shall take any action reasonably necessary and reasonably requested by Incyte in furtherance of seeking Regulatory Approval of the Product in the Field in the Incyte Territory. Incyte shall be responsible for, and shall solely bear, all Regulatory Costs for the Product in the Incyte Territory and, for clarity, shall reimburse Syndax for reasonable Regulatory Costs incurred by Syndax, if any, to the extent Syndax is performing such Regulatory Activities or supporting Pricing Activities for Incyte as reasonably requested by Incyte or as set forth in the Development Plan, ***provided that*** any such Regulatory Costs allocable to the Collaboration Trials shall be shared in accordance with the Pro Rata Percentage pursuant to Section 7.1 and any such Regulatory Costs allocable to Co-Commercialization (but excluding in any event any costs allocable to Trials, other Development Activities, or Development-related Manufacturing activities) shall be shared in accordance with the Pre-Tax Profit (Loss) pursuant to Section 7.6.

**(b) General Regulatory Activities and Pricing Activities in the Co-Commercialization Territory.** Subject to Section 4.1(c), Incyte shall be responsible for all Regulatory Activities and Pricing Activities in the Co-Commercialization Territory in the Field (including in connection with Labelling and Packaging for the Product in the Co-Commercialization Territory) in accordance with the Development Plan and the Co-Commercialization Plan. The Parties shall discuss (i) the regulatory strategy for filing and maintaining Regulatory Approvals in the Co-Commercialization Territory through the JDC and in alignment with the JCC and (ii) to the extent that Incyte is required to undertake Pricing Activities for the Product in the Co-Commercialization Territory, the strategy for carrying out such Pricing Activities(s) through the JCC. Syndax shall provide reasonable assistance with respect to Incyte's Regulatory Activities and Pricing Activities in the Co-Commercialization Territory as reasonably requested by Incyte and shall have the right to attend meetings and scheduled calls with the relevant Governmental Authorities in the Co-Commercialization Territory and to participate in the preparation and review of any Regulatory Materials and Pricing Materials in the Co-Commercialization Territory to the extent permitted by applicable Laws. Incyte will consider in good faith reasonable comments from Syndax with respect to the Regulatory Materials and Pricing Materials in the Co-Commercialization Territory, but will have final decision making authority with respect to such Regulatory Materials and Pricing Materials.

**(c) Syndax Trial Regulatory Activities.** Notwithstanding anything to the contrary with respect to Incyte's rights and responsibilities for Regulatory Activities and Pricing Activities as necessary or desirable for obtaining or maintaining Regulatory Approvals under Section 4.1(a) and Section 4.1(b), Syndax shall [\*\*\*]. The Parties shall discuss the regulatory strategy for filing and maintaining Regulatory Approvals and the preparation of Regulatory Materials with respect to the Syndax Trials through the JDC and in alignment with the JCC. Notwithstanding Syndax's ongoing responsibilities under Section 3.5 and this Section 4.1(c), Syndax shall transfer the IND(s) for all Trials to Incyte within [\*\*\*] after the Effective Date (the "**Regulatory Transfer**"). All INDs to be filed after the Regulatory Transfer with respect to Product will be submitted by Incyte.

## 4.2 Ownership of Regulatory Approvals.

**(a)Co-Commercialization Territory.** Subject to Section 4.1(c) and Section 7.5, all Regulatory Approvals, if applicable, for the Product in the Co-Commercialization Territory in the Field shall be in the name of Incyte, and Incyte shall own (*i.e.*, hold the BLA and Marketing Authorization in its name) all right, title and interest in and to all such Regulatory Approvals, if applicable, and all related Regulatory Materials and Pricing Materials.

**(b)Incyte Territory.** Subject to Section 4.1(b) and 7.5, all Regulatory Approvals, if applicable, for the Product in the Incyte Territory in the Field shall be in the name of Incyte, Incyte's Affiliates, Sublicensees or Distributor(s) designated by Incyte, and Incyte, Incyte's Affiliates, Sublicensees or Distributor(s), as applicable, shall own (*i.e.*, hold each applicable BLA and Marketing Authorization in its name) all right, title and interest in and to all such Regulatory Approvals, if applicable, and all related Regulatory Materials and Pricing Materials.

**4.3 Reporting and Review.** To the extent Syndax is performing any of the following activities pursuant to Section 4.1 or in connection with Syndax's conduct of any Syndax Trial, Syndax shall keep Incyte reasonably and regularly informed in connection with the preparation of all material Regulatory Materials, Governmental Authority review of Regulatory Materials, Regulatory Approvals, as applicable, with respect to the Product. Upon reasonable request, Syndax shall provide Incyte, in a timely manner, with copies of all material notices, questions, and requests for information in tangible form which it receives from a Governmental Authority with respect to the Product. Incyte shall keep Syndax reasonably and regularly informed in connection with the preparation of all material Regulatory Materials, Governmental Authority review of Regulatory Materials, Regulatory Approvals, as applicable, with respect to the Product in the Major Markets. Incyte shall keep Syndax reasonably and regularly informed in connection with the preparation of all material Pricing Materials and Governmental Authority review of the Pricing Materials in the Co-Commercialization Territory. Upon reasonable request, Incyte shall provide Syndax, in a timely manner, with copies of all material notices, questions, and requests for information in tangible form which it receives from a Governmental Authority with respect to the Product in the Field in the Co-Commercialization Territory for Collaboration Trials and in the Territory with respect to Syndax Trials. Incyte shall inform Syndax prior to or at a minimum within [\*\*\*] after submitting a material required report to any Governmental Authority with respect to Product in the Field in the Co-Commercialization Territory and in the Incyte Territory with respect to any Syndax Trial. Incyte will consider in good faith reasonable comments from Syndax with respect to the Regulatory Materials in respect of the foregoing. The Party reporting to the other Party pursuant to this Section 4.3 shall have the right to reasonably redact any information to the extent not related to the Licensed Antibody, Product.

**4.4 Price Reporting Obligations.** Incyte shall be responsible for all federal and state government price reporting and disclosure obligations for Product sold in the Co-Commercialization Territory or foreign equivalents in the Incyte Territory ("**Government Price Calculations and Reporting**"). Government Price Calculations and Reporting may include, but shall not be limited to, any U.S. federal, state or other jurisdiction legal reporting or compliance obligation with respect to a Product under the applicable statutes, rules, and regulatory guidance relating to the Medicaid Rebate Program, the Medicare Program, the Public Health Service 340B Program, the Department of Veterans Affairs Master Agreement, the Federal Supply Schedule contract, or applicable state or other jurisdiction laws.

## 4.5 Pharmacovigilance.

(a) **Syndax Trials, Independent Trials and Collaboration Trials.** For the Syndax Trials, Syndax shall be responsible for the collection, review, assessment, tracking and filing of information related to adverse events associated with the Product in accordance with applicable Laws and this Agreement and shall ensure that, in such Development of the Product, it will record, investigate, summarize, notify, report and review all adverse events in accordance with applicable Laws; ***provided that***, the details on operational responsibility for these activities will be defined in the Pharmacovigilance Agreement. For Collaboration Trials (other than Syndax Trials) and Incyte Independent Trials, Incyte shall be responsible for the collection, review, assessment, tracking and filing of information related to adverse events associated with the Product in accordance with applicable Laws and this Agreement and shall ensure that, in such Development of the Product, it will record, investigate, summarize, notify, report and review all adverse events in accordance with applicable Laws.

(b) **Exchange of Adverse Event Reports.** Each Party shall keep the other Party informed of (i) any Serious Adverse Event (“SAE”) and (ii) any Suspected Unexpected Serious Adverse Reaction (“SUSAR”) and other safety requirements or other information necessary or reasonably useful for such other Party to comply with its pharmacovigilance responsibilities as per the schedule set out in the Pharmacovigilance Agreement. The costs of establishing and maintaining the global safety database for the Product shall be shared in accordance with the Pro Rata Percentage.

(c) **Pharmacovigilance Agreement.** The safety representatives from each of the Parties shall meet and agree upon a written pharmacovigilance agreement for exchanging adverse event and other safety information relating to the Product within [\*\*\*] after the Effective Date (the “**Pharmacovigilance Agreement**”). Incyte shall at all times hold and be responsible for maintaining the global safety database, the Drug Safety Update Reports (DSUR), the Periodic Safety Update Reports (PSUR) and the core data sheet for each Product. Such Pharmacovigilance Agreement shall ensure that adverse event and other safety information is exchanged, and pharmacovigilance obligations are fulfilled, as described in Section 4.5(b), according to a schedule that will permit each Party (and its Affiliates, sublicensees (including Sublicensees, with respect to Incyte) or subcontractors) to comply with applicable Laws, current standards for pharmacovigilance practice and regulatory requirements as more fully set forth in the Pharmacovigilance Agreement.

**4.6 Governmental Authority Communications Received by a Party.** Each Party shall promptly inform the other Party of notification of any action by, or notification or other material information (including any audit notice, inspection notice, notice of initiation by Governmental Authorities of investigations, document or information requests, detentions, seizures or injunctions concerning the Product or this Agreement) which it receives (directly or indirectly) from any Governmental Authority in the Territory, whether in relation to the Co-Commercialization Territory or in relation to the Incyte Territory, which (i) raises any material concerns regarding the quality, safety or efficacy of the Product or materially modifies, delays, or halts any Trial, (ii) indicates or suggests a potential material liability of either Party to Third Parties in connection with the Product, (iii) is reasonably likely to lead to a recall, market withdrawal or market notification with respect to the Product, (iv) relates to expedited exchange of individual case safety reports and periodic safety reports with respect to the Product, or product complaints, and which is reasonably likely to have a material adverse impact on Regulatory Approvals or the continued Commercialization of the Product in the Field in the Territory or (v) raises any material concerns regarding the compliance of either

Party (or any of their respective Sublicensees, Distributors, or subcontractors) with Laws related to the Licensed Antibody or Product or this Agreement. Subject to Section 4.1(c) and 4.3, Incyte shall be solely responsible for responding to any such communications relating to the Product in the Territory in the Field. Each Party shall reasonably cooperate with and assist the other Party in complying with regulatory obligations, including by providing to the other Party, within [\*\*\*] (or such shorter period required by a Governmental Authority) after a request, such information and documentation which is in such Party's possession as may be necessary or reasonably helpful for the other Party to prepare a response to an inquiry from a Governmental Authority with respect to the Product. Each Party shall promptly provide, and ensure that its Affiliates and sublicensees provide the other Party with a copy of all material correspondence received from a Regulatory Authority specifically regarding the matters referred to above.

**4.7 Recall, Withdrawal, or Market Notification of Product.** In the event that any Governmental Authority suggests, threatens, recommends or initiates any action to remove the Product from the market whether in the Co-Commercialization Territory or in the Incyte Territory (in whole or in part, including in any Trial), or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal the Party receiving notice thereof or desiring such recall or similar action shall promptly notify the other Party of such communication promptly, but in no event later than [\*\*\*], after receipt or determination thereof. Notwithstanding the foregoing, in all cases Incyte shall determine whether to initiate any recall, withdrawal or market notification of the Product in the Territory (except in the case of a government-mandated recall or market withdrawal), including the scope of such recall or withdrawal (e.g., a full or partial recall, or a temporary or permanent recall) or market notification; ***provided, however***, that before Incyte initiates a recall, withdrawal or market notification, the Parties shall promptly meet and discuss in good faith the reasons therefor and Incyte shall consider Syndax's reasonable comments in good faith; ***provided, further***, that such discussions shall not delay any action that Incyte believes has to be taken in relation to any recall, withdrawal or market notification. Each Party shall at all times utilize a batch tracing system which will enable it to identify, on a prompt basis, customers within the Territory who have been supplied with Product of any particular batch, and to recall such Product from such customers.

**4.8 Cost Allocation re Recall; Withdrawal or Market Notification.** Subject to Section 14.3, all direct costs and expenses associated with implementing a recall, withdrawal or market notification with respect to the Product in any Territory shall be allocated between Incyte and Syndax as follows:

[\*\*\*].

## **5. COMMERCIALIZATION OF PRODUCTS**

### **5.1 Incyte Territory.**

**(a) General.** Incyte shall be solely responsible for all aspects of the Commercialization of the Products in the Incyte Territory in the Field during the Term, including distribution, Product positioning, Product strategy, Product branding, core messaging, marketing, promotion, Detailing Activities, Medical Affairs Activities and all decisions relating to the setting of Product prices in the Incyte Territory; invoicing and booking sales, and establishing all terms of sale; subject to Section 5.5, the selection and protection of relevant trademarks in the Incyte Territory; and subject to Article 4, all

Regulatory Activities in connection with any Commercialization of the Products in the Incyte Territory. The JSC shall oversee all Commercialization of Products in the Field in the Incyte Territory.

**(b) Commercialization Diligence.** Incyte shall use Commercially Reasonable Efforts to Commercialize Products in the Field [\*\*\*] in each case ([\*\*\*) with respect to which Incyte, its Affiliates or Sublicensees have received Marketing Authorization for such Product(s). For the avoidance of doubt Incyte may satisfy its obligations pursuant to clause (ii) of this Section 5.1(b) by [\*\*\*].

**(c) Commercialization Costs and costs for Medical Affairs Activities.** Incyte shall be responsible for all costs incurred in connection with the Commercialization of the Product and for costs in support of Medical Affairs Activities (other than Medical Affairs Activities Costs) in the Incyte Territory, in each case that are solely attributable to Commercialization or Medical Affairs Activities in the Incyte Territory.

**(d) Incyte Reports.** Incyte shall provide to Syndax a written update on its Commercialization for the Product(s) in the Incyte Territory on a regional or on a country-by-country basis no less than [\*\*\*] every calendar year.

## **5.2 Co-Commercialization Territory.**

**(a) General.** Subject to the Co-Commercialization Plan, the Co-Commercialization Budget and Syndax's rights upon exercise of the Co-Commercialization Option, Incyte shall be responsible for all Commercialization of the Product(s) in the Co-Commercialization Territory in the Field during the Term, including distribution, Product positioning, Product strategy, Product branding, core messaging, marketing, promotion, Detailing Activities, Medical Affairs Activities, invoicing and booking sales, and establishing all terms of sale in the Co-Commercialization Territory. Subject to Section 5.5, the selection and protection of relevant trademarks in the Co-Commercialization Territory; and subject to Article 4, all Regulatory Activities in connection with any Commercialization of the Products in the Co-Commercialization Territory.

**(b) JCC Oversight and Co-Commercialization Plan.** The JCC shall oversee all Commercialization of Products in the Field in the Co-Commercialization Territory. The Parties will jointly develop and agree through the JSC on a Co-Commercialization Plan and a Co-Commercialization Budget that shall define the overall commercial strategy and detail the operational activities, requirements and responsibilities of each Party.

**(c) Commercialization Diligence.** Incyte shall use Commercially Reasonable Efforts to Commercialize Products in the Field in the Co-Commercialization Territory following receipt of Marketing Authorization for such Products in the Co-Commercialization Territory. Each Party shall use Commercially Reasonable Efforts to execute and to perform, or cause to be performed, the activities assigned to it under the Co-Commercialization Plan.

**(d) Co-Commercialization Option.** For the first Indication, Syndax shall have the right, but not the obligation, to provide [\*\*\*] of the US Sales Representatives that Incyte determines to field for the first Indication on an FTE basis at the Commercial FTE Rate (the "**First Indication Co-Commercialization Option**") for the purpose of conducting Detailing Activities in accordance with the Co-Commercialization Plan. Incyte shall notify Syndax of its anticipated first launch of Product in the Co-Commercialization Territory no later than Incyte's BLA submission for the Product in the Co-Commercialization Territory (the "**First**

**Indication Launch Notice**”). Syndax shall have the right to exercise the First Indication Co-Commercialization Option by written notice to Incyte within [\*\*\*] after Syndax’s receipt of the First Indication Launch Notice, which written notice will establish the level of Sales Representative support that Syndax will provide for the first Indication in the Co-Commercialization Territory at the time of launch of the Product. In the event that Syndax does not timely exercise its First Indication Co-Commercialization Option following receipt of the First Indication Launch Notice and (i) Incyte later determines to submit a BLA or BLA Supplement for the Product for the treatment of IPF in the Co-Commercialization Territory and (ii) Incyte is seeking to increase headcount of its Sales Representatives for Product in the Co-Commercialization by [\*\*\*] in connection with the launch of IPF in the Co-Commercialization Territory (the **“IPF Launch”**), Incyte shall notify Syndax of its anticipated IPF Launch no later than the date of Incyte’s BLA submission for the Product in the Co-Commercialization Territory for the treatment of IPF (the **“IPF Launch Notice”**). For IPF, Syndax shall have the right, but not the obligation, to provide [\*\*\*] of the additional US Sales Representatives that Incyte determines to field for IPF on an FTE basis at the Commercial FTE Rate (the **“IPF Co-Commercialization Option”**) and together with the First Indication Co-Commercialization Option, the **“Co-Commercialization Option”**) for the purpose of conducting Detailing Activities in accordance with the Co-Commercialization Plan. Syndax shall have the right to exercise the IPF Co-Commercialization Option by written notice to Incyte within [\*\*\*] after Syndax’s receipt of the IPF Launch Notice, which written notice will establish the [\*\*\*] of Sales Representatives (on an FTE basis) that Syndax will provide for IPF in the Co-Commercialization Territory at the time of the IPF Launch.

**(e) Subcontracting.** Incyte may perform its Commercialization under this Agreement through one or more subcontractors as provided in Section 2.7.

**(f) Pre-Tax Profit (Loss) Share.** The Parties shall equally share the Pre-Tax Profit (Loss) of the Co-Commercialization in the Co-Commercialization Territory pursuant to Section 7.6.

**(g) Sales Force.** Both Parties shall ensure that all Sales Representatives performing Detailing Activities for the Product in the Co-Commercialization Territory shall do so in accordance with applicable law and complete the same training and certification process. Incyte will be responsible for the training of both Parties’ Sales Representatives and will prepare and implement a training program and training materials for such Sales Representatives, including Detail scripts. Without limiting the generality of the foregoing, each Party shall:

- (i)** be solely responsible for recruiting, hiring and maintaining its sales force of Sales Representatives, including determining incentive compensations, for the Commercialization of the Product in accordance with its standard procedures and the requirements of this Agreement;
- (ii)** be responsible for the activities of its Sales Representatives, including compliance by its Sales Representatives with training and Detailing Activities requirements established by Incyte and ensuring Sales Representatives have and maintain all credentials, licenses, or other governmental or institutional approvals necessary to engage in Detailing Activities and related activities;

- (iii) ensure that any of its Sales Representatives involved in the Commercialization of the Product will not have any legal or regulatory disqualifications, bars or sanctions, including but not limited to any suspension or revocation of required credentials, licensing, or other governmental or institutional approvals necessary to engage in Detailing Activities and related activities, or any record of debarment, exclusion, or other sanction under the U.S. Federal Food, Drug, and Cosmetic Act, the U.S. Social Security Act, and comparable statutes and regulatory requirements in other jurisdictions; and
- (iv) maintain records and otherwise establish procedures to ensure compliance with all applicable Laws and professional requirements that apply to the Commercialization of the Product.

**5.3 Legal Compliance.** Each Party shall, and shall ensure that its Affiliates, sublicensees (including Sublicensees, with respect to Incyte) and subcontractors, comply with all applicable Laws, including all applicable Regulatory Approvals for the Product, in the Territory in Commercializing the Product(s) in the Field and have in place a compliance program sufficient to monitor compliance with applicable Laws in connection with such Commercialization. Each Party shall be responsible for reporting its own expenditures in compliance with the Physician Payments Sunshine Act, subject to further agreement between the Parties as to any information exchange necessary to properly calculate and report spending on research and development which understanding shall be documented in the Co-Commercialization Plan. Notwithstanding anything to the contrary contained herein, a Party or its Affiliate shall not be obligated to undertake or continue any activities with respect to the Licensed Antibody or Products if such Party (or Affiliate) reasonably determines that performance of such activity would violate applicable Law or if a Regulatory Authority determines that such activities with respect to the Licensed Antibody or Product would pose an unacceptable safety risk to patients.

**5.4 Promotional Materials.**

- (a) **Incyte Territory.** Incyte will be solely responsible for the promotional strategy of the Product in the Incyte Territory.
- (b) **Co-Commercialization Territory.** Incyte shall be responsible for the promotional strategy of the Product in the Co-Commercialization Territory, subject to oversight of the JCC.

**5.5 Product Marks.**

(a) Subject to oversight of the JSC and JCC, Incyte shall be solely responsible for:

- (i) establishing a global branding for the Product, including identifying and selecting Product Marks and trademark standards for any Product Marks to be adopted as well as the global look and feel of Products and Product packaging in the Territory ("**Global Branding**"); ***provided that*** Incyte shall indicate with respect to any such Global Branding that such Product was in-licensed from Syndax to the extent permitted under applicable Law. Incyte and Syndax (and its Affiliates and sublicensees (including Sublicensees, with respect to Incyte) respectively) shall only use the Product Marks pursuant to

the terms of this Agreement **(i)** to identify the Product(s) and **(ii)** in connection with the Commercialization of the Product(s), and Incyte and Syndax shall not (and shall ensure that each of their Affiliates and sublicensees (including Sublicensees, with respect to Incyte) do not) use such Product Marks in the course of trade to identify, or otherwise in connection with, any other products; and

**(ii)** developing a global brand strategy and establishing commercial terms of sale ("**Global Brand Strategy**"). Such Global Brand Strategy may be updated from time to time by mutual agreement by the Parties. If the Parties do not mutually agree on the above, Incyte shall have the right to decide on the brand strategy for the Product(s) in the Territory, reasonably taking into account Syndax's comments.

**(b)** To the extent permissible by Regulatory Authorities and applicable Law, Incyte shall use the same Product Mark in the Incyte Territory and the Co-Commercialization Territory (a "**Global Product Mark**"). Any Global Product Mark shall be owned by Incyte in all countries and regions in which such Global Product Mark is applied for, registered, or used. Without limiting the foregoing, Incyte shall register and maintain the Product Marks in countries and regions it determines reasonably necessary.

**(c) Ownership of Product Marks.** All Product Marks shall be owned by Incyte. Incyte shall control the filing, prosecution, enforcement and maintenance of the Product Marks.

**(d) Infringement of Product Marks.** In the event that either Party becomes aware of any infringement of the Product Marks by a Third Party including, but not limited to, the existence of conflicting trademarks or company names of Third Parties in the Territory, such Party shall promptly notify the other Party and the Parties shall consult with each other in good faith with respect thereto. Incyte, at its sole discretion, shall have the right to determine how to proceed with respect to such infringement in the Territory, including by the institution of legal proceedings against such Third Party, in which case all costs and awards relating to such legal proceedings in the Incyte Territory will be borne exclusively by Incyte and all costs and awards relating to such legal proceedings in the Co-Commercialization Territory will be shared by the Parties in accordance with the Pre-Tax Profit (Loss) Share pursuant to Section 7.6.

**(e) Acknowledgments.** Syndax agrees that it will not at any time during or after the Term assert or claim any interest in, or do anything which may adversely affect the validity or enforceability of, any copyright, trademark, trade dress, logo or slogan used or intended to be used on or in connection with the marketing or sale of the Product in accordance with this Agreement. Syndax will not register, seek to register or cause to be registered any copyrights, trademarks, trade dress, logos or slogans owned by Incyte and used or intended to be used on or in connection with the marketing or sale of the Product or any variation thereof, under any applicable Laws providing for registration of copyrights, trademarks, service marks, trade names or fictitious names (including as an Internet domain name) or similar Laws, without Incyte's prior written consent (in its sole discretion). Syndax agrees that all use of the Product Marks will inure to the benefit of Incyte, including all goodwill in connection therewith. To the extent a Global Product Mark is used in the Co-Commercialization Territory and the Incyte Territory, Incyte will own rights to any internet domain names incorporating the Global Product Mark or any variation or part of such Global



Product Mark as its URL address or any part of such address under the country code top level domains corresponding to the countries of the Territory.

**6. MANUFACTURE OF PRODUCTS AND SUPPLY**

**6.1 Transition of Manufacturing Responsibilities to Incyte.**

**(a)** Within [\*\*\*] after receipt of written notice from Incyte, Syndax shall initiate a manufacturing technology transfer (including CMC transfer and assignment of any agreements by and between Syndax and any contract research organization relating to the Manufacture of Drug Substance or Drug Product) for the Manufacture of Drug Substance and Drug Product to Incyte (or its designated Affiliates or subcontractors), the conduct and completion of which shall be in accordance with the terms and conditions of a manufacturing technical transfer plan provided and overseen by the JSC (the "**Technology Transfer**"). Syndax shall complete the Technology Transfer as soon as reasonably practicable after the Effective Date. The Parties shall [\*\*\*] incurred by Incyte and Syndax to conduct such transfer in accordance with the Pro Rata Percentage. After successful completion of the Technology Transfer or otherwise after expiration of the Technology Transfer Period, Incyte shall keep Syndax reasonably informed of its supply activities and its ability to manufacture Drug Substance and Drug Product for Development and Commercialization hereunder. In addition, upon the reasonable request of Incyte from time to time after the Technology Transfer Period, Syndax shall provide to Incyte (or its designated Affiliates or subcontractors) such reasonable technical assistance that is necessary or reasonable useful in connection with the Manufacture of Licensed Antibody and Drug Product, with the Parties sharing the costs of such technical assistance in accordance with the Pro Rata Percentage. Subject to successful completion of the Technology Transfer and Syndax's provision of technical support in accordance with this Section 6.1(a), Incyte will use Commercially Reasonable Efforts to Manufacture or have Manufactured Product on a timeline that does not unreasonably delay the anticipated initial BLA filing with the FDA for the Product as set forth in the Development Plan.

**(b)** Until completion of the Technology Transfer or expiration of the Technology Transfer Period pursuant to Section 6.1(a), Syndax or any contract manufacturer on Syndax's behalf shall supply (i) Licensed Antibody, Drug Substance and Drug Product for the conduct of the Syndax Trials and (ii) Incyte with Licensed Antibody, Drug Substance and Drug Product for Collaboration Trials and Incyte Independent Trials; all subject to Syndax's suppliers' capacity and ability. At Incyte's request made during the [\*\*\*] after the Effective Date, (A) Syndax shall use Commercially Reasonable Efforts to assist Incyte in entering into supply agreements with Syndax's then-current contract manufacturers on substantially the same terms as such supply agreements between Syndax and such contract manufacturers for the purchase and manufacture of Drug Substance and Drug Product, or (B) Syndax shall assign to Incyte any existing agreements it has in place with contract manufacturing organizations related to the manufacture of Drug Substance and Drug Product.

**(c)** Syndax shall use Commercially Reasonable Efforts to assist Incyte in obtaining Third Party licenses that may be needed for the Manufacture of Product on Incyte's behalf and with Incyte bearing the costs associated with such license in the Incyte Territory, subject to the royalty offset set forth in Section 8.3(d), if applicable, and the sharing of such costs as part of the Pre-Tax Profit (Loss) Share to the extent allocable to the Co-Commercialization Territory.

**6.2 Clinical Supply Agreement.** The Parties will use their Commercially Reasonable Efforts to enter into, within [\*\*\*] after the Effective Date, a supply agreement (including a quality agreement) with respect to the Manufacture and supply by Incyte of Drug Substance and Drug Product for the Syndax Independent Trials and Collaboration Trials (the "**Supply Agreement**"), containing terms as shall be consistent with this Agreement and industry standards for a contract manufacturing agreement in the context of a collaborative effort.

**6.3 Clinical Supply.**

(a) Following the completion of the Technology Transfer, subject to the terms of the Supply Agreement, Incyte shall use Commercially Reasonable Efforts to source and to supply the demands of Licensed Antibody, Drug Substance and Drug Product reasonably required for the conduct of the Syndax Trials (other than Syndax Ongoing Trials) [\*\*\*], subject to Incyte's suppliers' capacity and ability.

(b) Following the completion of the Technology Transfer and subject to the terms of the Supply Agreement, Incyte shall use Commercially Reasonable Efforts to source and to supply the demands of Licensed Antibody, Drug Substance and Drug Product, and if applicable Placebo, combination or comparator products reasonably required for the conduct of any Collaboration Trial or Incyte Independent Trial.

(c) In the event of a potential shortfall or shortfall in the supply of Licensed Antibody, Drug Substance and Drug Product, the supply for the conduct of Collaboration Trials under Section 6.3(b) shall have preference over the supply for the conduct of the Syndax Trials (other than Syndax Ongoing Trials) under Section 6.3(a) or the supply for the conduct of Incyte Independent Trials under Section 6.3(b).

(d) Drug Substance and Drug Product inventory that exists as of the Effective Date (the "**Existing Supply**") will be included in the collaboration at no cost to Incyte. Other than the Existing Supply, costs associated with supply of Drug Product and Placebo for (i) Collaboration Trials under this Section 6.3 shall be included in Collaboration Costs, (ii) Incyte Independent Trial Activities will be borne by Incyte and (iii) Syndax Independent Trial Activities will be borne by Syndax. Labelling and Packaging of Drug Product for Collaboration Trials shall be discussed in the JDC and the associated costs shall be regarded as Collaboration Costs.

**6.4 Commercial Supply.** Incyte shall be responsible for sourcing Drug Substance and Drug Product for Commercialization in the Territory. Costs associated with supply of Drug Substance and Drug Product for Commercialization in the Co-Commercialization Territory are included in the Costs of Goods Sold and shared in accordance with the Pre-Tax Profit (Loss) Share.

**7. SHARING OF COLLABORATION COSTS AND PRE-TAX PROFIT (LOSS) SHARE**

**7.1 Collaboration Costs.** Beginning as of the Effective Date the Parties shall share all Collaboration Costs that are incurred after the Effective Date as set forth in the Development Plan in accordance with the Pro Rata Percentage. Collaboration Costs will be shared on a GAAP accrual basis, so that each Party can accurately report expenses in its financial statements. Within [\*\*\*] after each calendar quarter, each Party shall invoice the other Party by providing copies of all invoices received from Third Parties and records of the number of FTEs.

**7.2 Development Costs Not Shared.** Subject to Section 7.5, all Development costs and Manufacturing costs for Syndax Independent Trial Activities shall be fully borne by Syndax. Subject to Section 7.5, all Development costs and Manufacturing costs for Incyte Independent Trial Activities or otherwise with respect to the Incyte Territory shall be fully borne by Incyte (other than with respect to Collaboration Costs, which costs shall be shared in accordance with Section 7.1).

**7.3 Development and Co-Commercialization Budget Overruns.** Each Party shall promptly inform the other Party upon determining that it is likely to exceed the budget amounts set forth in the annual Collaboration Budget as may be updated from time to time or in the Co-Commercialization Budget as may be updated from time to time (each a "**Budget**"). To the extent that the Collaboration Budget for a particular calendar year is exceeded by [\*\*\*], each Party shall bear its share of such excess amount at its respective Pro Rata Percentage. To the extent that the Collaboration Budget for a particular calendar year is exceeded by [\*\*\*], the "**Excess Amount**"), each Party shall solely bear the full cost of such Excess Amount that such Party incurred.

**7.4 Report and Reconciliation of Collaboration Costs and Costs Shared for Independent Trial and Data Buy-In.**

**(a) Reporting.** Within [\*\*\*] of the end of any calendar quarter, each Party shall submit a calculation of all Collaboration Costs (including accurate records and books of accounts containing all data reasonably required for the calculation and verification of FTEs used by each Party in accordance with GAAP and the Development Plan) and other costs to be shared under Section 7.5 (including all information needed to calculate such costs) in accordance with GAAP on an accrual basis, incurred by such Party which may be subject to a reimbursement or cost sharing under this Agreement.

**(b) Reconciliation Calculation; Payment.** Incyte shall perform a reconciliation calculation to ensure that each Party bears its portion of the Pro Rata Percentage or other costs to be shared under Section 7.5. Incyte shall provide Syndax a report detailing the reconciliation calculation no later than [\*\*\*] following the end of each calendar quarter. If the reconciliation calculation reveals that a Party has borne less than its portion of the Pro Rata Percentage or other such costs, such Party shall pay the other Party an amount sufficient to reconcile to its portion of the Pro Rata Percentage or other such costs in such calendar quarter. The amounts resulting from the reconciliation calculation shall be payable for each calendar quarter within [\*\*\*] of receipt of the invoice for the reconciliation payment by the applicable Party.

**(c) Audits.** Each Party shall be entitled to audit the cost calculations claimed by the other Party under this Section 7.4 and the audit provisions set forth in Section 8.4 shall apply to any such audit.

**(d) Record Keeping.** Each Party shall keep and shall ensure that its Affiliates and Sublicensees keep, in accordance with GAAP, books and accounts of record in sufficient detail to permit accurate determination of all figures necessary for verification of the Collaboration Costs and other costs to be shared under Section 7.5. Each Party and its Affiliates and Sublicensees shall maintain such records for a period of at least [\*\*\*] after the end of the calendar quarter in which they were generated and make such records available upon request following the audit provisions set forth in Section 8.4 which shall apply to any such audit.

(e) **Currency Conversion.** Costs reported and reconciled under this Section 7.4 incurred in a currency other than US dollars shall be converted and payable in US dollars in accordance with Section 8.6 and 8.7.

## 7.5 Independent Trial and Data Buy-In Mechanism.

(a) **Responsibility for Independent Trials.** Subject to Section 3.4, each Party shall be fully responsible for its Independent Trials and costs associated therewith.

(b) **Independent Trial Data Buy-In.** This Section 7.5(b) shall apply to Independent Trials other than Phase 3 Trials in IPF that are conducted as Independent Trials (which are addressed in Section 7.5(c)).

- (i) Incyte shall have the right to elect to co-fund Syndax Independent Trials upon notice of such election to Syndax. Following such notice as to a Syndax Independent Trial, Incyte shall be obligated to pay to Syndax the buy-in fee and Pro Rata Percentage of Development costs set forth below and shall have the right to use Syndax's Independent Trial Data the same way it may use Collaboration Trial Data under this Agreement. As to each Syndax Independent Trial that Incyte elects to co-fund, Incyte shall pay to Syndax (A) a buy-in fee constituting [\*\*\*] of the Development costs incurred by Syndax as of delivery of the buy-in notice (including internal and External Costs) for the Development Activities associated with the applicable Independent Trial that Incyte would have otherwise been required to pay in accordance with Incyte's Pro Rata Percentage if such Development Activities had been Collaboration Development Activities (i.e., Development costs incurred multiplied by fifty five percent (55%) [\*\*\*]) and (B) Incyte's Pro Rata Percentage of Development costs that are incurred after delivery of the buy-in notice. Any such Development costs shall be considered part of Collaboration Costs as governed by Section 7.4, and budget overruns shall be considered Budget overruns as governed by Section 7.3.
- (ii) Syndax shall have the right to elect to co-fund Incyte Independent Trials upon notice of such election to Incyte. Following such notice as to an Incyte Independent Trial, Syndax shall be obligated to pay to Incyte the buy-in fee and Pro Rata Percentage of Development costs set forth below and shall have the right to use Incyte's Independent Trial Data the same way it may use Collaboration Trial Data under this Agreement. As to each Incyte Independent Trial that Syndax elects to co-fund, Syndax shall pay to Incyte (A) a buy-in fee constituting [\*\*\*] of the Development costs incurred by Incyte as of delivery of the buy-in notice (including internal and External Costs) for the Development Activities associated with the applicable Independent Trial that Syndax would have otherwise been required to pay in accordance with Syndax's Pro Rata Percentage if such Development Activities had been Collaboration Development Activities (i.e., Development costs incurred multiplied by forty five percent (45%) [\*\*\*]) and (B) Syndax's Pro Rata Percentage of Development costs that are incurred for such Incyte Independent Trial after delivery of the buy-in notice. Any such Development costs shall be considered part of Collaboration Costs as

governed by Section 7.4, and budget overruns shall be considered Budget overruns as governed by Section 7.3.

- (iii) Without limiting the foregoing Sections 7.5(b)(i) and 7.5(b)(ii), in the event that Independent Trial Data is the basis for Regulatory Approval by the FDA or EMA, the non-funding Party shall be required to pay the buy-in fee specified under Section 7.5(b)(i) or 7.5(b)(ii), as applicable, for the applicable Independent Trial upon such Regulatory Approval if such non-funding Party has not previously made the election to co-fund under Section 7.5(b)(i) or 7.5(b)(ii) for such Independent Trial.

(c) **IPF Independent Trial Data Buy-In Option.** This Section 7.5(c) (and not Section 7.5(b)) shall apply to Independent Trials that are Phase 3 Trials in IPF.

- (i) In the event that a Phase 3 Trial in IPF or a Pivotal Trial in IPF (except for the Syndax IPF Trial) is conducted as a Syndax Independent Trial, Incyte shall have the right to elect to co-fund such Syndax Independent Trial upon notice of such election to Syndax. Following such notice as to such Syndax Independent Trial, Incyte shall be obligated to pay to Syndax the buy-in fee and Pro Rata Percentage of Development costs set forth below and shall have the right to use Syndax's Independent Trial Data the same way it may use Collaboration Trial Data under this Agreement. As to each such Syndax Independent Trial that Incyte elects to co-fund, Incyte shall pay to Syndax (A) a buy-in fee constituting [\*\*\*] of the Development costs incurred by Syndax as of delivery of the buy-in notice (including internal and External Costs) for the Development Activities associated with the applicable Syndax Independent Trial that Incyte would have otherwise been required to pay in accordance with Incyte's Pro Rata Percentage if such Development Activities had been Collaboration Development Activities (i.e., Development costs incurred multiplied by fifty five (55%) [\*\*\*]) and (B) Incyte's Pro Rata Percentage of Development costs that are incurred for such Syndax Independent Trial after delivery of the buy-in notice. Any such Development costs shall be considered part of Collaboration Costs as governed by Section 7.4, and budget overruns shall be considered Budget overruns as governed by Section 7.3.
- (ii) In the event that a Phase 3 Trial in IPF is conducted as an Incyte Independent Trial, Syndax shall have the right to elect to co-fund such Incyte Independent Trial upon notice of such election to Incyte. Following such notice as to such Incyte Independent Trial, Syndax shall be obligated to pay to Incyte the buy-in fee and Pro Rata Percentage of Development costs set forth below and shall have the right to use Incyte's Independent Trial Data the same way it may use Collaboration Trial Data under this Agreement. As to each such Incyte Independent Trial that Syndax elects to co-fund, Syndax shall pay to Incyte (A) a buy-in fee constituting [\*\*\*] of the Development costs incurred by Incyte as of delivery of the buy-in notice (including internal and External Costs) for the Development Activities associated with the applicable Incyte Independent Trial that Syndax would have otherwise been required to pay in accordance with Syndax's Pro Rata Percentage if such Development Activities had been Collaboration Development Activities (i.e., Development costs incurred multiplied by forty

five (45%) [\*\*\*]) and **(B)** Syndax's Pro Rata Percentage of Development costs that are incurred for such Incyte Independent Trial after delivery of the buy-in notice. Any such Development costs shall be considered part of Collaboration Costs as governed by Section 7.4, and budget overruns shall be considered Budget overruns as governed by Section 7.3.

- (iii) Without limiting the foregoing Sections 7.5(c)(i) and 7.5(c)(ii), in the event that Independent Trial Data result in Regulatory Approval of a Product to treat IPF (the "**IPF Product**") by the FDA or EMA, the non-funding Party shall be required to pay the amounts specified under Section 7.5(c)(i) or 7.5(c)(ii), as applicable, for the applicable Independent Trial upon such Regulatory Approval if such non-funding Party has not previously made the election to co-fund under Section 7.5(c)(i) or 7.5(c)(ii) for such Independent Trial.
- (iv) If a Party becomes obligated to make payments to the other Party pursuant to Section 7.5(c)(i), 7.5(c)(ii) or 7.5(c)(iii) as to an Independent Trial, then such Party shall also pay to the other Party up to [\*\*\*] of the total Development costs incurred for the applicable Independent Trial (including internal and External Costs) that such paying Party would have otherwise been required to pay in accordance with the Pro Rata Percentage if such Development Activities had been Collaboration Development Activities (i.e., Development cost amounts for the applicable Independent Trial other than such amounts that such paying Party paid pursuant to Section 7.5(c)(i)(B) or 7.5(c)(ii)(B)). The amounts in this Section 7.5(c)(iv) shall be payable as a tiered royalty on US Net Sales of the IPF Product at the following rates for the applicable tier until such [\*\*\*] of such total Development costs has been paid:

Net Sales of IPF Product in US in any calendar year (US Dollars)	Royalty Rate
[***]	[***]
[***]	[***]
[***]	[***]

- (v) [\*\*\*].

- (d) The amounts payable pursuant to Sections 7.5(b) and 7.5(c) may, at the election of the payment receiving Party, be offset against any amount hereunder then-payable by such receiving Party to the other Party.

**7.6 Pre-Tax Profit (Loss) Share.**

- (a) **Principles.** Each of Incyte and Syndax shall be entitled to (and shall bear) fifty percent (50%) of Pre-Tax Profit (Loss) ("**Pre-Tax Profit (Loss) Share**"). To the extent any of the amounts included in the Pre-Tax Profit (Loss) are not attributable solely to the Commercialization of the Product in the Co-Commercialization Territory, then only the respective pro rata amount allocable to the Commercialization of the

Product in the Co-Commercialization Territory, which shall be agreed between the Parties in good faith, shall be included in the calculation of Pre-Tax Profit (Loss).

**(b) Report of Costs under the Pre-Tax Profit (Loss) Share.** Each Party shall furnish to the other Party a written report for each calendar quarter detailing such Party's (i) Co-Commercialization Costs, (ii) Cost of Goods Sold, (iii) Medical Affairs Activities Costs, (iv) Distribution Costs, and (v) Regulatory Costs (to the extent Regulatory Costs are included in Pre-Tax Profit (Loss) Share pursuant to Section 4.1(a)); in each case to the extent incurred with respect to the Co-Commercialization Territory during such calendar quarter. Such reports shall be furnished in reasonable detail for performing the Pre-Tax Profit (Loss) Share calculation. Such reports shall be due no later than [\*\*\*] following the end of each calendar quarter.

**(c) Reconciliation Calculation; Payment.** Incyte shall perform a reconciliation calculation to ensure that each Party receives (or bears) its portion of the Pre-Tax Profit (Loss) Share as set forth under this Agreement. Incyte shall provide Syndax a report detailing the reconciliation calculation no later than [\*\*\*] following the end of each calendar quarter. If the reconciliation calculation reveals that a Party has received (or borne) an amount in excess of its portion of the Pre-Tax Profit (Loss) Share, then (i) in the event that a Party that has received more than its share of the profits under the Pre-Tax Profit Share, such Party shall pay the other Party an amount sufficient to reconcile to its portion of the Pre-Tax Profit (Loss) Share in such Calendar Quarter and (ii) in the event that the Party that has borne less than its share of the losses under the Pre-Tax Profit Share, such Party shall pay the other Party an amount sufficient to reconcile to its portion of Pre-Tax Profit (Loss) Share in such Calendar Quarter. The amounts resulting from the reconciliation calculation of the Pre-Tax Profit (Loss) Share shall be payable for each calendar quarter within [\*\*\*] of receipt of the invoice for the reconciliation payment by the applicable Party. In calculation the Pre-Tax Profit (Loss), all amounts not denominated in US dollars shall be converted into US dollars by using the average closing exchange rate reported by Bloomberg for the respective quarter.

**(d) Audits.** Each Party shall be entitled to audit the cost reports and calculations of the Pre-Tax Profit (Loss) claimed by the other Party under this Section 7.6 and the audit provisions set forth in Section 8.4 shall apply to any such audit.

**(e) Record Keeping.** Incyte shall keep and shall ensure that its Affiliates and Sublicensees keep, in accordance with GAAP, books and accounts of record in connection with all sales and other dispositions of Products in the Co-Commercialization Territory (including use in Trials, or provision on a compassionate use basis or as marketing samples) in sufficient detail to permit accurate determination of all figures necessary for verification of the Pre-Tax Profit (Loss) Share hereunder. Incyte and its Affiliates and Sublicensees shall maintain such records until the later of (a) [\*\*\*] after the end of the in the period to which such books and records pertain and (b) the expiration of the applicable tax statute of limitations (or any extension thereof), or for such longer period as may be required by applicable Law. Incyte and its Affiliates and Sublicensees shall make such records available upon request following the audit provisions set forth in Section 8.4 which shall apply to any such audit.

## **8. LICENSE FEE, MILESTONES, ROYALTIES, GENERAL PAYMENT TERMS**

**8.1 License Fee and Contribution.**

(a) **Initial License Fee.** Incyte shall pay to Syndax a one-time, non-creditable, non-refundable upfront initial license fee of One Hundred Seventeen Million Dollars (\$117,000,000). This initial license fee shall become due within [\*\*\*] after the later of (i) the Effective Date and (ii) consummation of the Closing (as defined in the Securities Purchase Agreement).

(b) **Equity Purchase.** As partial consideration for the rights granted by Syndax to Incyte pursuant to the terms of this Agreement, the Parties shall consummate the transactions contemplated by the Securities Purchase Agreement as set forth therein.

**8.2 Milestone Payments.**

(a) **Development and Regulatory Milestones.** Incyte shall pay the following non-refundable milestone payments to Syndax, each due upon the first achievement of each milestone event indicated below (whether achieved by or on behalf of Incyte or its Affiliate, or Sublicensee) with respect to the first achievement of such milestone event by the first Product in the applicable Indication. Incyte shall notify Syndax upon achievement of any milestone event as set forth below and shall pay the applicable milestone payment within [\*\*\*] after achievement of such milestone event:

Milestone event	Indication (amounts in millions of US Dollars)			
	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
<b>Total Development &amp; Regulatory milestones</b>	[***]	[***]	[***]	[***]

[\*\*\*]

(b) **Sales Milestones.** Incyte shall notify Syndax upon achievement of any milestone event set forth below and Incyte shall make the following non-refundable one-time payments to Syndax based on Net Sales in any calendar year in the Co-Commercialization Territory or European Region, as applicable (for the first Product that achieves such milestone event), in accordance with the reporting and payment process set forth in Section 8.3(e):

Co-Commercialization Territory Milestone event (in US dollars)	Payment (in US dollars)
[***]	[***]
[***]	[***]
[***]	[***]



[***]	[***]
<b>Total Co-Commercialization Territory Sales Milestones</b>	[***]

<b>European Region Milestone event (in EURO)</b>	<b>Payment (in US dollars)</b>
[***]	[***]
[***]	[***]
[***]	[***]
<b>Total European Region Sales Milestones</b>	[***]

[\*\*\*]

### 8.3 Royalties from Incyte.

(a) **Royalties for Products in the [\*\*\*].** In further consideration of the licenses granted by Syndax to Incyte, Incyte shall pay to Syndax tiered royalties on incremental annual Net Sales of Products in the [\*\*\*] as follows:

<b>Net Sales of Products in [***] in any calendar year (in US dollars)</b>	<b>Royalty Rate</b>
Between [***]	[***]
Between [***]	[***]
Between [***]	[***]
Greater than [***]	[***]

The royalty rates under this Section 8.3 are incremental with respect to the annual Net Sales of Products. For example, if Products achieve in any given calendar year [\*\*\*] in Net Sales in the Incyte Territory, then a [\*\*\*] royalty shall be paid on the [\*\*\*], a [\*\*\*] royalty shall be paid on the [\*\*\*], and a [\*\*\*] royalty shall be paid on the [\*\*\*].

(b) **Net Sales of Products in ROW Territory.** In further consideration of the licenses granted by Syndax to Incyte, Incyte shall pay to Syndax a royalty of [\*\*\*] of Net Sales of Products in the ROW Territory.

(c) **Royalty Term.** The royalties under Section 8.3 shall be paid by Incyte to Syndax on a Product-by-Product and country-by-country basis during the Royalty Term. "**Royalty Term**" means the period commencing on the First Commercial Sale of a Product in a given country in the Territory and ending on the latest of: (i) the expiration of the last Valid Claim in the Syndax Background Patents and Syndax

Foreground Patents Covering such Product in such country, (ii) [\*\*\*] after the First Commercial Sale of such Product in such country and (iii) expiration of the Regulatory Exclusivity for such Product in such country.

**(d) Royalty Reductions.**

- (i)** The royalties payable with respect to Net Sales of Products shall be reduced by [\*\*\*] of the otherwise applicable rates with respect to Net Sales of a Product in a country during any portion of the Royalty Term to the extent there is neither (i) any Valid Claim Covering such Product in such country nor (ii) any Regulatory Exclusivity with respect to such Product in such country.
- (ii)** If, in order to Commercialize the Product in any country in the Incyte Territory, Incyte determines that it is reasonably necessary to obtain a license from a Third Party to any Third Party IP and Incyte obtains such a license, Incyte shall have the right to deduct from the royalty payments otherwise due to Syndax hereunder an amount equal to up to [\*\*\*] of any royalty payments paid under such Third Party license on a Product-by-Product and country-by-country basis.
- (iii)** In no event will the royalties for any Product and country in any calendar quarter be reduced as a result of the operation of Section 8.3(d)(i) and Section 8.3(d)(ii) below [\*\*\*] of the amounts otherwise due without such reductions; **provided, however,** that [\*\*\*].

**(e) Reporting of Net Sales.** Within [\*\*\*] after the end of each calendar quarter for which royalties are due, Incyte shall deliver to Syndax a written report setting forth the following information for such calendar quarter, on a Product-by-Product and country-by-country basis in the Territory (i) Net Sales of each Product, (i) gross sales of each Product (where readily available), and (i) the royalties due hereunder for the sale of each such Product. No reports under this Section 8.3(e) shall be due for any such Product before the First Commercial Sale of such Product or after the Royalty Term for such Product has expired in all countries in the Territory. All royalty payments shall be made by Incyte within [\*\*\*] after the end of the applicable calendar quarter to the bank account indicated by Syndax; **provided that** Syndax has issued the relevant invoice for royalty payment within [\*\*\*] after Syndax's receipt of the royalty report from Incyte. In the event Syndax fails to issue an invoice within such [\*\*\*] period as described above, Incyte's obligation to pay such amounts within [\*\*\*] after the end of the applicable calendar quarter shall be extended by the number of days that lapse between the date Syndax should have invoiced Incyte and the date Syndax actually invoices Incyte.

**(f) Record Keeping.** In accordance with GAAP, Incyte shall keep and shall ensure that its Affiliates and Sublicensees keep books and accounts of record in connection with the sales and other dispositions of Products (including use in Trials, or provision on a compassionate use basis or as marketing samples) in sufficient detail to permit accurate determination of all figures necessary for verification of royalties or other payments to be paid hereunder. Incyte and its Affiliates and Sublicensees shall maintain such records for a period of at least [\*\*\*] after the end of the calendar quarter in which they were generated and make such records available

to Syndax. Syndax shall be entitled to audit the relevant books and records of Incyte and its Affiliates and Sublicensees as may be reasonably necessary to verify the amounts reported by Incyte in accordance with Section 8.3(e) and the payment of royalties hereunder and the audit provisions set forth in Section 8.4 shall apply to any such audit.

**8.4 Audits.** Where a Party (the “**Auditing Party**”) is entitled to audit the other Party (the “**Audited Party**”) or the Audited Party’s Affiliates or Sublicensees hereunder, this Section 8.4 shall apply to such audit. Upon [\*\*\*] prior notice from the Auditing Party, the Audited Party shall permit an independent certified public accounting firm selected by the Auditing Party to examine the relevant books and records of the Audited Party and its Affiliates and Sublicensees as may be reasonably necessary to verify the amounts reported, costs shared, or payments made hereunder. An examination by the Auditing Party under this Section 8.4 shall occur not more than [\*\*\*] in any calendar year and shall be limited to the pertinent books and records for any calendar year ending not more than [\*\*\*] before the date of the request. The accounting firm shall be provided access to such books and records at the Audited Party’s or its Affiliates’ or Sublicensees’ facility(ies) where such books and records are normally kept and such examination shall be conducted during the Audited Party’s or its Affiliates’ or Sublicensees’ facility(ies), normal business hours. The Audited Party may require the accounting firm to sign a reasonably acceptable non-disclosure agreement before providing the accounting firm with access to the Audited Party’s or its Affiliates’ or Sublicensees’ facilities or records. Upon completion of the audit, the accounting firm shall provide both the Auditing Party and the Audited Party a written report disclosing any discrepancies in the reports submitted, costs shared, or payments made by the Audited Party and, in each case, the specific details concerning any discrepancies. If Syndax is the Auditing Party, Syndax shall be entitled to report the results of any such audit to UCB Biopharma. If such accounting firm concludes that additional payments were due by the Audited Party to the Auditing Party, then the Audited Party will pay to the Auditing Party the additional payments within [\*\*\*] of the date the Auditing Party receives such accountant’s written report plus interest on the amount of the additional payment, to the extent permitted by applicable Law, at a rate equal to the prime rate quoted by *The Wall Street Journal* on the date that the Auditing Party receives such accountant’s written report plus [\*\*\*] or the maximum applicable legal rate, if less, calculated on the total number of days from the original due date of such payment. Further, if the amount of such underpayments exceeds more than [\*\*\*] of the amount that was properly payable to the Auditing Party, then the Audited Party shall reimburse the Auditing Party for the Auditing Party’s costs in connection with the audit (otherwise such audit shall be at the Auditing Party’s cost). If such accounting firm concludes that Audited Party overpaid the Auditing Party, then the Auditing Party will refund such overpayments to the Audited Party within [\*\*\*] after the date the Auditing Party receives such accountant’s report plus interest on the amount of the overpayment, to the extent permitted by applicable Law, at a rate equal to the prime rate quoted by *The Wall Street Journal* on the date that the Auditing Party receives such accountant’s written report plus [\*\*\*] or the maximum applicable legal rate, if less, calculated on the total number of days from the original due date of such payment.

**8.5 Payments under the UCB Biopharma Agreement.** During the Term, Syndax shall be responsible for making the UCB Biopharma Payments to UCB Biopharma, provided, however, that UCB Biopharma US Royalties shall be shared in accordance with the Pre-Tax Profit (Loss) Share.

**8.6 General Payment Terms.** Unless otherwise specified, each Party shall make all payments to the other Party under this Agreement in US dollars. Unless otherwise specified, all payments due under this Agreement shall be made to the respective Party within [\*\*\*] following the receipt of an invoice therefor. Each payment under this Agreement shall be made by electronic transfer in immediately available funds via bank wire transfer to such bank account as the respective Party shall designate in writing to the other Party at least [\*\*\*] before the payment is due.

**8.7 Currency Exchange.** In the case of sales outside the United States with respect to royalty payments by Incyte to Syndax, or in the case of other costs to be shared under this Agreement that are incurred in a currency other than US dollars, such payments or costs, as applicable, shall be converted to US dollars in accordance with the following: the rate of currency conversion shall be calculated using the average of the last (bid) U.S. dollar/foreign currency rates for the last Business Day of [\*\*\*] in the calendar quarter for which the applicable payment is being reported or cost was incurred, as reported by *The Wall Street Journal* for the conversion of foreign currency sales into US Dollars. This method of conversion is and shall be consistent with the applicable Party's then current methods. Each Party shall give the other Party prompt written notice of any changes to such Party's customary and usual procedures for currency conversion, which shall only apply after such notice has been delivered and ***provided that*** such changes continue to maintain a set methodology for currency conversion. All payments will be made without deduction of exchange, collection or other charges.

**8.8 Late Payment.** Except as otherwise expressly set forth herein, any payment under this Agreement that is not paid on or before the date such payment is due will bear interest, to the extent permitted by applicable Law, at a rate equal to the prime rate quoted by *The Wall Street Journal* on the first Business Day after such payment is due plus [\*\*\*] or the maximum applicable legal rate, if less, calculated on the total number of days payment is delinquent.

**8.9 Withholding Tax.**

- (a) Incyte will make all payments to Syndax under this Agreement without deduction or withholding except to the extent that any such deduction or withholding is required by applicable Law to be made on account of Taxes (as that term is defined in Section 8.9(e) below).
- (b) Any Tax required to be withheld under applicable Law on amounts payable under this Agreement will promptly be paid by Incyte on behalf of Syndax to the appropriate Governmental Authority, and Incyte will furnish Syndax with proof of payment of such Tax. Any such Tax required to be withheld will be an expense of and borne by Syndax. Incyte will give notice of its intention to begin withholding any such Tax in advance and cooperate to use reasonable and legal efforts to reduce such Tax on payments made to Syndax hereunder.
- (c) Incyte and Syndax will cooperate with respect to all documentation required by any relevant Government Authority or reasonably requested by Incyte to secure a reduction in the rate of applicable withholding Taxes.
- (d) If Incyte had a duty to withhold Taxes in connection with any payment it made to Syndax under this Agreement but Incyte failed to withhold, and such Taxes were

assessed against and paid by Incyte, then Syndax will indemnify and hold harmless Incyte from and against such Taxes (including interest). If Incyte makes a claim under this Section 8.9(d), it will comply with the obligations imposed by Section 8.9(b) as if Incyte had withheld Taxes from a payment to Syndax.

(e) Solely for purposes of this Section 8.9, "Tax" or "Taxes" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including interest, penalties and additions thereto) that are imposed by a Government Authority.

(f) Notwithstanding this Section (a) – (e) of this Section 8.9, if, as a result of a Withholding Action (as defined below) by Incyte (including any assignee or successor), withholding is required by Applicable Law and the amount of such withholding exceeds the amount of withholding that would have been required if Incyte had not committed the Withholding Action, then Incyte shall pay an additional amount to Syndax such that, after withholding from the payment contemplated by this Agreement and such additional amount, Syndax receives the same amount as it would have received from Incyte absent such Withholding Action by Incyte. For the avoidance of doubt, if as a result of a Withholding Action by Syndax (including any assignee or successor) the amount of withholding under the law of the applicable jurisdiction exceeds the amount of such withholding that would have been required in the absence of such Withholding Action by Syndax, Incyte shall be required to pay any additional amount only to the extent that Incyte would be required to pay any additional amount to Syndax pursuant to the preceding sentence if Syndax had not committed such Withholding Action. In the event such additional withholding is actually credited and results in a corresponding reduction in cash taxes payable against the income tax liability of Syndax or its Affiliates, the tax gross-up contemplated above shall not apply to the extent of such creditable amount. For purposes of this Section 8.9(f), "Withholding Action" by a Party means (i) a permitted assignment of this Agreement (in whole or in part) by such Party to an Affiliate or a Third Party outside of the United States; and (ii) a redomiciliation of such Party, an assignee or a successor to a jurisdiction outside the United States.

**8.10 Blocked Payments.** In the event that, by reason of Laws in any country, it becomes impossible or illegal for a Party or its Affiliates to transfer, or have transferred on its behalf, payments to the other Party, such blocked Party shall promptly notify the other Party of the conditions preventing such transfer and such distribution fees or other payments shall be deposited in local currency in the relevant country to the credit of the receiving Party in a recognized banking institution within a period of [\*\*\*] designated by the receiving Party.

## **9. GOVERNANCE**

### **9.1 Joint Steering Committee.**

(a) **Formation.** The Parties shall establish a joint steering committee ("**JSC**") within [\*\*\*] after the Effective Date that will have the responsibility for the overall coordination and oversight of the Parties' activities under this Agreement. Each Party shall initially appoint [\*\*\*] representatives to the JSC. In addition to its JSC representatives, a Party may have other employees or consultants attend JSC meetings for informational purposes as nonvoting observers, subject to prior consent of the other Party or the other Party's JSC representatives (such agreement not to be

unreasonably withheld, conditioned or delayed) and provided such observers are bound by confidentiality and non-use obligations consistent with the terms of this Agreement (but of shorter duration if customary). Each Party may replace its JSC representatives at any time upon written notice to the other Party. A representative of Incyte shall be the chair of the JSC. The chairperson shall be responsible for administering JSC meetings, but shall have no additional powers or rights beyond those held by the other representatives on the JSC.

**(b) Specific Responsibilities of the JSC.** In addition to its general responsibilities, the JSC shall in particular:

[\*\*\*]

**(c) JSC Meetings.** The JSC shall meet at least [\*\*\*], unless otherwise agreed between the JSC members. Either Party may also call a special meeting of the JSC (including by videoconference or teleconference) with at least [\*\*\*] prior written notice to the other Party in the event such Party reasonably believes that a significant strategic matter must be addressed prior to the next scheduled meeting, and such requesting Party shall provide the JSC, no later than [\*\*\*] prior to the special meeting with materials reasonably adequate to enable an informed decision on the relevant matter; ***provided that*** for time sensitive matters, the requesting Party may call a special meeting of the JSC and provide relevant materials on shorter notice if the Parties agree that an issue warrants an expedited meeting. The JSC may meet in person, by videoconference or by teleconference. In-person JSC meetings, if any, shall be held at locations alternately selected by Syndax and by Incyte. Meetings of the JSC shall be effective only if at least [\*\*\*] of the representatives of each Party is present or participating in such meeting. Each Party shall report to the JSC on all strategically important issues relating to the Development, Manufacture or Commercialization of the Licensed Antibody or Product promptly after such issues arise. Each Party shall bear the expense of its respective JSC representatives' participation in JSC meetings. The JSC chairperson shall be responsible for preparing reasonably detailed written minutes of JSC meetings that reflect all decisions made at such meetings. The JSC chairperson shall send draft meeting minutes to each member of the JSC for review and approval within [\*\*\*] after each JSC meeting. Minutes shall be deemed approved unless [\*\*\*] or more members of the JSC object to the accuracy of such minutes within [\*\*\*] of receipt.

**(d) JSC Decision-Making.** The JSC shall make decisions by consensus. The representatives of Party shall collectively have [\*\*\*] on behalf of that Party. If the JSC cannot reach consensus within [\*\*\*] on any issue that comes before the JSC for which the JSC is responsible under this Agreement, then the Parties shall immediately refer the matter to the chief executive officers of the Parties ("**Executive Officers**") for attempted resolution by good faith negotiations within [\*\*\*] after such notice is received. If the Executive Officers are unable to resolve such dispute within [\*\*\*] after such dispute is first referred to them, then:

**(i)** Syndax shall have the final decision making authority [\*\*\*].

**(ii)** Incyte shall have the final decision making authority with respect to all other matters.

(iii) The respective Party shall not have the final decision making authority under (i) or (ii) and the other Party shall have a veto right (and if such veto right is exercised, no action shall be taken with respect to the applicable decision), if the other Party reasonably believes and shows that the outcome of such Party's decision or its execution:

- (1) would cause such other Party to violate Laws or breach agreements with Third Parties existing on the Execution Date and copies of which have been made available to the Party exercising final decision making authority prior to the Execution Date; or
- (2) would increase the overall financial burden of such other Party by more than [\*\*\*] in sharing Collaboration Costs pursuant to Section 7.1 or the decision relates to the proposed dose for a planned Trial and is inconsistent with the then-current dosing paradigm.

**9.2 Subcommittees; Working Groups.** The JSC may establish and disband such subcommittees as deemed necessary by the JSC including based on the then-current stage of Development and Commercialization. Each such subcommittee shall consist of the same number of representatives designated by each Party, which number shall be mutually agreed by the Parties. Each Party shall be free to change its representatives on notice to the other or to send a substitute representative to any subcommittee meeting; ***provided that*** each Party shall ensure that, at all times during the existence of any subcommittee, its representatives on such subcommittee are appropriate in terms of expertise and seniority for the then-current stage of Development and Commercialization of the Licensed Antibody and Products in the Field and have the authority to direct and approve the actions of such Party with respect to matters within the purview of the relevant subcommittee. Each Party's representatives and any substitute for a representative shall be bound by the obligations of confidentiality and non-use at least as restrictive as those set forth in Article 16. Each subcommittee shall report to the JSC, and any decisions that remain unresolved by such subcommittee shall be escalated to the JSC for resolution in accordance with Section 9.1(d). The initial subcommittees of the JSC will be the Joint Development Committee ("**JDC**") and the Joint Commercialization Committee ("**JCC**"). The JSC can modify the structure of any subcommittee to create project-specific or multi-project specific subcommittees as necessary. Additionally, the JSC may form working groups to facilitate specific activities in connection with this Agreement, which such working groups will have no decision-making authority. The initial working group will be the Finance Working Group (the "**Finance Working Group**").

**9.3 Joint Development Committee.**

(a) **Purpose of the JDC.** The JDC shall oversee the global Development Activities of the Licensed Antibody and Products in the Territory in the Field, as long as a Product is in Development in any country of the Territory in the Field.

(b) **Formation and Composition of JDC.** The Parties shall form a JDC promptly after the Execution Date to start planning Development Activities prior to the Effective Date, subject to jointly agreed guidance from the Parties' outside counsel in furtherance of the provisions of Section 18.16. Each Party shall initially appoint [\*\*\*]

representatives to the JDC, with each representative having knowledge, expertise or responsibility in the research, development and regulatory activities of products similar to the Products and the appropriate seniority. The JDC may change its size from time to time by mutual consent of its members; **provided, however**, that the JDC shall consist at all times of an equal number of representatives of each of Syndax and Incyte. In addition to its JDC representatives, a Party may have other employees or consultants attend JDC meetings for informational purposes as nonvoting observers, subject to prior consent of the other Party or the other Party's JDC representatives (such agreement not to be unreasonably withheld, conditioned or delayed) and provided such observers are bound by confidentiality and non-use obligations consistent with the terms of this Agreement (but of shorter duration if customary). Each Party may replace its JDC representatives at any time upon written notice to the other Party. A representative of Incyte shall be the chair of the JDC. The chairperson shall be responsible for administering JDC meetings, but shall have no additional powers or rights beyond those held by the other representatives on the JDC. The JDC may constitute working groups for addressing specific matters under its responsibility.

(c) **Specific Responsibilities of the JDC.** In addition to its general responsibilities, the JDC shall in particular:

[\*\*\*].

(d) **JDC Meetings.** The JDC shall meet at least [\*\*\*] per calendar quarter unless otherwise agreed between the JDC members. Either Party may also call a special meeting of the JDC (including by videoconference or teleconference) with at least [\*\*\*] prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, and such requesting Party shall provide the JDC, no later than [\*\*\*] prior to the special meeting with materials reasonably adequate to enable an informed decision on the relevant matter; **provided that** for time sensitive matters, the requesting Party may call a special meeting of the JDC and provide relevant materials on shorter notice if the Parties agree that an issue warrants an expedited meeting. The JDC may meet in person, by videoconference or by teleconference. Unless otherwise mutually agreed, there shall be at least [\*\*\*] in person per year. In-person JDC meetings shall be held at locations alternately selected by Syndax and by Incyte. Meetings of the JDC shall be effective only if at least [\*\*\*] of the representatives of each Party is present or participating in such meeting. Each Party shall report to the JDC on all material issues relating to the Development of any Licensed Antibody or Product promptly after such issues arise. Each Party shall bear the expense of its respective JDC representatives' participation in JDC meetings. The JDC chairperson shall be responsible for preparing reasonably detailed written minutes of JDC meetings that reflect all decisions made at such meetings. The JDC chairperson shall send draft meeting minutes to each member of the JDC for review and approval within [\*\*\*] after each JDC meeting. Minutes shall be deemed approved unless [\*\*\*] or more members of the JDC object to the accuracy of such minutes within [\*\*\*] of receipt.

(e) **JDC Decision-Making.** The JDC shall make decisions by consensus. The representatives of a Party shall collectively have [\*\*\*] on behalf of that Party. If the JDC cannot reach consensus within [\*\*\*] on any issue that comes before the JDC for



which the JDC is responsible, then the Parties shall immediately refer such matter to the JSC, which will decide the matter pursuant to Section 9.1(d).

#### 9.4 Joint Commercialization Committee.

**(a) Purpose of the JCC.** Subject to Section 5.1, The JCC shall govern and oversee the global Commercialization of Product in the Territory in the Field, as long as a Product is Commercialized in any country of the Territory in the Field.

**(b) Formation and Composition of JCC.** The Parties shall form a JCC at least [\*\*\*] prior to the anticipated first Regulatory Approval of a Product. Each Party shall initially appoint [\*\*\*] to the JCC, with each representative having knowledge, expertise or responsibility in the commercialization of products similar to the Products and the appropriate seniority. The JCC may change its size from time to time by mutual consent of its members; ***provided, however,*** that the JCC shall consist at all times of an equal number of representatives of each of Syndax and Incyte. In addition to its JCC representatives, a Party may have other employees or consultants attend JCC meetings for informational purposes as nonvoting observers, subject to prior consent of the other Party or the other Party's JCC representatives (such agreement not to be unreasonably withheld, conditioned or delayed) and provided such observers are bound by confidentiality and non-use obligations consistent with the terms of this Agreement (but of shorter duration if customary). Each Party may replace its JCC representatives at any time upon written notice to the other Party. A representative of Incyte shall be the chair of the JCC. The chairperson shall be responsible for administering JCC meetings, but shall have no additional powers or rights beyond those held by the other representatives on the JCC. The JCC may constitute working groups for addressing specific matters under its responsibility.

**(c) Specific Responsibilities of the JCC.** In combination with all the responsibilities of the JCC set forth in Article 5, the JCC shall in particular with respect to the Product in the Field discuss and agree on the [\*\*\*] and any updates and amendments thereto and shall have such other responsibilities as may be allocated to the JCC under this Agreement or by mutual written agreement of the Parties.

**(d) JCC Meetings.** The JCC shall meet at least [\*\*\*] per calendar quarter, unless otherwise agreed between the JCC members. Either Party may also call a special meeting of the JCC (including by videoconference or teleconference) by at least [\*\*\*] prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, and such requesting Party shall provide the JCC, no later than [\*\*\*] prior to the special meeting with materials reasonably adequate to enable an informed decision on the relevant matter; ***provided that*** for time sensitive matters, the requesting Party may call a special meeting of the JCC and provide relevant materials on shorter notice if the Parties agree that an issue warrants an expedited meeting. The JCC may meet in person, by videoconference, or by teleconference. Unless otherwise mutually agreed, there shall be at least [\*\*\*] in person per year. In-person JCC meetings shall be held at locations alternately selected by Syndax and by Incyte. Meetings of the JCC shall be effective only if at least [\*\*\*] of each Party is present or participating in such meeting. Each Party shall report to the JCC on all material issues relating to the Commercialization of Products promptly after such issues arise. Each Party shall

bear the expense of its respective JCC members' participation in JCC meetings. The JCC chairperson shall be responsible for preparing reasonably detailed written minutes of JCC meetings that reflect all discussions held at such meetings. The JCC chairperson shall send meeting minutes to each member of the JCC for review and approval within [\*\*\*] after each JCC meeting. Minutes shall be deemed approved unless [\*\*\*] or more members of the JCC object to the accuracy of such minutes within [\*\*\*] of receipt.

**(e) JCC Decision-Making.** The JCC shall make decisions by consensus. Representative of a Party shall collectively have [\*\*\*] on behalf of that Party. If the JCC cannot reach consensus within [\*\*\*] on any issue that comes before the JCC for which the JCC is responsible, then the Parties shall refer such matter to the JSC which will decide the matter pursuant to Section 9.1(d).

## 9.5 Joint Manufacturing Committee.

**(a) Purpose of the JMC.** The primary purpose of the JMC shall be to oversee, coordinate and facilitate the Manufacture of the Licensed Compound Bulk Drug Substance and Licensed Compound Drug Product.

**(b) Formation and Composition of JMC.** The Parties shall form a JMC promptly after the Execution Date to start planning Development Activities prior to the Effective Date, subject to jointly agreed guidance from the Parties' outside counsel in furtherance of the provisions of Section 18.16. Each Party shall initially appoint [\*\*\*] to the JMC, with each representative having knowledge, expertise or responsibility in the manufacturing of products similar to the Products and the appropriate seniority. The JMC may change its size from time to time by mutual consent of its members; ***provided, however,*** that the JMC shall consist at all times of an equal number of representatives of each of Syndax and Incyte. In addition to its JMC representatives, a Party may have other employees or consultants attend JMC meetings for informational purposes, subject to prior consent of the other Party or the other Party's JMC representatives (such agreement not to be unreasonably withheld, conditioned or delayed) and provided such observers are bound by confidentiality and non-use obligations consistent with the terms of this Agreement (but of shorter duration if customary). Each Party may replace its JMC representatives at any time upon written notice to the other Party. A representative of Incyte shall be the chair of the JMC. The chairperson shall be responsible for administering JMC meetings, but shall have no additional powers or rights beyond those held by the other representatives on the JMC. The JMC may constitute working groups for addressing specific matters under its responsibility.

**(c) Specific Responsibilities of the JMC.** The JMC shall (i) discuss [\*\*\*].

**(d) JMC Meetings.** The JMC shall meet at least [\*\*\*] per calendar quarter, unless otherwise agreed between the JMC members. Either Party may also call a special meeting of the JMC (by videoconference or teleconference) by at least [\*\*\*] prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, and such requesting Party shall provide the JMC, no later than [\*\*\*] prior to the special meeting with materials reasonably adequate to enable an informed decision on the relevant matter; ***provided that*** for time sensitive matters, the requesting Party may call a

special meeting of the JMC and provide relevant materials on shorter notice if the Parties agree that an issue warrants an expedited meeting. The JMC may meet in person, by videoconference, or by teleconference. Unless otherwise mutually agreed, there shall be at least [\*\*\*] in person per year. In-person JMC meetings shall be held at locations alternately selected by Syndax and by Incyte. Meetings of the JMC shall be effective only if at least [\*\*\*] JMC representative of each Party is present or participating in such meeting. Each Party shall report to the JMC on all material issues relating to the Commercialization of Products promptly after such issues arise. Each Party shall bear the expense of its respective JMC members' participation in JMC meetings. The chairperson shall be responsible for preparing reasonably detailed written minutes of JMC meetings that reflect all discussions held at such meetings. The JMC chairperson shall send meeting minutes to each member of the JMC for review and approval within [\*\*\*] after each JMC meeting. Minutes shall be deemed approved unless [\*\*\*] or more members of the JMC object to the accuracy of such minutes within [\*\*\*] of receipt.

(e) **JMC Decision-Making.** The JMC shall make decisions by consensus. The representatives of a Party shall collectively have [\*\*\*] on behalf of that Party. If the JMC cannot reach consensus within [\*\*\*] on any issue that comes before the JMC for which the JMC is responsible, then the Parties shall refer such matter to the JSC which will decide the matter pursuant to Section 9.1(d).

**9.6 Discontinuation of a Committee.** Except as otherwise specifically stated in this Agreement, each committee formed under this Agreement shall continue to exist until the earlier of the expiration or termination of this Agreement in its entirety or the JSC agrees by consensus to disband such committee. Once the committee is disbanded as provided above, such committee shall have no further obligations under this Agreement and all decisions previously allocated to such committee shall thereafter be made by the JSC.

**9.7 Alliance Managers.** Promptly after the Execution Date, each Party shall appoint a senior representative to act as a coordinator and alliance manager (the "**Alliance Manager**"). Each Party may, at any time, replace its Alliance Manager with another suitably qualified individual, on written notice to the other Party. The Alliance Managers shall be primarily responsible for facilitating communications between the Parties and coordinating the Parties' activities under this Agreement. The Alliance Managers may attend meetings of each of the committees.

**9.8 Authority.** The JSC and any subcommittee shall have only the powers assigned expressly to it in this Article 9 and elsewhere in this Agreement, and shall not have any power to amend, modify or waive compliance with this Agreement, or to impose any obligations on a Party that are inconsistent with this Agreement, unless agreed otherwise by the Parties in writing. In furtherance thereof, each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion shall be delegated or vested in the JSC or any subcommittee unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing.

## **10. INVENTIONS**

**10.1 Inventorship.** Inventorship of Inventions discovered, made or conceived during the course of the performance of activities pursuant to this Agreement shall be determined in accordance with the patent Laws of the United States.

## 10.2 Ownership of Incyte Inventions, Syndax Inventions and Joint Inventions.

- (a) Subject to the rights and licenses expressly granted under this Agreement, each Party shall retain all right, title and interest in, to and under any and all intellectual property rights that are Controlled by such Party prior to the Execution Date or independent of this Agreement, including Syndax Background Patents in the case of Syndax.
- (b) **Syndax Inventions and Incyte Inventions.** As between the Parties, Syndax shall solely own Patents for any Syndax Inventions and Incyte shall solely own, and it alone shall have the right to apply for Patents for, any Incyte Inventions.
- (c) **Joint Inventions.** Joint Inventions and Joint Foreground Patents shall be jointly owned by the Parties. Syndax and Incyte shall each own an undivided one-half interest in any Joint Inventions and any Joint Foreground Patents, in each case without obligation to seek consent from the other, or to account to the other, for the exploitation thereof and subject to the licenses and restrictions set forth in this Agreement.

**10.3 Disclosures; Disputes Regarding Inventions.** Each Party shall reasonably promptly disclose to the other Party all Inventions made by it (meaning by its, its Affiliates' or its Sublicensee's employees, consultants, or independent contractors) under this Agreement, including Joint Inventions. If the Parties disagree as to whether an Invention is a Joint Invention, a Syndax Invention or a Incyte Invention, and are unable to reach agreement within [\*\*\*] after commencing discussions, then the Parties shall resolve such dispute through the JSC pursuant to Section 9.1(d).

## 11. PROSECUTION AND ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

### 11.1 Prosecution and Maintenance of UCB Biopharma Background Patents.

- (a) Under the UCB Biopharma Agreement, [\*\*\*] has the first right, in its sole discretion, to perform the filing, prosecution and maintenance of the UCB Biopharma Background Patents on a worldwide basis. In the event that [\*\*\*] decides not to pursue or to abandon or otherwise cease to maintain any of the UCB Biopharma Background Patents pursuant to the terms of the UCB Biopharma Agreement (a [\*\*\*]), then Syndax shall promptly (but in any event within [\*\*\*]) notify Incyte and identify the relevant UCB Biopharma Background Patents and the provisions of Section 11.1(b) shall apply to any continued prosecution and maintenance of such UCB Biopharma Background Patents.
- (b) Unless agreed otherwise between the Parties, upon a [\*\*\*], Incyte shall prosecute, maintain and enforce the applicable UCB Biopharma Background Patent(s), to the extent permissible for Syndax to grant Incyte such right under the UCB Biopharma Agreement, ***provided that*** in the event that, at any time, Incyte intends or decides not to prepare, file, prosecute, or maintain a UCB Biopharma Background Patent in any country or jurisdiction, the procedure set forth under Section 11.4 shall apply accordingly. Notwithstanding the foregoing, if Syndax does not have the right to grant Incyte the right to prosecute, maintain and enforce the applicable UCB Biopharma Background Patent(s), then, at Incyte's request, direction, and expense, Syndax shall continue to prepare, file, prosecute and maintain such UCB Biopharma Background Patents.

**11.2 Prosecution and Maintenance of Syndax Background Patents and Foreground Patents.** [\*\*\*] shall have the first right to prepare, file, prosecute (including any reissues, re-examinations, post-grant proceedings, requests for patent term extensions, supplementary protection certificates, interferences, derivation proceedings, and supplemental examinations) and maintain the Syndax Background Patents (with respect to the UCB Biopharma Background Patents, subject to Section 11.1), Syndax Foreground Patents, and Incyte Foreground Patents in the Territory. [\*\*\*] shall keep [\*\*\*] reasonably informed as to material developments with respect to [\*\*\*] preparation, filing, prosecution and maintenance of Syndax Patents hereunder, including by providing [\*\*\*] with copies of all office actions or any other material communications or documents that [\*\*\*] sends to or receives from any patent office in the Territory with respect to such Syndax Patents, including notice of all reissues, re-examinations, post-grant proceedings, requests for patent term extensions, supplementary protection certificates, interferences, derivation proceedings, and supplemental examinations. [\*\*\*] shall also provide [\*\*\*] with a reasonable opportunity to review and comment substantively on the preparation, filing, prosecution and maintenance of such Syndax Patents sufficiently prior to taking material actions (including the filing of initial applications or submitting material correspondence) so as to allow [\*\*\*] reasonable time for review and comment, and will reasonably consider actions recommended by [\*\*\*] with respect to the Syndax Patents.

**11.3 Prosecution and Maintenance of Joint Foreground Patents.** Each Party shall promptly disclose to the other in writing, and shall ensure that its Affiliates, or licensees and Sublicensees, and its and their employees, agents and contractors so disclose, the development, making, conception or reduction to practice of any Joint Inventions. The Parties shall jointly decide on the optimal strategy for drafting, filing, prosecution and maintenance of Joint Foreground Patents. Such decision shall include the content and the timing of a respective patent application for the respective Joint Invention. Unless otherwise agreed, [\*\*\*] shall have the first right, to prepare, file, prosecute (including any reissues, re-examinations, post-grant proceedings, requests for patent term extensions, supplementary protection certificates, interferences, derivation proceedings, supplemental examinations) and maintain Joint Foreground Patents in the Territory, in all cases in accordance with the jointly decided strategy therefor. The Parties shall closely cooperate on all prosecutorial matters with respect to the Joint Foreground Patents.

**11.4 Right to Take Over.** In the event that, at any time, [\*\*\*] intends or decides not to prepare, file, prosecute, or maintain a Syndax Background Patent (in the case of a UCB Biopharma Background Patent, subject to Section 11.1), Syndax Foreground Patent or a Joint Foreground Patent, [\*\*\*] shall provide reasonable prior written notice to [\*\*\*] of such intention, which notice shall, in any event, be given, if practicable, no later than [\*\*\*] prior to the next deadline for any action that may be taken with respect to such Patent, and [\*\*\*] shall have the option, in its sole discretion, to assume the control and direction of the preparation, filing, prosecution, and maintenance of such Patent. Upon [\*\*\*] notice to [\*\*\*], [\*\*\*] may assume responsibility and full control for the preparation, filing, prosecution, and maintenance of any such Patent, and [\*\*\*] shall bear the costs in connection therewith.

**11.5 Costs.** From and after the Effective Date:

(a) Other than with respect to Joint Foreground Patents and except as set forth in the final sentence of Section 11.1(b), the Party prosecuting and maintaining a Patent under this Agreement will bear the costs and expenses associated with the prosecution and maintenance of such Patent.

(b) The Parties will share the costs and expenses of the prosecution and maintenance of Joint Foreground Patents, which costs and expenses shall be (i) allocated among the Parties in accordance with the Pro Rata Percentage with respect to Joint Foreground Patents in the Incyte Territory and (ii) shared by the Parties as Co-Commercialization Costs in accordance with the Pre-Tax Profit (Loss) Share pursuant to Section 7.6 with respect to Joint Foreground Patents in the Co-Commercialization Territory.

**11.6 Patent Term Extensions.** The Parties shall mutually discuss in good faith matters related to patent term extensions. Notwithstanding the foregoing, [\*\*\*] shall have the sole right in its sole discretion to apply to extend the patent term of a Syndax Background Patent, Syndax Foreground Patent, Incyte Foreground Patent, or Joint Foreground Patent, subject to applicable Laws, in each case in connection with Marketing Authorizations of Products. If any such Patent is in the Incyte Territory, Incyte shall solely bear the costs and expenses of such patent term extension. If such Patent is in the Co-Commercialization Territory, the costs and expenses of such patent term extension shall be shared as Co-Commercialization Costs in accordance with the Pre-Tax Profit (Loss) Share pursuant to Section 7.6. Upon the [\*\*\*] request [\*\*\*] shall provide to Incyte and execute all documents and instruments that may be reasonably required for [\*\*\*] to record or perfect an application for patent term extension.

**11.7 Patent Enforcement.**

(a) **Notification.** Each Party shall promptly notify the other Party in writing if the notifying Party reasonably believes that any Syndax Background Patent, Syndax Foreground Patent, Incyte Foreground Patent or any Joint Foreground Patent is being or has been infringed or misappropriated in any territory by a Third Party.

(b) **Enforcement.** [\*\*\*] shall have the first right with respect to the enforcement of any Syndax Background Patent, Syndax Foreground Patent, Incyte Foreground Patent, or Joint Foreground Patent with respect to all past, present and future activities or conduct of a Third Party in the Territory that may constitute an infringement of the respective Patent arising from or relating to the making, using, offering for sale, sale or importation or obtaining or applying for Regulatory Approvals of a product that is competitive with a Product (with respect to such Patents, “**Competitive Infringement**”).

(c) **UCB Biopharma Comments.** Syndax and Incyte shall reasonably consider UCB Biopharma’s comments, if any, on any such enforcement activities relating to UCB Biopharma Background Patents.

(d) **UCB Biopharma Background Patents.** The Parties acknowledge that Syndax has the first right, but not the obligation, under the UCB Biopharma Agreement to enforce the UCB Biopharma Background Patents with respect to any Infringement of any UCB Biopharma Background Patent. If Incyte elects to enforce any UCB Biopharma Background Patent pursuant to Section 11.7(b), Syndax shall exercise its right to enforce the UCB Biopharma Background Patents pursuant to the UCB Biopharma Agreement and shall take all steps reasonably necessary to enable Incyte to pursue the enforcement of the UCB Biopharma Background Patents, at Incyte’s sole cost and expense other than with respect to enforcement in the Co-Commercialization Territory, which costs and expenses shall be shared in accordance with the Pre-Tax Profit (Loss) Share pursuant to Section 7.6.

(e) **Right to Take Over.** If Incyte fails to institute an infringement suit or take other appropriate action to remedy the Competitive Infringement of a Syndax Background Patent, Syndax Foreground Patent, Incyte Foreground Patent or Joint Foreground Patent, within [\*\*\*] (or any shorter period required by applicable Laws or, in the case of the UCB Biopharma Background Patents, the UCB Biopharma Agreement) after first becoming aware of such Competitive Infringement pursuant to Section 11.7(b), then the Syndax will have the right (but not the obligation), at its own expense, to institute such suit or take other appropriate action by counsel of its own choice.

(f) **Enforcement of UCB Biopharma Step in Rights.** Notwithstanding anything to the contrary in the foregoing, to the extent that Syndax has step in rights to enforce any UCB Biopharma Background Patent, Syndax shall not exercise such right with respect to any UCB Biopharma Background Patent without Incyte's prior written consent, which consent shall not be unreasonably withheld.

**11.8 Conduct; Settlement.** The enforcing Party under Section 11.7 shall keep the other Party regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the other Party's comments on any such efforts, including with respect to the determination of litigation strategy and filing of material papers to the competent court. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party. Neither Party shall settle any claim brought under Section 11.7 without prior written consent of the other Party (not to be unreasonably withheld, conditioned or delayed) that would: (i) adversely affect the validity, enforceability or scope of, or admit non-infringement of, any of the applicable Patents of the other Party or UCB Biopharma, or the Joint Patents, (ii) give rise to liability of the other Party, its Affiliates, or its or their licensees, sublicensees and subcontractors, or UCB Biopharma (in each case, to the extent applicable); or (iii) impose any injunction or other similar restrictions upon the other Party or its Affiliates, or upon UCB Biopharma.

**11.9 Allocation of Proceeds.** Any settlements, damages or other monetary awards (a "**Recovery**") recovered pursuant to a suit, action or proceeding brought pursuant to Article 11 will be allocated, subject to [\*\*\*], first to the costs and expenses of the Party taking such action, and second, to the costs and expenses (if any) of the other Party, with any remaining amounts (if any) ("**Remaining Recovery**") to be allocated as follows:

(a) the portion of any such Remaining Recovery on an action brought under a Syndax Background Patent, Syndax Foreground Patent or Joint Foreground Patent in the Field in the Incyte Territory shall be allocated to Syndax in an amount equal to [\*\*\*]; and

(b) the portion of any Remaining Recovery on an action brought under a Syndax Background Patent, Syndax Foreground Patent or Joint Foreground Patent in the Field in the Co-Commercialization Territory shall be allocated [\*\*\*].

**11.10 Infringement of Third-Party Rights.** If the Development, Manufacture or Commercialization of the Product by either Party, its Affiliates, Sublicensees, as applicable, or other licensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent relating to the Manufacture, use, sale, offer for sale or importation of a Product, the Party first having notice of the claim or assertion shall promptly notify the other Party,

and the Parties shall promptly confer to consider the claim or assertion and the appropriate course of action. Unless the Parties otherwise agree in writing, each Party shall have the right to defend itself against a suit that names it as a defendant, subject to the indemnification provisions of Article 14. Neither Party shall enter into any settlement of any claim described in this Section 11.10 that affects the other Party's rights or interests without such other Party's written consent, which consent shall not be unreasonably withheld, conditioned or delayed. In any event, the Parties shall reasonably assist one another and cooperate in any such litigation at the other Party's request and expense.

**11.11 Patent Oppositions and Other Proceedings.** If either Party desires to bring an opposition, action for declaratory judgment, nullity action, interference, re-examination or other attack upon the validity, title or enforceability of a Patent owned or controlled by a Third Party that covers or may cover the Manufacture, use for the Field or sale of any Product, such Party shall notify the other Party (an "**Opposition**"). The Party with the right to control the prosecution and maintenance of such Patent (in the event of an Opposition not arising in the context of patent enforcement) or the Party with the right to control the enforcement of such Patent (in the event of an Opposition arising in the context of patent enforcement) shall have the right to control such Opposition, including whether or not to instigate the Opposition.

**11.12 Patent Assistance.** Each Party shall do or procure to be done all such acts and things, and execute or procure the execution of all such documents, as the other Party may from time to time reasonably request to assist the other Party in the preparation, filing, prosecution, maintenance and enforcement activities described in this Article 11. In the event that either Party takes action pursuant to Section 11.7(b) or 11.7(e), the other Party shall cooperate with the Party so acting to the extent reasonably possible, including joining the suit if necessary or desirable in order to enable the other Party to bring or maintain such action or to prove damages.

## **12. Exclusivity**

**12.1** During the Term, subject to the remainder of this Article 12, neither Party shall, and shall cause its Affiliates not to, [\*\*\*].

**12.2** If, during the Term, (x) there is a Change of Control of a Party (such Party, the "**Acquired Party**") and as of the effective date of such Change of Control, a Third Party described in the definition of "Change of Control" or any of its Affiliates (other than the Acquired Party and its Affiliates that exist immediately prior to the closing of such Change of Control and any successor thereto (such Affiliates of the Acquired Party, the "**Pre-Existing Affiliates**")) (the "**Acquirer**") is engaged, [\*\*\*] in any activities that, if carried out by the Acquired Party, would be a breach of the exclusivity obligations set forth in Section 12.1 (such activities, a "**Acquirer Program**"), or (y) as the result of an acquisition of a Third Party or the assets of a Third Party by a Party or one or more of its Affiliates (the "**Acquiring Party**"), the Acquiring Party [\*\*\*] acquires rights to a Competing Product in the Field that would be a breach of the exclusivity obligations set forth in Section 12.1 (an "**Acquired Product**"), the Acquired Party or the Acquiring Party (as the case may be) will not be deemed to be in breach of the restrictions set forth in Section 12.1, so long as Acquired Party or the Acquiring Party, as applicable, or its Affiliate, notifies the other Party in writing following the closing date of the transaction described in subsection (x) or (y), as applicable (a "**Third Party Acquisition**"), unless such Third Party Acquisition is publicly announced prior to such time (in which case no such notification shall be required) and:



(a) within [\*\*\*] of the Third Party Acquisition, the Acquired Party or Acquiring Party, as applicable, or its Affiliate, in good faith notifies the other Party of its decision to Divest the Acquirer Program or Acquired Product, and enters into a definitive agreement with a Third Party to Divest such Acquirer Program or Acquired Product in the applicable country(ies) in the Territory within [\*\*\*] (or such longer period that is required under Applicable Law) after the closing of such Third Party Acquisition, ***provided, however,*** that if at the end of such [\*\*\*] period the Acquired Party or Acquiring Party, as applicable (or its Affiliate) has not Divested such Acquirer Program or Acquired Product, the Acquired Party or Acquiring Party, as applicable (or its Affiliate) shall immediately discontinue the development and commercialization of the Acquirer Program or Acquired Product in the Territory and deliver written confirmation to the other Party that it and its Affiliates covenant not to restart such development or commercialization;

(b) discontinues the development and commercialization of the Acquirer Program or Acquired Product in the Territory no later than [\*\*\*] (or such longer period that is required under Applicable Law) after the closing of such Third Party Acquisition and delivers written confirmation to the other Party that it and its Affiliates covenant not to restart such development or commercialization; or

(c) [\*\*\*].

**12.3** If the Acquired Party or Acquiring Party, as applicable, elects to [\*\*\*] the Acquirer Program or Acquired Product, the Acquired Party or Acquiring Party, as applicable, shall not be precluded under Section 12.1 from conducting any activities (either directly, or with or through any Third Party) with respect to such Acquirer Program or Acquired Product during the period prior to completely such Divestment; ***provided, that*** any such activities are subject to [\*\*\*].

**12.4** [\*\*\*]

### **13. REPRESENTATION AND WARRANTIES, COVENANTS**

**13.1 Reciprocal Representations and Warranties.** Each Party represents and warrants to the other Party as of the Execution Date that:

(a) It is duly organized and validly existing under the Laws of its state or country of incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

(b) This Agreement is a legal and valid obligation binding upon its execution and enforceable against it in accordance with its terms and conditions;

(c) The execution, delivery and performance of this Agreement by such Party has been duly authorized by all necessary corporate action, and the person executing this Agreement on behalf of such Party has been duly authorized to do so by all requisite corporate actions;

(d) The execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material Law or regulation of any

court, governmental body or administrative or other agency having jurisdiction over it; and

(e) It has not granted, and shall not grant during the Term of the Agreement, any right to any Third Party which would conflict with the rights granted to the other Party hereunder.

**13.2 Syndax Representations and Warranties.** Syndax hereby warrants and represents to Incyte as of the Execution Date that:

(a) Syndax has the right to grant the licenses under the Syndax Patents and Syndax Know-How owned by Syndax, and Syndax has the right to grant the licenses under the Syndax Patents and Syndax Know-How in-licensed by Syndax (including the UCB Biopharma Background Patents and the UCB Biopharma Know-How), in each case as set forth in this Agreement and for Incyte's use in any Indication in the Field; Syndax has provided to Incyte the written consent of UCB Biopharma to the sublicenses under the UCB Biopharma Background Patents and UCB Biopharma Know-How granted to Incyte hereunder and the right to further sublicense such rights through multiple tiers, such written consent attached hereto as **Exhibit 13.2(a)** (the "**UCB Biopharma Consent**"); the UCB Biopharma Consent has been duly executed by UCB Biopharma and remains in full force and effect; and Syndax has not granted to any Third Party rights that are inconsistent with Incyte's rights hereunder and there are no agreements or arrangements to which Syndax or any of its Affiliates is a party relating to Licensed Antibody or Syndax Patents, Syndax Know-How, UCB Biopharma Background Patents or UCB Biopharma Know-How that would limit the rights granted to Incyte under this Agreement;

(b) UCB Biopharma Background Patents listed on **Schedule 1.204** and Syndax Background Patents listed on **Schedule 1.179**, and UCB Biopharma Know-How and Syndax Know-How are Controlled by Syndax free and clear of any liens, charges, and encumbrances or licenses in the Field, to the extent needed in order to grant the licenses and sublicenses as set forth in this Agreement;

(c) Neither Syndax nor any of its Affiliates have received from any Third Party any written notice stating any claim that any Patent right owned or controlled by such Third Party would be infringed by the Development, Manufacture, Commercialization of the Licensed Antibody or Product;

(d) Neither Syndax nor or any of its Affiliates have, to Syndax's Knowledge, in the past infringed or is currently infringing any Patents of a Third Party or misappropriated any Know-How of any Third Party through its or their activities related to the research, development, manufacture or, if applicable, commercialization of the Licensed Antibody;

(e) To Syndax's Knowledge, the UCB Biopharma Background Patents and the Syndax Patents are valid and enforceable and Syndax has complied with all applicable Laws in all material respects and duties of candor with respect to the filing, prosecution and maintenance of the UCB Biopharma Background Patents and the Syndax Patents. Syndax has paid (with respect to the Syndax Patents for which it is responsible for prosecution and maintenance) and, to Syndax's Knowledge, UCB Biopharma has paid (with respect to the UCB Biopharma Background Patents for

which UCB Biopharma is responsible for prosecution and maintenance), all maintenance and annuity fees with respect to the Syndax Patents, UCB Biopharma Background Patents due as of the Effective Date. To Syndax's Knowledge, no action or proceeding regarding inventorship of a Syndax Patent, or to Syndax's Knowledge, regarding inventorship of a UCB Biopharma Background Patent, has been brought or threatened in writing;

**(f)** Each person who has or has had any rights in or to any Syndax Patent or Syndax Know-How (other than Syndax Patents and Syndax Know-How licensed under a the UCB Biopharma Agreement), has assigned and has executed an agreement assigning its entire right, title, and interest in and to such Patents or Know-How to Syndax. To Syndax's Knowledge, no current officer, employee, agent, or consultant of Syndax or any of its Affiliates is in violation of any term of any assignment or other agreement regarding the protection of Patents or other intellectual property or proprietary information of Syndax or such Affiliate or of any employment contract or any other contractual obligation relating to the relationship of any such person with Syndax;

**(g)** To Syndax's Knowledge, each person who has or has had any rights in or to any UCB Biopharma Background Patent or UCB Biopharma Know-How has assigned and has executed an agreement assigning its entire right, title, and interest in and to such Patents or Know-How to UCB Biopharma;

**(h)** To Syndax's Knowledge (and except as set forth in Section 13.2(i)) the research, Development, Manufacture and Commercialization of the Licensed Antibodies as contemplated as of the Execution Date under this Agreement will not infringe any Patents of any Third Party or misappropriate any Know-How of a Third Party, in each case, in existence as of the Execution Date;

**(i)** The research, Development, Manufacture and Commercialization of the Licensed Antibodies as contemplated as of the Execution Date under this Agreement will not infringe any Patents or misappropriate any Know-How in the [\*\*\*] in existence as of the Execution Date;

**(j)** To Syndax's Knowledge, no Third Party is infringing or misappropriating any Syndax Patent, UCB Biopharma Background Patents, Syndax Know-How or UCB Biopharma Know-How in existence as of the Execution Date;

**(k)** Syndax has provided to Incyte a true and correct copy of the UCB Biopharma Agreement in its current form, which agreement is in full force and effect. Syndax has complied in all material respects with the terms of the UCB Biopharma Agreement, is not in breach of the UCB Biopharma Agreement and Syndax has not received any written notice of breach of the UCB Biopharma Agreement. To Syndax's Knowledge, UCB Biopharma has complied in all material respects with the UCB Biopharma Agreement, UCB Biopharma is not in breach of the UCB Biopharma Agreement and Syndax has not delivered any written notice of breach of the UCB Biopharma Agreement to UCB Biopharma;

**(l)** Syndax has complied with all applicable Law in all material respects in conducting the Syndax Ongoing Trials;

(m) The Development of any Licensed Antibody and/or the Product(s) by Syndax, or to Syndax's Knowledge with respect to any subcontractors, as of the Execution Date has been carried out in all material respects in accordance with all applicable Laws and applicable GLP, GCP and/or GMP standards, and Syndax is not aware of any problems concerning the safety or efficacy of any Licensed Antibody and/or the Product(s) raised by any Regulatory Authority with respect thereto, beyond what has been publicly disclosed as of the Execution Date;

(n) Syndax and its Affiliates have complied with the Data Protection Laws in all material respects at all times in accessing, collecting, using or otherwise processing any Personal Data in connection with the Development of any Licensed Antibody and/or the Product(s), including by entering into appropriate contractual arrangements with any Third Parties, and to Syndax's Knowledge, no material claim, action, proceeding, suit, investigation or complaint: (i) is pending by or against Syndax or its Affiliates; or (ii) has been threatened by or against Syndax or its Affiliates, alleging a violation or potential violation of any person's rights in relation to their Personal Data under Data Protection Laws; and

(o) Syndax has provided to Incyte all material information about, and data in Syndax's possession or Control relating to, the Syndax Trials, Syndax's Development of the Licensed Antibody and Products and Syndax has provided to Incyte all material information about, and data in Syndax's possession, relating to the Syndax Know-How and Syndax Patents.

**13.3 Incyte Representations and Warranties.** Incyte hereby warrants, covenants and represents to Syndax as of the Execution Date that:

(a) Incyte and its Affiliates do not own or Control any Competing Product;

(b) Subject to the representations and indemnities expressly contained in this Agreement, Incyte accepts the Licensed Antibody program in the condition it is in on the Execution Date, based upon its own inspection, examination and determination with respect thereto (including the due diligence investigation conducted by it), without reliance upon any express or implied representations or warranties of any nature of Syndax or any employee, advisor or other representative of Syndax.

**13.4 Mutual Covenants.**

(a) Neither Party nor its Affiliates or sublicensees shall use in any capacity, in connection with its Development or Commercialization of the Product in the Territory hereunder, any person who has been debarred pursuant to Section 306 of the U.S. Federal Food, Drug and Cosmetic Act, or who is the subject of a conviction described in such section, and each Party shall, to the extent permitted by applicable Data Protection Laws, inform the other Party in writing immediately if it or any person who is performing services for each Party hereunder is debarred or is the subject of a conviction described in Section 306 (or similar Laws outside of the US), or if any action, suit, claim, investigation or legal administrative proceeding is pending or, to such Party's knowledge, is threatened, relating to the debarment of such Party or any person used in any capacity by such Party in connection with its Development or Commercialization of the Product(s) hereunder; **provided, however**, that the

foregoing shall apply with respect to persons in the European Region solely to the extent that a Party has actual knowledge of such debarment, conviction or proceeding. Each Party shall be responsible for reporting its own expenditures in compliance with the Physician Payments Sunshine Act, subject to further agreement between the Parties as to any information exchange necessary to properly calculate and report spending on research and development which understanding shall be documented in the Co-Commercialization Plan.

(b) Each Party will perform all activities under this Agreement in compliance with all applicable Laws.

**13.5 Additional Syndax Covenants.** Syndax agrees that, during the Term:

(a) it will not, and will cause its Affiliates not to (i) terminate, whether for convenience or otherwise, the UCB Biopharma Agreement or the UCB Biopharma Consent; (ii) amend or modify the UCB Biopharma Agreement in any manner that adversely affects the rights granted to Incyte under this Agreement; or (iii) amend or modify the UCB Biopharma Consent, in each case ((i) - (iii)) except with Incyte's prior written consent;

(b) it will, and will cause its Affiliates to, comply in all material respects with the terms of the UCB Biopharma Agreement; and

(c) it will, at Incyte's cost, upon Incyte's request and following Incyte's direction, enforce the terms of the UCB Biopharma Consent against UCB Biopharma for the benefit of Incyte.

**13.6 DISCLAIMER OF WARRANTY.** EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN SECTIONS 13.1 TO 13.3, THE PATENTS AND KNOW-HOW PROVIDED BY EACH PARTY HEREUNDER ARE PROVIDED "AS IS" AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES, IN ALL CASES WITH RESPECT TO THE PATENTS AND KNOW-HOW OR OTHERWISE WITH RESPECT TO THE ACTIVITIES UNDER THIS AGREEMENT. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, EACH PARTY EXPRESSLY DOES NOT WARRANT (I) THE SUCCESS OF ACTIVITIES PERFORMED PURSUANT TO THIS AGREEMENT OR (II) THE SAFETY, EFFICACY OR USEFULNESS FOR ANY PURPOSE OF THE PATENTS OR KNOW-HOW IT PROVIDES UNDER THIS AGREEMENT OR THE SUBJECT MATTER OF THEM.

**14. INDEMNIFICATION AND INSURANCE**

**14.1 General Indemnification by Syndax.** Syndax shall defend, indemnify and hold harmless Incyte, its Affiliates, and its and their respective directors, officers, employees and agents ("**Incyte Indemnitees**") from and against any losses, damages, liabilities, fines, amounts paid in settlements, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any demand, claim, action or proceeding brought or initiated by a Third Party (each, a "**Third Party Claim**") to the extent arising from or occurring as a result of or in connection with (i) Syndax's, its Affiliates' or its

sublicensees' Development, Manufacture or Commercialization of any Licensed Antibody or Product outside of the Co-Commercialization Territory; **(ii)** any Syndax Independent Trial; **(iii)** any breach by Syndax of its representations, warranties, covenant or obligations under this Agreement; or **(iv)** the gross negligence or wilful misconduct of any Syndax Indemnitee; **provided, however,** that Syndax shall not defend, indemnify or hold harmless the Incyte Indemnitees from and against any Losses arising out of Third Party Claims to the extent that Incyte has an indemnification obligation pursuant to Section 14.2 for such Loss.

**14.2 General Indemnification by Incyte.** Incyte shall defend, indemnify and hold harmless Syndax, its Affiliates, and its and their respective directors, officers, employees, and agents ("**Syndax Indemnitees**") from and against any Losses in connection with any Third Party Claim to the extent arising from or occurring as a result of or in connection with: **(i)** Incyte's, its Affiliates' or its Sublicensees' Development, Manufacture or Commercialization of any Licensed Antibody or Product with respect to the Incyte Territory; **(ii)** Incyte Independent Trial; **(iii)** any breach by Incyte of its representations, warranties, covenants or obligations under this Agreement, or **(iv)** the gross negligence or willful misconduct of any Incyte Indemnitee; **provided, however,** that Incyte shall not defend, indemnify or hold harmless the Syndax Indemnitees from and against any Losses arising out of Third Party Claims to the extent that Syndax has an indemnification obligation pursuant to Section 14.1 for such Loss.

**14.3 Product Liability.** Any Losses arising out of a Third Party Claim brought against any Incyte Indemnitee or Syndax Indemnitee resulting from the Development, Manufacture or Commercialization of any Licensed Antibody or Product with respect to the Co-Commercialization Territory, other than such claims entitled to indemnification under Section 14.1 or 14.2, (such Losses, collectively, "**Shared Losses**" and such Third Party Claims, collectively, "**Shared Claims**") shall be treated as Collaboration Costs or Co-Commercialization Costs, respectively, and each party shall indemnify, without duplication, the other Party for its applicable percentage share of such Shared Losses under Section 7.1 (with respect to Collaboration Costs) or under Section 7.6 (with respect to Co-Commercialization Costs).

**14.4 Indemnification Procedure.** The following shall apply to all indemnification claims under this Agreement:

**(a) Notice of Claim.** All indemnification claims in respect of a Party, its Affiliates or their respective directors, officers, employees and agents (collectively, the "**Indemnitees**" and each an "**Indemnitee**") shall be made solely by such Party to this Agreement (the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party (the "**Indemnifying Party**") prompt written notice (an "**Indemnification Claim Notice**") of any Third Party Claim or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under Section 14.1, Section 14.2 or Section 14.3; **provided, however,** that the failure to give such prompt written notice shall not relieve Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that the Indemnifying Party is actually prejudiced as a result of such failure. In no event shall the Indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the Third Party Claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss are known at such time). The Indemnified Party

shall furnish promptly to the Indemnifying Party copies of all papers and official documents received in respect of any Losses.

**(b) Control of Defense.** At its option, the Indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [\*\*\*] after the Indemnifying Party's receipt of an Indemnification Claim Notice. Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel of its own choice. In the event the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by any Indemnitee in connection with the Third Party Claim. Should the Indemnifying Party assume the defense of a Third Party Claim, the Indemnifying Party shall not be liable to the Indemnified Party or any other Indemnitee for any legal expenses subsequently incurred by such Indemnified Party or other Indemnitee in connection with the analysis, defense or settlement of the Third Party Claim.

**(c) Right to Participate in Defense.** Without limiting Section 14.4(b) above, any Indemnitee shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; **provided, however**, that such employment shall be at the Indemnitee's own expense unless (i) the employment thereof has been specifically authorized by the Indemnifying Party in writing, or (ii) the Indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 14.4(b) (in which case the Indemnified Party shall control the defense).

**(d) Settlement.** With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the Indemnitee's becoming subject to injunctive relief or any other relief that may adversely affect the business of the Indemnitee in any manner, and as to which the Indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnitee hereunder, the Indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, shall deem appropriate, and shall transfer to the Indemnified Party all amounts which said Indemnified Party shall be liable to pay prior to the time prior to the entry of judgment. With respect to all other Losses in connection with Third Party Claims, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 14.4(b), the Indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; **provided, however**, that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld). The Indemnifying Party shall not be liable for any settlement or other disposition of a Loss by an Indemnitee that is reached without the written consent of the Indemnifying Party. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnitee shall admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the prior written consent of the Indemnifying Party.

**(e) Cooperation.** The Indemnified Party shall, and shall cause each other Indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such

records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested by the Indemnifying Party in connection with the defense or prosecution of any Third Party Claim. Such cooperation shall include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable External Costs in connection therewith.

**14.5 Expenses.** Except as provided above, the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim shall be reimbursed on a calendar quarter basis by the Indemnifying Party, without prejudice to the Indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

**14.6 Insurance.** Each Party shall have and maintain such types and amounts of liability insurance, including by self-insurance, as is normal and customary in the industry generally for parties similarly situated, and shall upon request provide the other Party with a certificate of insurance in that regard, along with any amendments and revisions thereto.

**15. LIMITATION OF LIABILITY**

**15.1 EXCLUSION OF INDIRECT DAMAGES.** IN NO EVENT SHALL EITHER PARTY BE LIABLE UNDER THIS AGREEMENT FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, HOWEVER CAUSED, ON ANY THEORY OF LIABILITY AND WHETHER OR NOT SUCH DAMAGES WERE FORESEEABLE AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, ARISING UNDER ANY CAUSE OF ACTION AND ARISING IN ANY WAY OUT OF THIS AGREEMENT. THE FOREGOING LIMITATIONS SHALL NOT APPLY TO AN AWARD OF ENHANCED DAMAGES AVAILABLE UNDER 3 U.S.C. § 284 FOR WILFUL PATENT INFRINGEMENT. THIS LIMITATION OF LIABILITY DOES NOT APPLY IN CASES OF (I) WILFUL MISCONDUCT OR GROSS NEGLIGENCE, (II) DEATH OR PERSONAL INJURY CAUSED BY A PARTY'S OR ITS EMPLOYEES, AGENTS OR SUBCONTRACTORS NEGLIGENCE TO THE EXTENT SUCH EXCLUSION IS PROHIBITED BY APPLICABLE LAWS (III) BREACHES OF ARTICLE 16 (CONFIDENTIALITY), (IV) BREACHES OF ARTICLE 12 (EXCLUSIVITY), OR (V) A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTIONS 14.1, 14.2 OR 14.3.

**16. CONFIDENTIALITY**

**16.1 Disclosure and Use Restriction.** During the Term and subject to the terms and conditions of this Agreement, a Party or its Affiliates (each, a "**Disclosing Party**") may communicate to the other Party or its Affiliates (each, a "**Receiving Party**") Confidential Information in connection with this Agreement or the performance of its obligations, or the use of its rights hereunder. Any confidential information disclosed under the Prior Confidentiality Agreement shall be treated as Confidential Information subject to the terms of this Agreement. Except as expressly provided herein, the Parties agree that, during the



Term and for [\*\*\*] thereafter, a Receiving Party shall keep completely confidential and shall not publish or otherwise disclose and shall not use for any purpose except for the purposes contemplated by this Agreement any Confidential Information of a Disclosing Party.

**16.2 Exclusions.** Notwithstanding the foregoing, the restrictions on the disclosure and use of Confidential Information by a Receiving Party shall not apply to Confidential Information that:

- (a) was already known to the Receiving Party, as evidenced by their written records, other than under an obligation of confidentiality or non-use, at the time of disclosure to the Receiving Party or its Affiliates;
- (b) was generally available or was otherwise part of the public domain at the time of its disclosure to the Receiving Party;
- (c) became generally available or otherwise became part of the public domain after its disclosure to the Receiving Party, through no fault of or breach of its obligations under this Article 16 by the Receiving Party;
- (d) was disclosed to the Receiving Party, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to the Receiving Party; or
- (e) was independently discovered or developed by or on behalf of the Receiving Party or its Affiliates, as evidenced by their written records, without the use of, reference to, or reliance upon, Confidential Information belonging to the Disclosing Party.

**16.3 Authorized Disclosure.** Notwithstanding anything to the contrary, a Receiving Party may disclose Confidential Information of a Disclosing Party to the extent that such disclosure is:

- (a) made in response to a valid order of a court of competent jurisdiction or other governmental or regulatory body of competent jurisdiction, or is otherwise required by Law; ***provided, however,*** that such Receiving Party shall first have given notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or governmental or regulatory body or, if disclosed, be used only for the purposes for which the order was issued; and ***further provided*** that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;
- (b) made by such Party to Regulatory Authorities as required in connection with the submission of any Regulatory Materials; ***provided, however,*** that reasonable measures shall be taken to assure confidential treatment of such information;
- (c) made by a Receiving Party in connection with the performance of its obligations or exercise of its rights under this Agreement, to its Affiliates and its and its Affiliate's sublicensees, directors, officers, employees, legal and financial advisors,

consultants, representatives or agents who have a need to know such information, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least as restrictive as those set forth in this Article 16 (or, in the case of legal and financial advisors, ethical obligations);

(d) made by a Receiving Party on a need-to-know-basis to (i) existing or potential acquirers or merger candidates; (ii) existing or potential sublicensees (including Sublicensees, with respect to Incyte) or existing or potential contractors (to the extent contemplated hereunder); (iii) investment bankers; (iv) existing or potential investors, venture capital firms or other financial institutions or investors for purposes of obtaining financing (**provided that** the confidentiality period may be shorter than provided in this Article 16, so long as such period is commercially reasonable); or to Third Parties or Sublicensees as may be necessary or useful in connection with the Development, Manufacture, Commercialization or other activities related to the Licensed Antibodies or Products, each of whom (as described in clauses (i) through (iv)) prior to disclosure must be bound by obligations of confidentiality and non-use at least as restrictive as those set forth in this Article 16;

(e) made by the Receiving Party with the prior written consent of the Disclosing Party; or

(f) made by Syndax to UCB Biopharma to the extent necessary for Syndax to comply with its reporting obligations to UCB Biopharma under the UCB Biopharma Agreement.

**16.4 Use of Name.** Neither Party may make public use of the other Party's name without such other Party's prior written consent, except (i) in connection with announcements or other disclosures relating to this Agreement and the activities contemplated hereby (including the Securities Purchase Agreement) as permitted in Section 16.5, (ii) as required by applicable Laws, (iii) as otherwise expressly permitted under this Agreement, or (iv) otherwise as agreed in writing by such other Party.

**16.5 Press Releases and Publications.**

(a) **Public Disclosures.** Except as required by judicial order or applicable Law, or with respect to disclosures of information for which consent has previously been obtained, or as otherwise set forth in this Agreement (including Section 16.5(b) and Section 16.5(c)), neither Party shall issue any press release or make any public announcement concerning this Agreement or the Securities Purchase Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. The Party preparing any such press release or public announcement shall provide the other Party with a draft thereof at least [\*\*\*] prior to the date on which such Party would like to issue such press release or make such public announcement, and the other Party shall have a reasonable opportunity to review and comment on any such press release or public announcement in advance thereof, which shall be considered by the Party preparing such press release or public announcement in good faith. Notwithstanding anything to the contrary, the Parties shall issue a joint press release in the form attached as **Exhibit 16.5**, within [\*\*\*] after the Execution Date to announce the execution of this Agreement and describe the material financial and operational terms of this Agreement and the Securities Purchase Agreement.

**(b) Press Releases.** Incyte may issue a press release or make a public disclosure relating to this Agreement or the Parties' activities under this Agreement to the extent that such disclosure describes the commencement or results of a Trial conducted by Incyte or Syndax for the Licensed Antibody or Product (including the Syndax Ongoing Trials), the achievement of any Development events with respect to the Licensed Antibody or Product, or the filing for or receipt of Regulatory Approval with respect to the Product. Syndax may issue a press release or make a public disclosure relating to this Agreement or the Parties' activities under this Agreement to the extent that such disclosure describes the commencement or results of a Syndax Independent Trial for the Licensed Antibody or Product. Either Party may issue a press release in respect of the achievement of any milestone events under Section 8.2 or the termination of this Agreement. Prior to making any such disclosure, the Party making the disclosure shall provide the other Party with a draft of such proposed disclosure at least [\*\*\*] (or, to the extent timely disclosure of a material event is required by Law or stock exchange or stock market rules, such period of time sufficiently in advance of the disclosure so that the other Party will have the opportunity to comment upon the disclosure) prior to making any such disclosure, for the other Party's review and comment, which shall be considered in good faith by the disclosing Party. For clarity, the Party making such disclosure shall have the final say over the contents of such disclosure.

**(c) Public Domain.** A Party may publicly disclose, without regard to the preceding requirements of this Section 16.5, information that was previously disclosed in a public disclosure that was in compliance with such requirements.

**(d) Development Results.** Each Party and/or its Affiliates or sublicensees (including Sublicensees, with respect to Incyte) under this Agreement may wish to publish the results generated under this Agreement including studies of the Products or other data generated under this Agreement. In order to safeguard intellectual property rights, the Party (or Affiliate or Sublicensee) wishing to publish or otherwise publicly disclose the results of such research and development shall first submit a draft of each proposed manuscript or presentation or poster to the other Party for review, comment and consideration of appropriate patent action at least [\*\*\*] prior to any submission for publication or other public disclosure. Within [\*\*\*] after receipt of the pre-publication materials, such other Party shall advise the Party seeking publication as to whether a patent application shall be prepared and filed or whether trade secret protection should be pursued or if Confidential Information should be removed and, if so, such other Party shall determine the appropriate timing and content of any such publications. Approval of a publication shall not be unreasonably withheld, conditioned or delayed. Any publication shall include recognition of the contributions of the other Party according to standard practice for assigning scientific credit, either through authorship or acknowledgement, as may be appropriate. Each Party shall use Commercially Reasonable Efforts to cause investigators and institutions participating in the Trials for the Products under this Agreement with which it contracts to agree to terms substantially similar to those set forth in this Section 16.5(d), which efforts shall satisfy such Party's obligations under this Section 16.5 with respect to such investigators and institutions.

**16.6 Terms of Agreement.** The Parties agree that the terms of this Agreement and the Securities Purchase Agreement are Confidential Information of each Party and shall not be

disclosed by either Party to any Third Party (except as permitted for Confidential Information under Sections 16.3 and 16.4) without prior written permission of the other Party; **provided, however**, that (i) either Party may make any filings of this Agreement or the Securities Purchase Agreement required by Law or regulation in any country as set forth in Section 16.7; and (ii) a Party may publicly disclose information that was previously disclosed in compliance with this Section 16.6 and Section 16.7.

**16.7 SEC Filings.** The Parties acknowledge that they may be obligated to make one or more filings (including to file a copy of this Agreement or the Securities Purchase Agreement) with the United States Securities and Exchange Commission ("**SEC**") or other Governmental Authorities in connection with the Parties' entry into, or performance of, this Agreement or the Securities Purchase Agreement. Each Party shall be entitled to make such a required filing, **provided that** (i) the Parties will coordinate in advance with each other in connection with the redaction of certain provisions of this Agreement or the Securities Purchase Agreement with respect to any filings with the SEC, (ii) the Party shall use Commercially Reasonable Efforts consistent with applicable Laws to maintain confidential treatment of all terms redacted from this Agreement or the Securities Purchase Agreement for such period permitted by applicable Law, and (iii) if such Governmental Authority requests any changes to such redactions, use Commercially Reasonable Efforts consistent with applicable Laws to support such redactions originally filed and, to the extent practical, provide such changes with the other Party. Each Party shall be responsible for its own legal and other External Costs in connection with any such filing, registration or notification.

**16.8 Data Protection.** Each Party shall comply with all applicable Data Protection Laws. The Parties shall, to the extent required by applicable Data Protection Laws, within [\*\*\*] after the Effective Date, and prior to the processing of Personal Data hereunder, enter into a data processing agreement the terms of which shall be incorporated herein by reference.

## **17. TERM AND TERMINATION**

### **17.1 Term and Expiration.**

**(a) Term.** The term of this Agreement shall commence as of the Execution Date and, unless earlier terminated in accordance with this Article 17, will continue on a country-by-country and Product-by-Product basis (a) in each country in the Incyte Territory until the end of the Royalty Term of such Product in such country, and (b) with respect to the Co-Commercialization Territory, for so long as Incyte is Developing or Commercializing such Product in the Co-Commercialization Territory (the "**Term**").

**(b) Expiration.** Following expiration of the Term, on a country-by-country and Product-by-Product basis, Incyte shall retain the licenses granted to it in Section 2.1 as exclusive, royalty-free, irrevocable, perpetual, fully paid-up licenses.

**(c) No relief from Existing Obligations.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination (including payment obligations).

### **17.2 Termination for Material Breach or Insolvency.**

**(a) Termination for Breach.** Any material breach of this Agreement (a "**Material Breach**") by a Party ("**Breaching Party**") shall entitle the other Party ("**Non-Breaching Party**") to give to the Breaching Party written notice specifying the nature of the Material Breach, requiring the Breaching Party to cure such Material Breach. If such Material Breach is not cured within [\*\*\*] after the receipt of notice pursuant to this Section 17.2 (except for a Material Breach consisting of non-payment, in which case the cure period shall be [\*\*\*]) (the "**Cure Period**"), the Non-Breaching Party shall be entitled to terminate this Agreement with immediate effect (unless such Material Breach (excluding any payment breach), by its nature, cannot reasonably be cured within the Cure Period, and the Breaching Party has (i) notified the Non-Breaching Party of its plan for curing such Material Breach, (ii) commenced and sustained the required efforts to cure such Material Breach during the Cure Period, and (iii) ultimately does cure such Material Breach within [\*\*\*] after the end of the Cure Period, or such longer period as may be agreed upon between the Parties) by providing a written notice pursuant to this Section 17.2 ("**Termination Notice**") to the Breaching Party and without prejudice to any of its other rights conferred on it by this Agreement and other remedies available under applicable Laws; **provided, that** Syndax shall only be entitled to terminate this Agreement (x) outside of the European Region, on a country-by-country basis with respect to an uncured Material Breach of Incyte's obligations under Section 3.7 or Section 5.1 in the applicable country and (y) with respect to the European Region, in the event of an uncured Material Breach of Incyte's obligations under Section 3.7 and Section 5.1 with respect to [\*\*\*].

**(b) Termination for Bankruptcy.** Each Party shall have the right to terminate this Agreement in its entirety upon written notice as a result of the other Party experiencing any of the following events: (i) the entry of an order for relief under United States Bankruptcy Code (Title 11, U.S. Code), as amended (the "**Bankruptcy Code**") (or any other bankruptcy, insolvency, reorganization or other similar Law of any jurisdiction now or hereafter in effect, collectively with the Bankruptcy Code the "**Bankruptcy Laws**") by such Party; (ii) the commencement of an involuntary proceeding under any applicable Bankruptcy Laws against such Party, if not dismissed, bonded or stayed within [\*\*\*] after such commencement; (iii) the making by such Party of a general assignment for the benefit of creditors; or (iv) the appointment of or taking possession by a receiver, liquidator, assignee, custodian, or trustee of all or substantially all of the business or property of such Party, **provided that** any such termination shall be effective only if such event is not dismissed within [\*\*\*] after the institution thereof.

**17.3 Termination for Patent Challenge.** Syndax may terminate this Agreement in its entirety upon [\*\*\*] prior written notice if Incyte or its Affiliates or Sublicensees challenges in a court or before a patent office the validity, enforceability or scope of any (a) UCB Biopharma Background Patent or (b) any Syndax Patent, and such challenge is not irrevocably withdrawn within [\*\*\*] after written notice to Incyte from Syndax of such challenge.

**17.4 Termination for Convenience.** Incyte shall have the right to terminate this Agreement on a Product-by-Product and/or a country-by-country basis or in its entirety for convenience (i) upon [\*\*\*] prior written notice to Syndax if such notice is delivered prior to the First Commercial Sale of a Product in the Field in the Territory and (ii) upon [\*\*\*] prior written notice to Syndax if such notice is delivered after the First Commercial Sale of a Product in the Field in the Territory.

**17.5 Termination of Securities Purchase Agreement.** Upon termination of the Securities Purchase Agreement pursuant to Section 9.1 thereof, this Agreement will automatically terminate.

**17.6 Alternative Remedy in Lieu of Termination.** If Incyte gives Syndax a written notice of Material Breach by Syndax pursuant to Section 17.2(a) and Syndax does not cure such Material Breach within the Cure Period, then Incyte may elect, in lieu of terminating this Agreement pursuant to Section 17.2(a), for the rights and obligations of the Parties under this Agreement to continue, including the licenses and rights granted by Syndax to Incyte under Article 2, and for Incyte's financial obligations to Syndax under Sections 7.6, 8.2 and 8.3 accrued on or after the date of Incyte's written notice of Material Breach to be reduced to [\*\*\*] of such financial obligations, ***provided that*** (i) if, prior to the end of the applicable Cure Period, Syndax brings an action in a court of competent jurisdiction disputing such Material Breach and, if applicable, Syndax's failure to cure such Material Breach within the applicable Cure Period, such election shall not take effect until it is determined by the applicable court of competent jurisdiction (excluding any preliminary, provisional, or temporary decision) that Incyte has the right to terminate this Agreement pursuant to Section 17.2(a); (ii) if such election takes effect, [\*\*\*] of any of Incyte's financial obligations to Syndax under Sections 7.6, 8.2 and 8.3 accrued and paid without such reduction on or after the date of Incyte's written notice of Material Breach by Syndax prior to such election taking effect will, at Incyte's election, be refunded by Syndax to Incyte within [\*\*\*] of Incyte's election or recovered by Incyte through additional reductions of Incyte's financial obligations to Syndax under this Agreement that next become payable following such election, and (iii) if Incyte initiates an action seeking damages from Syndax resulting from such Material Breach, then any payment reductions taken by Incyte pursuant to this Section 17.6 will be applied to reduce the damages (if any) awarded to Incyte by a final decision of a court of competent jurisdiction; ***provided, however,*** that the reduction to Incyte's financial obligations under Section 8.3 set forth above in this Section 17.6 shall not apply to the extent that such reduction to Incyte's payment obligations would result in payments to Syndax that are [\*\*\*].

**17.7 Syndax's Rights upon Syndax's Termination Notice and Effects of Syndax's Termination.** Upon any termination (but not expiration under Section 17.1 or termination under Section 17.5) of this Agreement, then the following will apply:

- (a) **License Termination.** The licenses granted by Syndax to Incyte under Article 2 shall terminate.
- (b) **Termination of Co-Commercialization.** If this Agreement is terminated in its entirety or with respect to the Co-Commercialization Territory, the Co-Commercialization in the Co-Commercialization Territory and the Pre-Tax Profit (Loss) Share shall terminate.
- (c) **Survival and Extension of Granted License.** At Syndax's option, to be exercised no later than [\*\*\*] Section 2.3 shall survive and become perpetual, irrevocable, royalty-free, and fully paid; ***provided, however,*** that all such licenses shall, from the effect of the applicable termination notice, also grant Syndax the right to research, have researched, develop, have developed, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, have imported, export and have exported the Licensed Antibody and/or the Product(s) in the Field in the Territory. Incyte shall (and ensure that its Affiliates or Sublicensees) transfer prosecution, maintenance and enforcement of Patents licensed under Section 2.4 to

Syndax. If Syndax elects to receive the rights under this Section 17.7(c), Syndax shall assume financial responsibility and all other obligations towards Third Parties under any applicable licenses.

**(d) Regulatory.** To the extent requested by Syndax in writing within [\*\*\*] following the applicable termination notice and to the full extent permitted by Laws, Incyte shall (and shall ensure that its Affiliates or Sublicensees) take all actions reasonably necessary to transfer to Syndax all INDs, BLAs, Marketing Authorizations, Pricing Approvals and other regulatory filings related to Licensed Antibody or Product that Incyte or its Affiliates or Sublicensees hold as of the time of such termination, in each case to the extent reasonably required to support continued clinical and other Development and Commercialization of Products in the Field.

**(e) Cessation of Ongoing Incyte Independent Trials.** If this Agreement is terminated in its entirety, and any Incyte Independent or Collaboration Trials with Licensed Antibody or Product are ongoing at the time of termination, then Incyte shall, at Incyte's discretion with respect to Incyte Independent Trials and at Syndax's discretion with respect to Collaboration Trials, (and Incyte shall cause its Affiliates or Sublicensees to) either (i) transfer responsibility for activities and costs for such Trials to Syndax or (ii) wind down such Trials and shall be fully and solely responsible for all costs associated with such wind-down, and shall continue to comply with all remaining obligations and commitments made to Regulatory Authorities by Incyte and by Affiliates or Sublicensees (including if applicable, patient registries), to the extent the compliance with such obligations and commitments is required by applicable Laws, at Incyte's sole cost.

**17.8 Survival.** Notwithstanding anything to the contrary contained herein, the following provisions shall survive any expiration or termination of this Agreement: Article 1, Article 14, Article 15 and Article 16 and Section 3.8, Section 3.9, Section 5.5(c), Section 7.4 (with respect to any obligations accrued but unpaid prior to the effectiveness of such termination or expiration), Section 7.6 (with respect to any obligations accrued but unpaid prior to the effectiveness of such termination or expiration), Sections 8.3 through 8.10 (in each case solely with respect to any obligations accrued but unpaid prior to the effectiveness of such termination or expiration), Section 10, Section 13.6, Section 17.1(c), Section 17.7, Section 17.8, Section 17.9 and Sections 18.1 through 18.15. Except as set forth in this Section 17.8 or otherwise expressly set forth herein, upon termination or expiration of this Agreement all other rights and obligations shall cease.

**17.9 Rights in Bankruptcy.** All rights and licenses or sublicenses granted under or pursuant to this Agreement by a Party ("**Grantor**") are and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code (or analogous section in any other Bankruptcy Laws) licenses of rights to "intellectual property" as defined under Section 101 of the Bankruptcy Code. The Parties understand and agree that each Party, as licensee or sublicensee of such rights under this Agreement ("**Grantee**"), shall retain and may fully exercise all of its rights and elections under any Bankruptcy Laws. If (i) a bankruptcy proceeding is commenced during the Term by or against the Grantor under any Bankruptcy Laws, (ii) this Agreement is rejected by or on behalf of such Grantor as provided for under any Bankruptcy Laws, and (iii) the Grantee elects to retain its rights hereunder as provided for under the Bankruptcy Laws, then the Grantor shall (x) provide to the Grantee, promptly following the Grantee's written request and if not already in the Grantee's possession, copies of all such intellectual property (including embodiments thereof) held by the Grantor and

necessary for the Grantee to practice its license or sublicense to such intellectual property and (y) not interfere with the Grantee's rights under this Agreement to such intellectual property, including any right to obtain such intellectual property from another entity, to the extent provided in the Bankruptcy Laws. All rights, powers and remedies of the Grantee as provided in this Section 17.9 are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including under any Bankruptcy Laws) in the event of the commencement of a case by or against the Grantor under any Bankruptcy Laws.

## **18. MISCELLANEOUS**

**18.1 Assignment.** Neither this Agreement nor any right or obligation hereunder may be assigned or otherwise transferred by a Party to any Third Party without the prior written consent of the other Party; ***provided, however,*** that each Party may, without such consent, assign this Agreement in its entirety (i) to an Affiliate or (ii), subject to Section 12.2, (a) if such Party merges with, or all or substantially all of its business or assets to which this business relates are acquired by another entity (whether by merger, sale of assets, sale of stock or otherwise), or (b) to the Party's merger partner or the Acquirer as part of such acquisition. Any permitted assignment shall be binding on the successors of the assigning Party. Other than an assignment permitted under the first sentence of this Section 18.1, any assignment or attempted assignment by either Party of rights or obligations hereunder shall be null and void. In the event of a Change of Control of either Party, intellectual property rights of the acquiring party (together with any entities that were Affiliates of such Third Party immediately prior to such Acquisition) shall not be included in the technology licensed hereunder or otherwise subject to this Agreement.

**18.2 Severability.** If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future Laws, and if the rights or obligations of either Party under this Agreement shall not be materially and adversely affected thereby, (i) such provision shall be fully severable, (ii) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (iii) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance here from, and (iv) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties herein.

## **18.3 Governing Law, Dispute Resolution.**

**(a) Governing Law, Jurisdiction.** This Agreement, and any disputes between the Parties related to or arising out of this Agreement (including the Parties' relationship created hereby, the negotiations for and entry into this Agreement, its conclusion, binding effect, amendment, coverage, termination, or the performance or alleged non-performance of a Party of its obligations under this Agreement) (each a "**Dispute**"), shall be governed by the Laws of the State of Delaware, without regard to any choice of law principle that would require the application of the Law of another jurisdiction. The United Nations Convention on Contracts for International Sales of Goods (CISG) shall not apply to this Agreement.



**(b) Dispute Resolution.** Matters before the JSC and subcommittees shall be governed by the process specified in Section 9.1(d). Any Dispute that is not subject to Section 9.1(d) shall be settled, if possible, through good faith negotiations between the Parties. If the Parties are unable to settle such dispute within [\*\*\*], and a Party wishes to pursue the matter, the matter may be referred by either Party to the Executive Officers, who shall meet to attempt to resolve the dispute in good faith. Such resolution, if any, of a referred issue shall be final and binding on the Parties. All negotiations pursuant to this Section 18.3(b) are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence. If the Executive Officers are unable to settle the dispute within [\*\*\*] (or sooner if the circumstances require that the dispute be settled more rapidly) after referral thereto pursuant to this Section 18.3(b), then each Party reserves its right to any and all remedies available under Law or equity with respect to the dispute, subject to Section 18.3(c).

**(c) Injunctive Relief.** Notwithstanding the foregoing, nothing in this Section 18.3 shall limit either Party's right to seek immediate temporary injunctive or other temporary equitable relief whenever the facts or circumstances would permit a Party to seek such relief in a court of competent jurisdiction.

**18.4 Notices.** All notices or other communications that are required or permitted hereunder shall be in writing and delivered personally, sent by facsimile (and promptly confirmed by personal delivery or overnight courier as provided herein), or sent by internationally-recognized overnight courier addressed as follows:

If to Syndax, to:

Syndax Pharmaceuticals, Inc.,  
35 Gatehouse Drive, Building D, Floor 3,  
Waltham, Massachusetts 02451  
Attention: CEO  
With a copy to: General Counsel

If to Incyte, to:

Incyte Corporation  
1801 Augustine Cut-Off  
Wilmington, DE 19803  
Attention: CEO  
With a copy to: General Counsel

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such communication shall be deemed to have been given when delivered. It is understood and agreed that this Section is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

**18.5 Entire Agreement, Modifications.** This Agreement, including the Exhibits attached hereto, each of which is hereby incorporated and made part of in this Agreement by reference, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and supersedes all prior agreements, understanding, promises and representations, whether written or oral, with respect thereto,

including the Prior Confidentiality Agreement. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. No amendment or modification of this Agreement shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

**18.6 Force Majeure.** Neither Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and neither Party shall be deemed in breach of its obligations, if such failure or delay is due to a Force Majeure Event. In the event of the occurrence of a Force Majeure Event, the Party affected thereby shall use Commercially Reasonable Efforts to cure or overcome the same and resume performance of its obligations hereunder.

**18.7 Independent Contractors.** It is understood and agreed that the relationship between the Parties is that of independent contractors and that nothing in this Agreement shall be construed to create a joint venture or any relationship of employment, agency or partnership between the Parties to this Agreement. Neither Party is authorized to make any representations, commitments or statements of any kind on behalf of the other Party or to take any action that would bind the other Party except as explicitly provided in this Agreement. Furthermore, none of the transactions contemplated by this Agreement shall be construed as a partnership for any tax purposes.

**18.8 Waiver.** No failure on the part of Incyte or Syndax to exercise, and no delay by either Party in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at Law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege by such Party or be construed as a waiver of any breach of this Agreement or as an acquiescence therein by such Party, nor shall any single or partial exercise of any such right, power, remedy or privilege by a Party preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.

**18.9 No Third Party Beneficiaries.** This Agreement is for the sole benefit of the Parties hereto and their successors and permitted assigns, and it shall not be construed as conferring any rights on any other person.

**18.10 Further Assurance.** Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement and the performance thereunder, or to carry out more effectively the provisions and purposes, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

**18.11 No Drafting Party.** This Agreement has been submitted to the scrutiny of, and has been negotiated by, both Parties and their counsel, and shall be given a fair and reasonable interpretation in accordance with its terms, without consideration or weight being given to any such terms having been drafted by any Party or its counsel. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

**18.12 Anti-Corruption and Bribery.** Each Party shall, and its officers, directors, employees, agents, representatives, or any other person acting on its behalf (collectively its

"Representatives") shall, in connection with exercise of its rights or performance of its obligations under this Agreement, comply at all times with all applicable Laws combating bribery and corruption, including the U.S. Foreign Corrupt Practices Act and the U.K. Bribery Act, ("**Anti-Bribery Laws**"). Each Party further represents and warrants that neither it nor any of its Representatives has offered to pay, paid, or accepted, and undertakes that neither it nor any of its Representatives will offer, pay, or accept, any bribes (including any improper advantages, such as, but not limited to, cash or cash equivalents, improper gifts, excessive entertainment, lavish travel, substantial favors etc.) to or by any person (including, in particular, any Government Official or Healthcare Professional of any jurisdiction) to secure or retain a business advantage for such Party's own benefit, the benefit of the other Party under or in connection with this Agreement, or for the benefit of any other party. Each Party shall take appropriate steps, in particular maintain and effectively enforce internal policies and procedures, to ensure that Representatives will not breach any Anti-Bribery Laws in connection with exercise of its rights or performance of its obligations under this Agreement. Each Party shall be responsible for any breach of Anti-Bribery Laws by its Representatives under or in connection with this Agreement. In addition, Each Party shall ensure that any person engaged by such Party for purposes of performing services or providing goods under or in connection with this Agreement does so only on the basis of a written contract which imposes on and secures from such person terms equivalent to those imposed on each Party in this and the foregoing paragraphs of this Section.

**18.13 Construction.** Except where the context otherwise requires, wherever used, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein means including, without limiting the generality of any description preceding such term. The word "any" means "any" unless otherwise clearly indicated by context. Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document refer to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (ii) any reference to any Laws refer to such Laws as from time to time enacted, repealed or amended, (iii) the words "herein", "hereof" and "hereunder", and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof, and (iv) all references herein to Articles, Sections and Exhibits, unless otherwise specifically provided, refer to the Articles, Sections and Exhibits of this Agreement. Definitions using the singular shall be applicable also to the plural and vice-versa. Headings are for convenience only.

**18.14 Cumulative Remedies.** Except to the extent otherwise expressly set forth in this Agreement, the rights and remedies of the Parties set forth herein or otherwise available at law or equity are cumulative and not alternative or exclusive.

**18.15 Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. If any signature is delivered by facsimile transmission or by e-mail delivery of a "PDF" format data file, such signature shall create a valid and binding obligation of the Party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or "PDF" signature page were an original thereof, ***provided that*** such facsimile or "PDF" signature is confirmed by an original signature.

## 18.16 Antitrust Filings.

(a) Each of the Parties shall prepare and make appropriate filings under applicable antitrust regulations and laws in all required jurisdictions relating to the transaction contemplated by this Agreement (“**Antitrust Filings**”) as soon as reasonably practicable after the Execution Date (and in the case of filings under the Hart-Scott Antitrust Improvement Act of 1976, as amended, no later than [\*\*\*], unless the Parties mutually agree otherwise). The Parties agree to (i) cooperate with one another to the extent necessary in the preparation and execution of all Antitrust Filings and, (ii) to the extent permitted under applicable law and by the applicable Governmental Authorities, provide each other reasonable advance notice of any meetings or telephone conferences with a Governmental Authority in connection with the Antitrust Filings and permit each other to attend and participate in those meetings and telephone conferences; (iii) provide the other with reasonable opportunity to review and comment on any written submissions, and to consider comments in good faith, and (iv) keep the other Party apprised of the status of any communications with, and any inquiries or requests for information from, any Governmental Authority in connection with the Antitrust Filings; **provided that** neither Party will be obligated to disclose any commercially sensitive or privileged information, and to the extent the Parties agree to share information of this nature, such exchange and review may be limited to the Parties’ outside counsel only. Each Party shall bear its own expenses in connection with the Parties’ cooperation under this Section 18.16 except that Incyte shall pay all filing fees due with respect to any filings with respect to any antitrust filing in any jurisdiction.

(b) Other than the provisions of this Section 18.16 and Article 16, the rights and obligations of the Parties under this Agreement shall not become effective until the Effective Date. Upon the occurrence of the Effective Date, all provisions of this Agreement shall become effective automatically without the need for further action by the Parties.

(c) Upon the terms and subject to the conditions of this Agreement, each of the Parties shall use its best efforts to take, or cause to be taken, all appropriate action, and to do, or cause to be done, all things necessary, proper or advisable under applicable Laws to consummate and make effective this transaction, and the other transactions contemplated by this Agreement, including using its best efforts to obtain all Clearances pursuant to the Antitrust Filings; **provided, that** the term “best efforts” as used in this Section 18.16(c) shall not require any Party to (a) sell, divest (including through a license or a reversion of licensed or assigned rights), hold separate, transfer, or dispose of any portion of the assets, operations, rights, product lines, or businesses, or interests therein, of itself or any of its Affiliates (or consent to any of the foregoing actions), (b) restrain, restrict, prohibit or limit the ability of any Party to conduct its business or own its assets (or consent to any of the foregoing actions) or (c) litigate or otherwise formally oppose any determination (whether judicial or administrative in nature) by a Governmental Authority seeking to challenge the transactions contemplated by this Agreement or impose any of the restrictions referenced in clause (a) or (b) above. In the event a provision of this Agreement needs to be deleted or substantially revised in order to obtain Clearance of this transaction, the Parties will negotiate in good faith an amendment to this Agreement.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, and intending to be legally bound hereby, the Parties have caused this collaboration and license agreement to be executed by their respective duly authorized officers.

**SYNDAX PHARMACEUTICALS, INC.**

By: /s/ Luke J. Albrecht  
Name: Luke J. Albrecht  
Title: General Counsel and Secretary

**INCYTE CORPORATION**

By: /s/ Hervé Hoppenot  
Name: Hervé Hoppenot  
Title: President and Chief Executive Officer

## STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (this “**Agreement**”) is made as of the 24th day of September 2021 (the “**Signing Date**”), by and between Syndax Pharmaceuticals, Inc., a Delaware corporation (the “**Company**”), and Incyte Corporation, a Delaware corporation (the “**Investor**”).

WHEREAS, pursuant to the terms and subject to the conditions set forth in this Agreement, the Company desires to issue and sell to the Investor, and the Investor desires to subscribe for and purchase from the Company, certain shares of common stock, par value \$0.0001 per share, of the Company (“**Common Stock**”); and

WHEREAS, simultaneously with the execution of this Agreement, the Company and the Investor are entering into that certain Collaboration and License Agreement (the “**Collaboration Agreement**”) of even date herewith.

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for good and valuable consideration, the adequacy and sufficiency of which are hereby acknowledged, the Investor and the Company agree as follows:

**1. Purchase and Sale of Stock.**

Subject to the terms and conditions of this Agreement, at the Closing (as defined below), the Company shall issue and sell to the Investor, and the Investor shall purchase from the Company, 1,421,523 shares of Common Stock (the “**Shares**”) for an aggregate purchase price of \$35,000,000 (the “**Aggregate Purchase Price**”).

**2. Closing Date. Deliveries.**

**2.1 Closing Date.** Subject to the satisfaction or waiver of all the conditions to the Closing set forth in Sections 6, 7 and 8 hereof, the closing of the transaction contemplated by Section 1 hereunder (the “**Closing**”) shall be held on the second (2<sup>nd</sup>) Business Day after the satisfaction of the conditions to Closing set forth in Sections 6, 7 and 8 (other than those conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction at such time of such conditions), through the electronic exchange of documents and signatures, or at such other time, date and location as may be jointly designated by the parties for the Closing. The date the Closing occurs is hereinafter referred to as the “**Closing Date.**” For purposes of this Agreement, “**Business Day**” shall mean a day on which banking institutions in New York, New York are open for business, excluding any Saturday or Sunday.

**2.2 Deliveries by the Company.** At the Closing, the Company shall deliver to the Investor the Shares, registered in the name of the Investor, and the Company shall instruct its transfer agent to register in book-entry form such issuance at the time of such issuance. The Company shall also deliver at the Closing: (i) a certificate in form and substance reasonably satisfactory to the Investor and duly executed on behalf of the Company by an authorized executive officer of the Company, certifying that the conditions to Closing set forth in Sections 6.1, 6.2, and 6.3 of this Agreement have been fulfilled; (ii) a legal opinion addressed to the Investor from Cooley LLP as counsel to the Company in the form to be agreed to between the

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Company and the Investor; (iii) a duly executed Collaboration Agreement; (iv) a duly executed cross-receipt in form and substance reasonably satisfactory to both parties (the “**Cross-Receipt**”); and (v) a certificate of the secretary of the Company dated as of the Closing Date certifying (A) that attached thereto is a true and complete copy of the Amended and Restated By-laws of the Company as in effect at the time of the actions by the Board of Directors of the Company referred to in clause (B) below, and on the Closing Date; (B) that attached thereto is a true and complete copy of all resolutions adopted by the Board of Directors of the Company authorizing the execution, delivery and performance of this Agreement and the transactions contemplated hereby and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby as of the Closing Date; (C) that attached thereto is a true and complete copy of the Company’s Amended and Restated Certificate of Incorporation as in effect at the time of the actions by the Board of Directors of the Company referred to in clause (B) above, and on the Closing Date; and (D) as to the incumbency and specimen signature of any officer of the Company executing this Agreement or any agreement or certificate contemplated hereby on behalf of the Company.

**2.3 Deliveries by the Investor.** At the Closing, the Investor shall deliver, or cause to be delivered, to the Company the Aggregate Purchase Price by wire transfer of immediately available United States funds to an account designated by the Company. The Company shall notify the Investor in writing of the wiring instructions for such account not fewer than five (5) Business Days before the Closing Date. The Investor shall also deliver, or cause to be delivered, at the Closing: (i) a certificate in form and substance reasonably satisfactory to the Company duly executed by an authorized executive officer of the Investor certifying that the conditions to Closing set forth in Section 7 of this Agreement have been fulfilled; and (ii) a duly executed Cross-Receipt.

### **3. Representations and Warranties of the Company.**

The Company hereby represents and warrants to the Investor that:

**3.1** The Company meets the requirements for use of Form S-3 under the Securities Act of 1933, as amended (the “**Securities Act**”), and has filed with the Securities and Exchange Commission (the “**Commission**”) a registration statement on such Form (Registration File No. 333-254661), which became automatically effective upon filing on March 24, 2021, for the registration under the Securities Act of the Shares. Such registration statement meets the requirements set forth in Rule 415(a)(1) (x) under the Securities Act and complies with said Rule. The Company will file with the Commission pursuant to Rule 424(b) under the Securities Act, and the rules and regulations (the “**Rules and Regulations**”) of the Commission promulgated thereunder, a supplement to the form of prospectus filed with the Commission on March 24, 2021. Such registration statement, including the exhibits thereto, as amended at the date of this Agreement, is hereinafter called the “**Registration Statement**”; such prospectus in the form filed with the Commission on March 24, 2021, is hereinafter called the “**Base Prospectus**”; and the form of prospectus supplement, in the form provided to the Investor prior to the execution of this Agreement and in which it will be filed with the Commission pursuant to Rule 424(b) (including the Base Prospectus as so supplemented) is hereinafter called the “**Prospectus Supplement**.” Any reference herein to the Registration Statement, the Base Prospectus or the Prospectus Supplement shall be deemed to refer to and include the documents incorporated by reference



therein (the “**Incorporated Documents**”) pursuant to Item 12 of Form S-3 which were filed under the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), on or before the date of this Agreement, or the issue date of the Base Prospectus or the Prospectus Supplement, as the case may be; and any reference herein to the terms “amend,” “amendment” or “supplement” with respect to the Registration Statement, the Base Prospectus or the Prospectus Supplement shall be deemed to refer to and include the filing of any document under the Exchange Act after the date of this Agreement, or the issue date of the Base Prospectus or the Prospectus Supplement, as the case may be, deemed to be incorporated therein by reference. All references in this Agreement to financial statements and schedules and other information which is “contained,” “included,” “described,” “set forth” or “stated” in the Registration Statement, the Base Prospectus or the Prospectus Supplement (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information which is or is deemed to be incorporated by reference in the Registration Statement, the Base Prospectus or the Prospectus Supplement, as the case may be. No stop order suspending the effectiveness of the Registration Statement or the use of the Base Prospectus or the Prospectus Supplement has been issued, and no proceeding for any such purpose is pending or has been initiated or, to the Company’s knowledge, is threatened by the Commission.

**3.2** The Registration Statement contains all exhibits and schedules as required by the Securities Act. Each of the Registration Statement and any post-effective amendment thereto, at the time it became effective, complied in all material respects with the Securities Act and the Exchange Act and the applicable Rules and Regulations and did not and, as amended or supplemented, if applicable, will not, contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Base Prospectus and the Prospectus Supplement, each as of its respective date, complied or will comply in all material respects with the Securities Act and the Exchange Act and the applicable Rules and Regulations. Each of the Base Prospectus and the Prospectus Supplement, as amended or supplemented, did not and will not contain as of the date thereof any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The Incorporated Documents, when they were filed with the Commission, conformed in all material respects to the requirements of the Exchange Act and the applicable Rules and Regulations and none of such Incorporated Documents, when they were filed with the Commission, contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading; and any further documents so filed and incorporated by reference in the Base Prospectus or Prospectus Supplement, when such documents are filed with the Commission, will conform in all material respects to the requirements of the Exchange Act and the applicable Rules and Regulations, as applicable, and will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. No post-effective amendment to the Registration Statement reflecting any facts or events arising after the date thereof which represent, individually or in the aggregate, a fundamental change in the information set forth therein is required to be filed with the Commission. There are no documents required to be filed with the Commission in connection with the transaction contemplated hereby that have not been filed as required pursuant to the Securities Act or will not be filed within the requisite time period.

**3.3** The Company has been duly organized and is validly existing as a corporation and is in good standing under the laws of the State of Delaware as of the date hereof, and is duly qualified to do business and is in good standing in each other jurisdiction in which its ownership or lease of property or the conduct of business requires such qualification, except where the failure to be so qualified would not (i) have, individually or in the aggregate, a material adverse effect on the earnings, business, properties, assets, liabilities, operations, condition (financial or otherwise) or prospects of the Company and its subsidiaries taken as a whole or (ii) prevent the consummation of the transactions contemplated hereby (the occurrence of any such effect or any such prevention described in the foregoing clauses (i) and (ii) being referred to as a “**Material Adverse Effect**”). All direct and indirect subsidiaries of the Company (“**Subsidiaries**”) are duly organized and in good standing under the laws of the place of organization or incorporation, and each Subsidiary is in good standing in each jurisdiction in which its ownership or lease of property or the conduct of business requires such qualification, except where the failure to qualify would not have a Material Adverse Effect on the assets, business or operations of the Company taken as a whole.

**3.4** The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and the Collaboration Agreement and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement by the Company and the consummation by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action on the part of the Company and no further corporate consent or action is required to be obtained by the Company, its Board of Directors or its stockholders in connection therewith other than the filing of the LAS (as defined below) with The Nasdaq Stock Market LLC (“**Nasdaq**”) with respect to the Shares. This Agreement has been duly executed by the Company and constitutes the legally valid and binding obligation of the Company enforceable against the Company in accordance with its terms except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors’ rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

**3.5** The authorized, issued and outstanding capital stock of the Company is as set forth in the Registration Statement, the Base Prospectus and the Prospectus Supplement under the caption “Capitalization” (other than for subsequent issuances, if any, pursuant to employee benefit plans, or upon the exercise of outstanding options or warrants, in each case described in the Registration Statement, the Base Prospectus and the Prospectus Supplement). The Shares conform in all material respects to the description thereof contained in the Registration Statement, the Base Prospectus and the Prospectus Supplement and have the same voting rights as all other shares of Common Stock outstanding. The Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company pursuant to this Agreement, will be validly issued, fully paid and non-assessable, and free and clear of all liens imposed by the Company. No preemptive, anti-dilution or similar rights of stockholders exist with respect to any of the Shares or the issue and sale thereof. Neither the filing of the Registration Statement nor the offering or sale of the Shares as contemplated by this Agreement gives rise to any rights, other than those which have been waived or satisfied, for or relating to the registration of any shares of Common Stock.

**3.6** The Company and its Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement), or other similar anti-takeover provision pursuant to the Amended and Restated Certificate of Incorporation, the Amended and Restated Bylaws or the laws of its state of incorporation that is or could become applicable to the Investor as a result of the Investor and the Company fulfilling their obligations or exercising their rights pursuant to the Agreement and the transactions contemplated hereby, including without limitation, as a result of the Company's issuance of the Shares and the Investor's ownership of the Shares.

**3.7** All issued and outstanding securities of the Company issued prior to the transactions contemplated by this Agreement have been duly authorized and validly issued and are fully paid and non-assessable; the holders thereof have no rights of rescission with respect thereto, and are not subject to personal liability by reason of being such holders; and none of such securities were issued in violation of the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company.

**3.8** The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock pursuant to the Exchange Act nor has the Company received any notification that the Commission is currently contemplating terminating such registration. The Company is currently in compliance with all applicable listing and maintenance requirements of Nasdaq and, except as disclosed in its filings with the Commission, the Company has not, in the 12 months preceding the Signing Date, received notice from Nasdaq to the effect that the Company is not in compliance with such listing or maintenance requirements.

**3.9** The execution and delivery of this Agreement and the consummation of the transactions herein contemplated and the fulfillment of the terms hereof do not and will not conflict with or result in a breach of any of the terms or provisions of, or constitute a default under, (i) any indenture, mortgage, deed of trust or other agreement or instrument to which the Company or any of its Subsidiaries is a party or by which the Company or any of its Subsidiaries or any of their respective properties is bound, or of (ii) the certificate of incorporation or formation, articles of incorporation or association, charter, by-laws or other organizational documents, as applicable, of the Company or any of its Subsidiaries or (iii) any law, order, rule or regulation judgment, order, writ or decree applicable to the Company or any of its Subsidiaries of any court or of any government, regulatory body or administrative agency or other governmental body having jurisdiction over the Company or any such Subsidiary, or any of their properties or assets, except, with respect to (i) and (iii), for such violations as would not, individually or in the aggregate, result in a Material Adverse Effect.

**3.10** Since the date of the most recent financial statements included or incorporated by reference in the Registration Statement, the Base Prospectus and the Prospectus Supplement, (i) there has not been any material adverse change or any development involving a prospective material adverse change in or affecting the earnings, business, management, properties, assets, rights, operations, condition (financial or otherwise), or prospects of the Company and its Subsidiaries taken as a whole, whether or not occurring in the ordinary course of business, (ii)

there has not been any material transaction entered into or any material transaction that is probable of being entered into by the Company or its Subsidiaries, other than transactions in the ordinary course of business, as each may be amended or supplemented, and (iii) neither the Company nor its Subsidiaries have sustained any loss or interference with its business that is material to the Company and its Subsidiaries taken as a whole and that is either from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor disturbance or dispute or any action, order or decree of any court or arbitrator or governmental or regulatory authority, except in each case as has been disclosed in the Registration Statement, the Base Prospectus and the Prospectus Supplement.

**3.11** Each approval, consent, order, authorization, designation, declaration or filing by or with any regulatory, administrative or other governmental body necessary in connection with the execution and delivery by the Company of this Agreement and the consummation of the transactions herein contemplated has been obtained or made and is in full force and effect.

**3.12** None of the Company or its Subsidiaries nor, to the Company's knowledge, any of their affiliates, has taken or may take, directly or indirectly, any action designed to cause or result in, or which has constituted or which might reasonably be expected to constitute, the stabilization or manipulation of the price of the shares of Common Stock to facilitate the sale or resale of the Shares.

**3.13** Except as otherwise disclosed in the Registration Statement, the Base Prospectus, and the Prospectus Supplement, the Company and its Subsidiaries own or have obtained licenses or sublicenses for all patents, patent applications, inventions, trademarks, trade names, service marks, logos, trade dress, designs, data, database rights, Internet domain names, rights of privacy, rights of publicity, copyrights, works of authorship, license/sublicense rights, trade secrets, know-how and proprietary information (including unpatented and unpatentable proprietary or confidential information, inventions, systems or procedures) and other industrial property and intellectual property rights described in the Registration Statement, the Base Prospectus, and the Prospectus Supplement as being owned or licensed/sublicensed by them, as well as related rights, such as moral rights and the right to sue for all past, present and future infringements or misappropriations of any of the foregoing, and registrations and applications for registration of any of the foregoing (collectively, "**Intellectual Property**") necessary in all material respects for the conduct of their business as presently conducted and as presently proposed to be conducted in the future as disclosed in the Registration Statement, the Base Prospectus, and the Prospectus Supplement, and such Intellectual Property has not been adjudged by a court of competent jurisdiction to be invalid or unenforceable, in whole or in part. Neither the Company nor any of its Subsidiaries has materially infringed, misappropriated, otherwise violated, or is currently materially infringing, misappropriating, or otherwise violating, and none of the Company or any of its Subsidiaries has received any communication or notice of infringement of, misappropriation of, conflict with or violation of, any Intellectual Property of any other person or entity. To the Company's knowledge: (i) there are no third parties who have rights to any Intellectual Property, except for (x) customary reversionary rights of third-party licensors with respect to Intellectual Property that are disclosed in the Registration Statement, the Base Prospectus, and the Prospectus Supplement as licensed or sublicensed to the Company or its Subsidiaries, (y) third parties who have been explicitly granted licenses or sublicenses by the Company or (z) as set forth in that certain License Agreement by and between the Company and

UCB Biopharma Sprl, dated July 1, 2016; and (ii) there is no infringement by third parties of any Intellectual Property. There is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others: (A) challenging the Company's rights in or to any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (B) challenging the validity, enforceability or scope of any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; or (C) asserting that the Company infringes, misappropriates, or otherwise violates, or would, upon the commercialization of any product or service described in the Registration Statement, the Base Prospectus or the Prospectus Supplement as under development, infringe, misappropriate, or violate, any patent, trademark, trade name, service name, copyright, trade secret or other proprietary rights of others, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim. The Company and its Subsidiaries have complied in all material respects with the terms of each agreement pursuant to which Intellectual Property has been licensed or sublicensed to the Company, and all such agreements are in full force and effect. The Company and its Subsidiaries have taken all reasonable steps necessary to secure their interests in the Intellectual Property from their employees and contractors and to protect the confidentiality of all of their confidential information and trade secrets. The product candidates described in the Registration Statement, the Base Prospectus and the Prospectus Supplement as under development by the Company fall within the scope of the claims of one or more patents or patent applications owned by, or exclusively licensed or sublicensed to, the Company. To the Company's knowledge, there is no patent or published patent application in the U.S. or other jurisdiction which contains claims that dominate or may dominate the Intellectual Property described in the Registration Statement, the Base Prospectus and the Prospectus Supplement or that interferes with the issued or pending claims of any such Intellectual Property (for the avoidance of doubt, the Company makes no such representation as to the intellectual property covering PD1/PD-L1 inhibitors described therein as owned or controlled by third parties). There is no prior art of which the Company is aware that would render any patent held by the Company invalid, except as would not, individually or in the aggregate, have a Material Adverse Effect, and all prior art of which the Company is aware that may be material to the validity of a U.S. patent or to the patentability of a U.S. patent application has been disclosed to the U.S. Patent and Trademark Office, and all such prior art has been disclosed to the patent office of other jurisdictions where required. To the Company's knowledge, there are no material defects in any of the patents or patent applications included in the Intellectual Property. To the Company's knowledge, the duties of candor and good faith required by the United States Patent and Trademark Office during the prosecution of the United States patents and patent applications included in the Intellectual Property have been complied with, and all such requirements in foreign offices having similar requirements applicable to the Company or its Subsidiaries have been complied with. To the Company's knowledge, no employee of the Company is in or has been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company.

**3.14** Neither the Company nor any of its Subsidiaries is or, after receipt of the Aggregate Purchase Price, will be required to register as an "investment company" or an entity

“controlled” by an “investment company” within the meaning of the Investment Company Act of 1940, as amended, and the rules and regulations of the Commission thereunder.

The preclinical tests and clinical trials, and other studies (collectively, “**studies**”) that are described in, or the results of which are referred to in, the Registration Statement, the Base Prospectus, the Prospectus Supplement or the Confidential Materials (as defined below) were and, if still pending, are being conducted in all material respects in accordance with the protocols, procedures and controls designed and approved for such studies and with standard medical and scientific research procedures; each description of the results of such studies is accurate and complete in all material respects and fairly presents the data derived from such studies, and the Company has no knowledge of any other studies the results of which are inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement, the Base Prospectus, the Prospectus Supplement or the Confidential Materials; the Company or, to the Company’s knowledge, the clinical trial sponsor of the trials or studies, has made all such filings and obtained all such approvals or authorizations as may be required by the Food and Drug Administration of the U.S. Department of Health and Human Services or from any other U.S. or foreign government or drug or medical device regulatory agency, or health care facility Institutional Review Board or independent ethics committee (collectively, the “**Regulatory Agencies**”), except where the failure to make such filing or obtain such approval would not reasonably be expected to, individually or in the aggregate, result in a Material Adverse Effect; except as described in the Registration Statement, the Base Prospectus, the Prospectus Supplement or the Confidential Materials, the Company and, to the Company’s knowledge, the clinical trial sponsor of such trials, has not received any notice of, or correspondence from, any Regulatory Agency requiring the termination, suspension or material modification of any clinical trials that are described or referred to in the Registration Statement, the Base Prospectus, the Prospectus Supplement or the Confidential Materials, nor is the Company aware of any reasonable grounds for such notice or correspondence; the Company has operated and currently is in compliance in all material respects with all applicable rules and regulations of the Regulatory Agencies; and, as of the date hereof, the Company has no plans to, and does not intend to, publicly release any material data from any studies during the period from the date hereof through November 1, 2021. For purposes of this Agreement, the “**Confidential Materials**” means: (i) the confidential materials presented to the Investor on August 30, 2021 and (ii) the contents of the electronic data room made available to the Investor in connection with this Agreement and the Collaboration Agreement (together, the “**Confidential Materials**”).

#### **4. Representations and Warranties of the Investor.**

The Investor hereby represents and warrants to the Company that the Investor has full right, power and authority to enter into this Agreement and to consummate the transactions contemplated hereby and has taken all necessary action to authorize the execution, delivery and performance of this Agreement. This Agreement constitutes a valid and binding obligation of the Investor enforceable against the Investor in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors’ rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other

equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

## 5. Additional Covenants.

**5.1 Conduct of Business.** During the period from the Signing Date through the Closing Date, except as consented to in writing by the Investor, the Company shall not (a) declare, set aside or pay any dividend or make any other distribution or payment (whether in cash, stock or property or any combination thereof) in respect of its capital stock, or establish a record date for any of the foregoing, or (ii) make any other actual, constructive or deemed distribution in respect of any shares of its capital stock or otherwise make any payments to stockholders in their capacity as such, except pursuant to repurchases of equity pursuant to the terms of its equity compensation plans.

**5.2 Maintenance of Property and Insurance.** During the period from the Signing Date through the Closing Date, the Company shall, and shall cause each of its Subsidiaries to, (i) keep and maintain all tangible property material to the conduct of its business in good working order and condition, ordinary wear and tear and casualty and (ii) maintain, in all material respects, with carriers reasonably believed by the Company to be financially sound and reputable in such amounts and against such risks and such other hazards, as is customarily maintained by companies engaged in the same or similar businesses operating in the same or similar locations or where the Subsidiaries operate.

**5.3 Market Listing.** During the period from the Signing Date through the Closing Date, the Company shall use all reasonable efforts to (i) maintain the listing and trading of the Common Stock on Nasdaq and (ii) effect the listing of the Shares on Nasdaq, including submitting the Notification Form: Listing of Additional Shares (the “LAS”) to Nasdaq no later than fifteen (15) calendar days prior to the Closing Date.

**5.4 Assistance and Cooperation.** Prior to the Closing, upon the terms and subject to the conditions set forth in this Agreement, each of the parties agrees to use all reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, and to assist and cooperate with the other party in doing, all things necessary, proper or advisable to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated by this Agreement, including taking all reasonable acts necessary to cause the conditions precedent set forth in Sections 6, 7 and 8 to be satisfied (including, in the case of the Company, promptly notifying the Investor of any notice from Nasdaq with respect to the LAS). In connection with obtaining Clearance (as defined in the Collaboration Agreement), each of the parties agrees to cooperate on the terms set forth in Section 18.16 of the Collaboration Agreement. In connection with public disclosures regarding this Agreement, each of the parties agrees to cooperate on the terms set forth in Sections 16.4 and 16.5 of the Collaboration Agreement.

**5.5 Investor Lock-Up.** The Investor hereby undertakes to the Company that for a period of six (6) months following Closing Date, it will not, sell, transfer, pledge, encumber or otherwise dispose of any Shares without the prior written consent of the Company. The foregoing restrictions shall not apply to: (i) any transfers to the Investor’s affiliates, (ii) any transfers made following termination of the Collaboration Agreement pursuant to Section 17.2(a)

thereof where the Company is the breaching party and (iii) any transfers in connection with or following a Change of Control (as defined in the Collaboration Agreement) of the Company; *provided* that in each transfer pursuant to clause (i), the transferee agrees to be bound in writing by the terms of this Agreement prior to such transfer. The Company may issue stop transfer instructions to its transfer agent in connection with such lock-up restrictions.

**5.6 Collaboration Agreement.** Each of the Company and the Investor shall have duly executed and delivered the Collaboration Agreement, on final terms as are mutually agreed by the Company and the Investor, and there shall have been no termination of the Collaboration Agreement that, as of the Closing, is effective and the Collaboration Agreement shall be in full force and effect.

**6. Investor's Conditions to Closing.**

The Investor's obligation to purchase the Shares at the Closing is subject to the fulfillment as of the Closing of the following conditions (unless waived in writing by the Investor):

**6.1 Representations and Warranties.** The representations and warranties made by the Company in Section 3 hereof shall be true and correct in all material respects (except for those representations and warranties which are qualified as to materiality or Material Adverse Effect, in which case such representations and warranties shall be true and correct in all respects) as of the date of this Agreement and as of the Closing Date as though made on and as of such Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date.

**6.2 Covenants.** All covenants and agreements contained in this Agreement to be performed or complied with by the Company on or prior to the Closing Date shall have been performed or complied with in all material respects.

**6.3 No Material Adverse Effect.** From and after the date of this Agreement until the Closing Date, there shall have occurred no event that has caused or that is reasonably likely to result in a Material Adverse Effect.

**6.4 Listing.** Nasdaq shall have raised no objection to the consummation of the transactions contemplated by this Agreement in the absence of stockholder approval of such transactions.

**6.5 Closing Deliverables.** All closing deliverables as required under Section 2.2 shall have been delivered by the Company to the Investor.



## 7. **Company's Conditions to Closing.**

The Company's obligation to issue and sell the Shares at the Closing is subject to the fulfillment as of the Closing of the following conditions (unless waived in writing by the Company):

**7.1 Representations and Warranties.** The representations and warranties made by the Investor in Section 4 hereof shall be true and correct as of the date of this Agreement and as of the Closing Date as though made on and as of such Closing Date, except where any failure to be true and correct would not have a material adverse effect on the Investor's ability to perform its obligations, or consummate the transactions contemplated hereby in accordance with the terms of this Agreement.

**7.2 Covenants.** All covenants and agreements contained in this Agreement to be performed or complied with by the Investor on or prior to the Closing Date shall have been performed or complied with in all material respects.

**7.3 Closing Deliverables.** All closing deliverables as required under Section 2.3 shall have been delivered by the Investor to the Company.

## 8. **Mutual Conditions to Closing.**

The obligations of the Investor and the Company to consummate the Closing are subject to the fulfillment as of the Closing Date of the following conditions:

**8.1 No Governmental Prohibition; HSR Clearance.** The sale of the Shares by the Company and the purchase of the Shares by the Investor will not be prohibited by any applicable law at the time of the Closing. Clearance shall have been obtained.

**8.2 Absence of Litigation.** There shall be no action, suit, proceeding or investigation by a governmental or regulatory authority pending or currently threatened in writing against the Company or the Investor that questions the validity of this Agreement or any transaction contemplated hereby, the right of the Company or the Investor to enter into this Agreement or to consummate the transactions contemplated hereby or which, if determined adversely, would impose substantial monetary damages on the Company or the Investor as a result of the consummation of the transactions contemplated by this Agreement.

## 9. **Termination.**

**9.1 Ability to Terminate.** This Agreement may be terminated at any time prior to the Closing by:

(i) mutual written consent of the Company and the Investor;

(ii) (A) the Investor, upon written notice to the Company no earlier than the date that is six (6) months from the Signing Date and (B) the Company, upon written notice to the Investor no earlier than the date that is twelve (12) months from the Signing Date (any

such date, the “**Termination Date**”), if the transactions contemplated hereby shall not have been consummated by the Termination Date; or

(iii) either the Company or the Investor, upon written notice to the other, if any of the mutual conditions to the Closing set forth in Section 8 shall have become incapable of fulfillment by the Termination Date and shall not have been waived in writing by the other party within ten business days after receiving receipt of written notice of an intention to terminate pursuant to this clause (iii) *provided*, however, that the right to terminate this Agreement under this Section 9.1(iii) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been the cause of, or resulted in, the failure to consummate the transactions contemplated hereby prior to the Termination Date.

**9.2 Automatic Termination.** This Agreement shall terminate automatically in the event that the Collaboration Agreement is terminated prior to the Closing.

**9.3 Effect of Termination.** In the event of the termination of this Agreement pursuant to Section 9.1 or Section 9.2 hereof, this Agreement (except for this Section 9.3 and Section 10 hereof) shall forthwith become void and have no effect, without any liability on the part of any party hereto or its affiliates; *provided, however*, that nothing contained in this Section 9.3 shall relieve any party from liability for fraud or any intentional or willful breach of this Agreement.

## **10. Miscellaneous.**

**10.1 Successors and Assigns.** Neither party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other party; *provided*, that the Investor may assign or transfer this Agreement without the Company’s consent to (i) an affiliate of the Investor or (ii) an acquirer of all or substantially all of the Investor’s business (whether by merger, consolidation, sale of assets or otherwise). Any permitted successor or assignee of rights or obligations hereunder shall, in a writing to the other party, expressly assume performance of such rights or obligations. Any permitted assignment shall be binding on the successors of the assigning party. Any assignment or attempted assignment by either party in violation of the terms of this Section 10.1 shall be null, void and of no legal effect.

**10.2 Governing Law; Submission to Jurisdiction; Waiver of Jury Trial.** All issues and questions concerning the application, construction, validity, interpretation and enforcement of this Agreement shall be governed by and construed in accordance with the internal laws of the State of Delaware, without giving effect to any choice or conflict of law provision or rule (whether of the State of Delaware or any other jurisdiction) that would cause the application of laws of any jurisdiction other than those of the State of Delaware. Except as expressly set forth herein, the parties hereby agree that any suit, action or proceeding seeking to enforce any provision of, or based on any matter arising out of or in connection with, this Agreement or the transactions contemplated hereby, whether in contract, tort or otherwise, shall be brought in the United States District Court for the District of Delaware or in the Court of Chancery of the State of Delaware (or, if such court lacks subject matter jurisdiction, in the Superior Court of the State of Delaware), so long as one of such courts shall have subject-matter jurisdiction over such suit,

action or proceeding, and that any cause of action arising out of this Agreement shall be deemed to have arisen from a transaction of business in the State of Delaware. Each of the parties hereby irrevocably consents to the jurisdiction of such courts (and of the appropriate appellate courts therefrom) in any such suit, action or proceeding and irrevocably waives, to the fullest extent permitted by law, any objection that it may now or hereafter have to the laying of the venue of any such suit, action or proceeding in any such court or that any such suit, action or proceeding which is brought in any such court has been brought in an inconvenient forum. Service of process, summons, notice or other document by registered mail to the address set forth in Section 10.4 shall be effective service of process for any suit, action or other proceeding brought in any such court. Each party hereby acknowledges and agrees that any controversy which may arise under this Agreement is likely to involve complicated and difficult issues and, therefore, each such party irrevocably and unconditionally waives any right it may have to a trial by jury in respect of any legal action arising out of or relating to this Agreement or the transactions contemplated hereby.

**10.3 Execution.** This Agreement or any instrument pursuant to Section 10.7 hereof may be executed in two or more counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument. Counterparts may be delivered via facsimile, electronic mail (including any electronic signature covered by the U.S. federal E-SIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., www.docuSign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

**10.4 Titles and Subtitles.** The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

**10.5 Notices.** All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth on below and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service or (d) sent by facsimile transmission or electronic mail, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile or electronic mail (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either party may change its address by giving notice to the other party in the manner provided above.

If to the Investor:

Incyte Corporation  
1801 Augustine Cut-Off  
Wilmington, Delaware 19803  
Attention: CFO and General Counsel

with a copy, which shall not constitute notice, to:

Wilmer Cutler Pickering Hale & Dorr LLP  
7 World Trade Center  
New York, New York 10007  
Attention: Robert Finkel and Glenn Pollner

If to the Company:

Syndax Pharmaceuticals, Inc.  
35 Gatehouse Drive  
Building D, Floor 3  
Waltham, Massachusetts 02451  
Attention: Luke J. Albrecht

with a copy, which shall not constitute notice, to:

Cooley LLP  
3175 Hanover Street  
Palo Alto, California 94304  
Attention: Laura Berezin and Jaime Chase

**10.6 Finder's Fee.** Each party represents that it neither is nor will be obligated for any finders' fee or commission in connection with this transaction.

**10.7 Amendments and Waivers.** Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of the Company and the Investor.

**10.8 Severability.** If one or more provisions of this Agreement are held to be unenforceable under applicable law, such provision shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

**10.9 Entire Agreement.** This Agreement, the Collaboration Agreement and the other documents referred to herein and therein constitute the entire agreement among the parties and no party shall be liable or bound to any other party in any manner by any warranties, representations, or covenants except as specifically set forth herein or therein.

**10.10 Indemnification.** Subject to the provisions of this Section 10.10, the Company will indemnify and hold the Investor and its directors, officers, shareholders, members, partners, employees and agents (and any other persons with a functionally equivalent role of a person holding such titles notwithstanding a lack of such title or any other title), each person who controls the Investor (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, shareholders, agents, members, partners or employees (and any other persons with a functionally equivalent role of a person holding such

titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a “**Investor Party**”) harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys’ fees and costs of investigation that any the Investor Party may suffer or incur as a result of or relating to (a) any breach of any of the representations, warranties, covenants or agreements made by the Company in this Agreement or (b) any action instituted against an Investor, or any of them or their respective affiliates, by any stockholder of the Company who is not an affiliate of the Investor or any governmental or regulatory agency, with respect to any of the transactions contemplated by this Agreement (unless such action is based upon a material breach of the Investor’s representations, warranties or covenants in this Agreement or any material violations by the Investor of state or federal securities laws or any conduct by the Investor which constitutes fraud, gross negligence, willful misconduct or malfeasance). If any action shall be brought against any Investor Party in respect of which indemnity may be sought pursuant to this Agreement, the Investor Party shall promptly notify the Company in writing, and the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Investor Party. Any Investor Party shall have the right to engage separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of the Investor Party except to the extent that (i) the engagement thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is, in the reasonable opinion of such separate counsel, a material conflict on any material issue between the position of the Company and the position of the Investor Party, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel. The Company will not be liable to any Investor Party under this Agreement (i) for any settlement by an Investor Party effected without the Company’s prior written consent, which shall not be unreasonably withheld or delayed or (ii) to the extent, but only to the extent, that a loss, claim, damage or liability is attributable to any Investor Party’s breach of any of the representations, warranties, covenants or agreements made by the Investor Party in this Agreement. To the extent that the Investor wishes to seek indemnification under this Section 10.10, such Investor must provide the Company with written notice asserting a claim under this Section 10.10, with such notice to be provided within one year from the Closing. If the Investor fails to provide such written notice within this one-year period, the Investor shall no longer be entitled to indemnification by the Company hereunder.

**10.11 Expenses.** Each party shall pay the fees and expenses of its advisers, counsel, accountants and other experts, if any, and all other expenses incurred by such party incident to the negotiation, preparation, execution, delivery and performance of this Agreement. The Company shall be liable for and pay all transfer agent fees, stamp taxes and other taxes and duties levied in connection with the delivery of the Shares to the Investor.

**10.12 Equitable Remedies.** Each party acknowledges that a breach or threatened breach by such party of any of its obligations under this Agreement would give rise to irreparable harm to the other party, for which monetary damages would not be an adequate remedy, and hereby agrees that in the event of a breach or a threatened breach by such party of any such obligations, the other party shall, in addition to any and all other rights and remedies that may be available to them in respect of such breach, be entitled to equitable relief, including a temporary

restraining order, an injunction, specific performance and any other relief that may be available from a court of competent jurisdiction (without any requirement to post bond).

**10.13 Remedies Cumulative.** The rights and remedies under this Agreement are cumulative and are in addition to and not in substitution for any other rights and remedies available at law or in equity or otherwise.

**10.14 Survival of Warranties.** The representations and warranties of the Company and the Investor contained in this Agreement shall survive the Closing and the delivery of the Shares.

**10.15 Construction.** The parties agree that each of them and/or their respective counsel has reviewed and had an opportunity to revise this Agreement and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of this Agreement or any amendments hereto.

[Signature Pages Follow]

**IN WITNESS WHEREOF**, the parties hereto have executed this Stock Purchase Agreement as of the day and year first above written.

**SYNDAX PHARMACEUTICALS, INC.**

By: /s/ Luke J. Albrecht

Name: Luke J. Albrecht

Title: General Counsel and Secretary

Address: 35 Gatehouse Drive, Building D, Floor 3  
Waltham, Massachusetts

**INCYTE CORPORATION**

By: /s/ Hervé Hoppenot

Name: Hervé Hoppenot

Title: President and Chief Executive Officer

Address: 1815 Augustine Cut Off  
Wilmington, Delaware

## CERTIFICATIONS

I, Briggs W. Morrison, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Syndax Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in exchange act rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2021

By: /s/ Briggs W. Morrison, M.D.  
Briggs W. Morrison, M.D.  
Chief Executive Officer  
(Principal Executive Officer)



## CERTIFICATIONS

I, Alexander Nolte, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Syndax Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in exchange act rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2021

By: /s/ Alexander Nolte  
Alexander Nolte  
Chief Accounting Officer  
(Principal Accounting Officer, Interim Principal  
Financial Officer)

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

In connection with the Quarterly Report on Form 10-Q of Syndax Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his or her knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 15, 2021

By /s/ Briggs W. Morrison, M.D.  
Briggs W. Morrison, M.D.  
Chief Executive Officer

Date: November 15, 2021

By /s/ Alexander Nolte  
Alexander Nolte  
Chief Accounting Officer