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, 2018

or

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

For the transition period from _____ to _____

Commission File Number: 001-37708

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

Delaware	**32-0162505**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
35 Gatehouse Drive, Building D, Floor 3 Waltham, Massachusetts	**02451**
(Address of Principal Executive Offices)	**(Zip Code)**

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

As of November 2, 2018, there were 24,835,951 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:

- 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 1b/2 clinical trials of entinostat in lung cancer, melanoma, microsatellite stable colorectal cancer, ovarian cancer, and triple negative breast cancer;
- the timing of the progress and receipt of data from the Phase 3 clinical trial of entinostat in advanced hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+, HER2-) breast cancer;
- the timing of the progress and receipt of data from the Phase 1 clinical trials of SNDX-6352 and the potential use of SNDX-6352 to treat various cancer and cancer-related indications;
- the scope, timing of the commencement, progress and receipt of data from any other clinical trials that we and our collaborators may conduct;
- our ability to replicate results in future clinical trials;
- our expectations regarding the potential safety, efficacy or clinical utility of our product candidates;
- 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;
- the potential use of entinostat to treat additional tumor types;
- our ability to maintain our licenses with Bayer Pharma AG, Kyowa Hakko Kirin Co., Ltd., UCB Biopharma Sprl, and Vitae Pharmaceuticals, Inc., a subsidiary of Allergan plc;
- 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; and
- developments relating to our competitors and our industry.

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)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,705	$ 35,168
Restricted cash	101	106
Short-term investments	62,894	94,806
Prepaid expenses and other current assets	6,146	3,362
Total current assets	95,846	133,442
Long-term investments	—	3,246
Property and equipment, net	396	267
Other assets	225	231
Total assets	$ 96,467	$ 137,186
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,180	$ 2,232
Accrued expenses and other current liabilities	12,319	11,993
Current portion of deferred revenue	1,517	1,573
Total current liabilities	17,016	15,798
Long-term liabilities:		
Deferred revenue, less current portion	15,029	16,759
Other long-term liabilities	148	310
Total long-term liabilities	15,177	17,069
Total liabilities	32,193	32,867
Commitments		
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized; 0 shares outstanding at September 30, 2018 and December 31, 2017	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized; 24,051,364 and 24,390,033 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	2	2
Additional paid-in capital	484,893	470,571
Accumulated other comprehensive loss	(35)	(143)
Accumulated deficit	(420,586)	(366,111)
Total stockholders' equity	64,274	104,319
Total liabilities and stockholders' equity	$ 96,467	$ 137,186

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,	
	2018	2017	2018	2017
Revenue:				
License fees	$ 379	$ 305	$ 1,138	$ 915
Total revenues	379	305	1,138	915
Operating expenses:				
Research and development	14,095	12,188	44,286	31,603
General and administrative	4,125	3,563	13,395	11,777
Total operating expenses	18,220	15,751	57,681	43,380
Loss from operations	(17,841)	(15,446)	(56,543)	(42,465)
Other income (expense):				
Interest income, net	488	411	1,422	959
Other income (expense)	15	(53)	(3)	(193)
Total other income (expense)	503	358	1,419	766
Net loss	$ (17,338)	$ (15,088)	$ (55,124)	$ (41,699)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	$ 54	$ (8)	$ 108	$ (28)
Comprehensive loss	$ (17,284)	$ (15,096)	$ (55,016)	$ (41,727)
Net loss attributable to common stockholders	$ (17,338)	$ (15,088)	$ (55,124)	$ (41,699)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.68)	$ (0.68)	$ (2.21)	$ (2.08)
Weighted-average number of common shares used to compute net loss per share attributable to common stockholders —basic and diluted	25,471,587	22,239,996	24,888,738	20,004,409

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)

	Nine Months Ended September 30,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (55,124)	$ (41,699)
Adjustments to reconcile net loss to net cash from operating activities:		
Depreciation, amortization and accretion	(282)	233
Stock-based compensation	4,729	4,170
Other	(1)	8
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(2,784)	(248)
Accounts payable	948	(206)
Deferred revenue	(1,138)	(915)
Accrued expenses and other liabilities	164	4,008
Net cash used in operating activities	(53,488)	(34,649)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(173)	(42)
Purchases of short-term investments	(60,141)	(113,012)
Proceeds from sales and maturities of short-term investments	95,750	94,432
Net cash provided by (used in) investing activities	35,436	(18,622)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock in follow-on public stock offering, net	—	48,674
Proceeds from issuance of common stock in at-the-market stock offering, net	9,438	1,121
Proceeds from stock option exercises	26	276
Proceeds from Employee Stock Purchase Plan	129	39
Other	(9)	(2)
Net cash provided by financing activities	9,584	50,108
NET DECREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(8,468)	(3,163)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH—beginning of period	35,389	24,110
CASH, CASH EQUIVALENTS AND RESTRICTED CASH —end of period	$ 26,921	$ 20,947
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
SUPPLEMENTAL DISCLOSURES OF NONCASH INVESTING AND FINANCING ACTIVITIES:		
Property and equipment purchases included in accounts payable and accrued expenses	$ —	$ 42
Vesting of restricted stock	$ —	$ 59

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

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, 2018, and the results of operations and comprehensive loss for the three and nine months ended September 30, 2018 and 2017, and cash flows for the nine months ended September 30, 2018 and 2017. The results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018, 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, 2017, and the notes thereto, which are included in the Company's Annual Report on Form 10-K that was filed with the Securities and Exchange Commission ("SEC") on March 8, 2018.

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. 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, 2017 and the notes thereto are included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 8, 2018. Certain amounts reported in the previous year have been recast as a result of the retrospective adoption of new accounting standards in the first quarter of 2018. Refer to *Recently Issued and Adopted Accounting Pronouncements* and Note 4 "Revenue from Contracts with Customers" for further discussion.

Revenue Recognition

The Company adopted Accounting Standards Codification Rule 606 Revenue from Contracts with Customers (ASC 606), on January 1, 2018, using the modified retrospective method for all contracts not completed as of the date of adoption. The reported results for 2018 reflect the application of ASC 606 guidance while the reported results for 2017 were prepared under the guidance of ASC 605, Revenue Recognition (ASC 605). For the Company's accounting policy for revenue recognition under ASC 605, refer to Item 8 of the Annual Report on Form 10-K for the year ended December 31, 2017. As of January 1, 2018, the Company had only one contract within the scope of ASC 606, a license agreement with Kyowa Hakko Kirin Co., Ltd. ("KHK"), under which the Company granted KHK an exclusive license to develop and commercialize entinostat in Japan and Korea (the "KHK License Agreement"). The KHK License Agreement is discussed further in Footnote 6.

The Company enters into license agreements for the development and commercialization of its product candidates. License agreements may include non-refundable upfront payments, contingent payments based on the occurrence of specified events under the Company's license arrangements, partial or complete reimbursement of research and development expenses, and license fees and royalties on sales if they are successfully approved and commercialized. The Company's performance obligations under the license agreements may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and related materials and participation on certain development and/or commercialization committees.

Revenue is recognized when, or as, performance obligations are satisfied, which occurs when control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer ("transaction price"). To the extent that the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the most likely amount method. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company's anticipated performance and all information (historical, current and forecasted) that is reasonably available.

The Company assesses the promises to determine if they are distinct performance obligations. Once the performance obligations are determined, the transaction price is allocated based on a relative standalone selling price basis. Milestone payments and royalties are typically considered variable consideration at the outset of the contract and are recognized in the transaction price either upon occurrence or when the constraint of a probable reversal is no longer applicable.

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. Arrangements containing licenses to the Company's intellectual property typically provide for a know-how transfer period. These arrangements may or may not also include rights to future updates of that intellectual property and related know-how. Revenues from non-refundable, up-front fees allocated to the licenses are recognized as the license is transferred to the customer and the customer is able to use and benefit from the license. This generally takes place over the related know-how transfer period, or if applicable, over the term of transfer of future updates to the intellectual property.

Development Milestone Payments: At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license fees and earnings in the period of adjustment. For development milestones related to the KHK Agreement, the Company does not take a substantive role or control the research, development or commercialization of any products generated by KHK. Therefore, the Company is not able to reasonably estimate when, if at all, any development milestone payments may be payable to the Company. As such, the development milestone payments associated with the KHK Agreement involve a substantial degree of uncertainty and risk that they may never be received.

Commercial Milestone Payments and Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of commercial sales, and the license is deemed to be the predominant item to which the royalties or commercial milestones relate, the Company will recognize revenue at the later of when the related sales occur or when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date no commercial milestone payments or royalties have been achieved.

When no performance obligations are required of the Company, or following the completion of the performance obligation period, such amounts are recognized as revenue upon transfer of control of the goods or services to the customer. Generally, all amounts received or due other than sales-based milestones and royalties are classified as license fees. Sales-based milestones and royalties will be recognized as royalty revenue at the later of when the related sales occur or when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods as performance obligations are satisfied. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability. Upfront payment contract liabilities resulting from the Company's license agreements do not represent a financing component as the payment is not financing the transfer of goods or services, and the technology underlying the licenses granted reflects research and development expenses already incurred by the Company.

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.

Recently Issued and Adopted Accounting Pronouncements

In June 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 is intended to simplify several aspects of the accounting for nonemployee share-based payment transactions by expanding the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. This ASU is effective for public reporting companies for interim and annual periods beginning after December 15, 2018, with early adoption permitted but no earlier than an entity's adoption date of Topic 606. The Company is in the process of evaluating the effect of the new guidance on the Company's consolidated financial statements and related disclosures.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"). ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. An entity should account for the effects of a modification unless all of the following are met: (1) the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification; (2) the vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified; (3) the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The Company adopted ASU 2017-09 on January 1, 2018, and it did not have a material impact on its condensed consolidated balance sheet, condensed statement of comprehensive loss or condensed statement of cash flows. As part of the adoption of this guidance, the Company adopted a policy to account for the effects of a modification unless certain exclusions are met.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* ("ASU 2016-18"). ASU 2016-18 requires that restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The statement of cash flows must also explain the change during the period in the total of cash, cash equivalents, and restricted cash or restricted cash equivalents. The Company adopted ASU 2016-18 on January 1, 2018, utilizing the retrospective transition method and it did not have a material impact on its condensed statement of cash flows. As part of the adoption of this guidance, the Company included restricted cash with cash and cash equivalents in the condensed statement of cash flows for the periods ending September 30, 2018 and 2017. The following table provides a reconciliation of the cash, cash equivalents, and restricted cash balances as of September 30, 2018 and December 31, 2017, as shown above:

	September 30, 2018	December 31, 2017
	(In thousands)	
Cash and cash equivalents	$ 26,705	$ 35,168
Restricted cash included in current and noncurrent assets	216	221
Cash, cash equivalents and restricted cash	$ 26,921	$ 35,389

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). Under ASU 2016-02, lessees will be required to recognize, for all leases of 12 months or more, a liability to make lease payments and a right-of-use asset representing the right to use the underlying asset for the lease term. Additionally, the guidance requires improved disclosures to help users of financial statements better understand the nature of an entity's leasing activities. This ASU is effective for public reporting companies for interim and annual periods beginning after December 15, 2018, with early adoption permitted, and must be adopted using a modified retrospective approach. The standard will be effective for the Company on January 1, 2019. The Company is currently assessing the impact of the standard, including optional practical expedients that the Company may elect upon adoption and is progressing with an implementation plan. The implementation plan includes identifying the Company's lease population, updating the Company's lease database and identifying changes to processes and controls. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

In May 2014, the Financial Accounting Standards Board (FASB) issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"). The Company adopted ASU 2014-09 and its related amendments (collectively known as ASC 606) effective on January 1, 2018 using the modified retrospective method. See Note 4 "Revenue from Contracts with Customers" for the required disclosures related to the impact of adopting this standard and a discussion of the Company's updated policies related to revenue recognition.

4. Revenue from Contracts with Customers

Financial Statement Impact of Adopting ASC 606

On January 1, 2018, the Company adopted ASC 606 applying the modified retrospective method, which only impacted the accounting for the KHK License Agreement. As a result of applying the modified retrospective method to adopt the new revenue guidance, the following adjustments were made to accounts on the consolidated balance sheet as of January 1, 2018:

	As Reported at December 31, 2017	Adjustments Due to ASC 606	Balance at January 1, 2018
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Current portion of deferred revenue	1,573	(56)	1,517
Total current liabilities	15,798	(56)	15,742
Long-term liabilities:			
Deferred revenue, less current portion	16,759	(593)	16,166
Total long-term liabilities	17,069	(593)	16,476
Total liabilities	32,867	(649)	32,218
Stockholders' equity:			
Accumulated deficit	(366,111)	649	(365,462)
Total stockholders' equity	104,319	649	104,968
Total liabilities and stockholders' equity	$ 137,186	—	$ 137,186

Impact of New Revenue Guidance on Financial Statement Line Items

Results for reporting periods beginning after January 1, 2018 were presented under Topic 606, while prior period amounts were not adjusted and reported under the accounting standards in effect for the prior periods. The following tables show the impact on the reported condensed consolidated balance sheet for the nine months ended September 30, 2018, and the statement of income for the three and nine months ended September 30, 2018, for pro-forma amounts had the previous guidance been in effect (in thousands):

Financial Statement Line Item *	**Increase (Decrease)**	
Condensed Consolidated Statement of Income	**Three months ended September 30, 2018**	**Nine months ended September 30, 2018**
License fee	(14)	(42)
Net loss	(14)	(42)
Comprehensive loss	(14)	(42)

Condensed Consolidated Balance Sheet **	**September 30, 2018**
Current portion of deferred revenue	(56)
Deferred revenue, less current portion	(551)
Accumulated deficit	607

* Excludes line items that were not affected by the Company's adoption of ASC 606. The adoption had no impact to cash provided by or used in net operating, investing or financing activities in the Condensed Consolidated Statement of Cash Flows.

** Balance sheet line item amounts include the cumulative-effect adjustment recorded on December 31, 2017.

Impact to KHK License Agreement Revenue

Under ASC 606, the Company determined that the performance obligations associated with the KHK 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 KHK 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, as opposed to the initial delivery of the clinical trial materials in June 2015. 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 KHK 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 though 2029. In 2017, KHK 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 KHK 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 KHK, 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.

Contract liabilities consisted of deferred revenue, as presented on the consolidated balance sheet, as of September 30, 2018. Deferred revenue related to the KHK License Agreement was $16.5 million as of September 30, 2018 and will be recognized over the remainder of the contract term. The Company recognized license fees revenue of $0.4 million during the three months ended September 30, 2018 that was included in the deferred revenue balance as of January 1, 2018.

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,	
	2018	2017	2018	2017
	(In thousands, except share and per share data)		(In thousands, except share and per share data)	
Numerator—basic and diluted:				
Net loss	$ (17,338)	$ (15,088)	$ (55,124)	$ (41,699)
Net loss attributable to common stockholders—basic and diluted	$ (17,338)	$ (15,088)	$ (55,124)	$ (41,699)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.68)	$ (0.68)	$ (2.21)	$ (2.08)
Denominator—basic and diluted:				
Weighted-average number of common shares used to compute net loss per share attributable to common stockholders—basic and diluted	25,471,587	22,239,996	24,888,738	20,004,409

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,	
	2018	2017
Options to purchase common stock	4,272,646	3,286,936
Common stock warrant	—	357,840
Employee Stock Purchase Plan	29,736	11,321

6. Significant Agreements

Vitae Pharmaceuticals, Inc.

In October 2017, the Company entered into a license agreement (the "Allergan License Agreement") with Vitae Pharmaceuticals, Inc., a subsidiary of Allergan plc ("Allergan"), under which Allergan granted the Company an exclusive, sublicensable, worldwide license to a portfolio of preclinical, orally available, small molecule inhibitors of the interaction of Menin with the Mixed Lineage Leukemia ("MLL") protein (the "Menin Assets"). The Company made a nonrefundable upfront payment of $5.0 million to Allergan in the fourth quarter of 2017. Additionally, subject to the achievement of certain milestone events, the Company may be required to pay Allergan up to $99.0 million in one-time development and regulatory milestone payments over the term of the Allergan License Agreement. In the event that the Company or any of its affiliates or sublicensees commercializes the Menin Assets, the Company will also be obligated to pay Allergan low single to low double-digit royalties on sales, subject to reduction in certain circumstances, as well as up to an aggregate of $70.0 million in potential one-time, sales-based milestone payments based on achievement of certain annual sales thresholds. Under certain circumstances, the Company may be required to share a percentage of non-royalty income from sublicensees, subject to certain deductions, with Allergan. The Company is solely responsible for the development and commercialization of the Menin Assets. Each party may terminate the Allergan License Agreement for the other party's uncured material breach or insolvency; and the Company may terminate the Allergan License Agreement at will at any time upon advance written notice to Allergan. Allergan may terminate the Allergan License Agreement if the Company or any of its affiliates or sublicensees institutes a legal challenge to the validity, enforceability, or patentability of the licensed patent rights. Unless terminated earlier in accordance with its terms, the Allergan License Agreement will continue on a country-by-country and product-by-product basis until the later of: (i) the expiration of all of the licensed patent rights in such country; (ii) the expiration of all regulatory exclusivity applicable to the product in such country; and (iii) 10 years from the date of the first commercial sale of the product in such country. As of the date of the Allergan License Agreement, the asset acquired had no alternative future use nor had it reached a stage of technological feasibility. As the processes or activities that were acquired along with the license do not constitute a "business," the transaction has been accounted for as an asset acquisition.

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 SNDX-6352, 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 SNDX-6352, 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 SNDX-6352, except that UCB is performing a limited set of transitional chemistry, manufacturing and control tasks related to SNDX-6352. 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 has been recorded as research and development expense in the condensed consolidated statement of comprehensive loss.

Kyowa Hakko Kirin Co., Ltd.

On December 19, 2014 (the "Effective Date"), the Company entered into the KHK License Agreement, under which the Company granted KHK an exclusive license to develop and commercialize entinostat in Japan and Korea. Under the terms of the KHK 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 KHK 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, KHK will receive the right to the intellectual property when and if available. KHK will conduct the development, regulatory approval filings, and commercialization activities of entinostat in Japan and Korea. KHK 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, KHK 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 KHK 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, KHK paid the Company a $5.0 million milestone payment which the Company received in December 2017. Please refer to Note 4, Revenue from Contracts, for further discussion related to the accounting for the milestone.

In October 2016, the Company entered into a clinical trial co-funding agreement with KHK under which the Company expanded its clinical trial agreement with Eastern Cooperative Oncology Group (the "ECOG Agreement") to include enrollments from sites in Korea.

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. During the second quarter of 2016, the ECOG Agreement was amended to provide additional study activities and the contractual obligation increased by $0.8 million. During the first quarter of 2017, the ECOG Agreement was amended to expand the study to include enrollments from sites in Korea and to provide additional study activities and the contractual obligation increased by $2.0 million. As of September 30, 2018, the Company's aggregate payment obligations under this agreement were approximately $24.3 million; and its remaining payment obligations are approximately $10.2 million over an estimated period of approximately three years.

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. In June 2014, a development milestone was achieved, and the Company recorded $2.0 million of research and development expense, which has been fully paid.

In connection with the Bayer Agreement, the Company issued to Bayer a warrant to purchase the number of shares of the Company's common stock equal to 1.75% of the shares of common stock outstanding on a fully diluted basis as of the earlier of the date the warrant was exercised or the closing of the IPO. The warrant contained anti-dilution protection to maintain Bayer's potential ownership at 1.75% of the shares of common stock outstanding on a fully diluted basis, requiring that the actual number of shares of common stock issuable pursuant to the warrant be increased or decreased for any changes in the fully diluted shares of common stock outstanding. The warrant was exercisable at an exercise price of $1.54 per share and would have expired upon the earlier of the 10-year anniversary of the closing of the IPO or the date of the consummation of a disposition transaction. The warrant was classified as a long-term liability and recorded at fair value with the changes in the fair value recorded in other expense. The Company used the Black-Scholes option-pricing model to determine the fair value of the warrant. Upon the closing of the IPO, the anti-dilution protection for the warrant expired, resulting in the reclassification of the warrant liability to additional paid-in capital. The warrant was re-measured using current assumptions just prior to the reclassification. On March 1, 2018, Bayer notified the Company of its election to exercise the warrant utilizing the net exercise feature contained therein, resulting in the Company's issuance to Bayer of 299,215 shares of the Company's common stock for no net cash proceeds.

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 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:

	Total Carrying Value	Fair Value Measurements Using: Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	(In thousands)			
September 30, 2018				
Assets:				
Cash and cash equivalents	$ 26,705	$ 25,706	$ 999	$ —
Short-term investments	62,894	—	62,894	—
Total assets	$ 89,599	$ 25,706	$ 63,893	$ —
December 31, 2017				
Assets:				
Cash and cash equivalents	$ 35,168	$ 24,972	$ 10,196	$ —
Short-term investments	94,806	—	94,806	—
Long-term investments	3,246	—	3,246	—
Total assets	$ 133,220	$ 24,972	$ 108,248	$ —

Cash of $25.7 million and $25.0 million as of September 30, 2018 and December 31, 2017, 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 $1.0 million and $10.2 million as of September 30, 2018 and December 31, 2017, 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 $62.9 million and $94.8 million as of September 30, 2018 and December 31, 2017, respectively, and long-term investments of $3.2 million as of December 31, 2017 consisted of commercial paper and highly rated corporate bonds 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, 2018, 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 nine months ended September 30, 2018 and 2017. 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, 2018, 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)			
September 30, 2018				
Commercial paper	$ 31,725	$ 2	$ (12)	$ 31,715
Corporate bonds	32,203	1	(26)	$ 32,178
	$ 63,928	$ 3	$ (38)	$ 63,893
December 31, 2017				
Commercial paper	$ 36,567	$ —	$ (40)	$ 36,527
Corporate bonds	71,824	—	(103)	71,721
	$ 108,391	$ —	$ (143)	$ 108,248

8. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	September 30, 2018	December 31, 2017
	(In thousands)	
Short-term deposits	$ 1,925	$ 1,286
Prepaid clinical supplies	2,106	220
Interest receivable on investments	254	377
Reimbursable costs	1,142	1,029
Prepaid insurance	379	192
Other	340	258
Total prepaid expenses and other current assets	$ 6,146	$ 3,362

9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2018	December 31, 2017
	(In thousands)	
Accrued professional fees	$ 624	$ 265
Accrued compensation and related costs	2,321	2,393
Accrued clinical costs	9,043	9,177
Other	331	158
Total accrued expenses and other current liabilities	$ 12,319	$ 11,993

10. Stock-Based Compensation

In January 2018, the number of shares of common stock available for issuance under the 2015 Omnibus Incentive Plan ("2015 Plan"), was increased by 975,601 shares due to the automatic annual provision to increase shares available under the 2015 Plan. As of September 30, 2018, the total number of shares of common stock available for issuance under the 2015 Plan was 1,403,338. The Company recognized stock-based compensation expense related to the issuance of stock option awards to employees and non-employees and related to the 2015 Employee Stock Purchase Plan ("ESPP") in the condensed consolidated statements of comprehensive loss as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(In thousands)		(In thousands)	
Research and development	$ 472	$ 355	$ 1,440	$ 985
General and administrative	1,265	991	3,289	3,185
Total	$ 1,737	$ 1,346	$ 4,729	$ 4,170

Compensation expense by type of award in the three and nine months ended September 30, 2018 and 2017 was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(In thousands)		(In thousands)	
Stock options	$ 1,701	$ 1,329	$ 4,635	$ 4,153
Employee Stock Purchase Plan	36	17	94	17
Total	$ 1,737	$ 1,346	$ 4,729	$ 4,170

During the three and nine months ended September 30, 2018, the Company granted 76,000 and 1,049,400 stock options to certain executives and employees. The grant date fair value of the options granted in the nine months ended September 30, 2018, was $6.5 million, or $6.17 per share on a weighted-average basis and will be recognized as compensation expense over the requisite service period of three to four years.

No options were exercised in the three months ended September 30, 2018 and 7,850 options exercised during the nine months ended September 30, 2018, resulting in total proceeds of $26,000. The intrinsic value of the options exercised was $91,000. In accordance with the Company's policy, the shares were issued from a pool of shares reserved for issuance under the 2007 and 2015 Plans.

As of September 30, 2018, there was $10.3 million of unrecognized compensation cost related to employee and non-employee unvested stock options and unvested restricted stock share-based compensation arrangements granted under the 2015 and 2007 Plans, which is expected to be recognized over a weighted-average remaining service period of 2.5 years. Stock compensation costs have not been capitalized by the Company.

11. Employee Stock Purchase Plan

In January 2018, the number of shares of common stock available for issuance under the ESPP, was increased by 243,900 shares as a result of the automatic increase provision of the ESPP. As of September 30, 2018, the total number of shares of common stock available for issuance under the ESPP was 651,453. The Company issued 24,684 shares during the first nine months of 2018.

The ESPP is considered a compensatory plan with the related compensation cost expensed over the six-month offering period starting on February 1 and on August 1. The compensation expense related to the ESPP for the three and nine months ended September 30, 2018 was approximately $36,000 and $94,000, respectively. The compensation expense related to the ESPP recorded in the three and nine months ended September 30, 2017 was approximately $17,000.

12. Stockholders' Equity

The following table presents the changes in stockholders' equity for the nine months ended September 30, 2018:

(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, 2017	24,390,033	$ 2	$ 470,571	$ (143)	$ (366,111)	$ 104,319
Stock purchase under ESPP	24,684	—	—	—	—	—
Proceeds from 'At-the-market' offering, net	1,329,582	—	9,438	—	—	9,438
Stock-based compensation expense	—	—	4,729	—	—	4,729
Stock issuance due to warrant exercise, cashless	299,215	—	—	—	—	—
Proceeds from exercise stock options	7,850	—	26	—	—	26
Unrealized gains on short-term investments	—	—	—	108	—	108
Employee withholdings ESPP	—	—	129	—	—	129
Cumulative effect adjustment of adoption ASU 2014-09	—	—	—	—	649	649
Retirement of common stock in exchange for common stock warrant[1]	(2,000,000)	—	(16,780)	—	—	(16,780)
Issuance of common stock warrant in exchange for retirement of common stock[1]	—	—	16,780	—	—	16,780
Net loss	—	—	—	—	(55,124)	(55,124)
Balance as of September 30, 2018	24,051,364	$ 2	$ 484,893	$ (35)	$ (420,586)	$ 64,274

[1] On June 18, 2018, the Company signed an exchange agreement with Biotechnology Value Fund and certain affiliated funds ("BVF") under which BVF exchanged 2,000,000 shares of common stock for 2,000,000 warrant shares. The Company recorded the issuance of the warrants and the retirement of the common stock at fair value within additional paid-in capital. BVF can exercise the warrant shares at an exercise price per share equal to $0.0001 per share and the warrant shares expire 20 years from issuance. Per the terms of the warrant agreement, the outstanding warrants to purchase shares of common stock may not be exercised if the holder's ownership of the Company's common stock would exceed 9.99 percent following such exercise.

In April 2017, the Company entered into a sales agreement with Cowen and Company, LLC ("Cowen") under which the Company may issue and sell shares of our common stock having aggregate sales proceeds of up to $50.0 million from time to time through Cowen, acting as agent, in a series of one or more at-the-market ("ATM") equity offerings. 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. In the third quarter of 2018, the Company sold 1,329,582 shares of common stock under the ATM program for net proceeds of $9.4 million. In the fourth quarter of 2018, through November 2, 2018, the Company sold 784,587 shares of common stock under the ATM program for net proceeds of $6.1 million. As of November 2, 2018, we have $32.1 million of common stock available for sale under the ATM program.

13. Income Taxes

The Company has not recorded any net tax provision for the periods presented due to the losses incurred and the need for a full valuation allowance on net deferred tax assets. The difference between the income tax expense at the U.S. federal statutory rate and the recorded provision is primarily due to the valuation allowance provided on all deferred tax assets.

In the first quarter of 2018 we completed our evaluation of the accounting for the tax effects of enactment of the Tax Cuts and Jobs Act of 2017 (the "Act"). The only impact of the Act was the remeasurement of the Company's deferred tax assets and liabilities, which was recorded in fiscal 2017 as a result of the reduction in U.S. corporate tax rates from 35% to 21%. As of December 31, 2017, the Company determined it had no accumulated unrepatriated foreign earnings, and therefore had recorded no liability for the repatriation transition tax. No changes have been made to the estimates recorded in fiscal 2017.

14. Related-Party Transactions

The Company's chief executive officer and member of the board of directors is also a managing director at MPM Asset Management, LLC, which holds an investment in the Company's common stock.

15. Subsequent Events

The Company considers events and transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The Company has completed an evaluation of all subsequent events through the date of this filing of this Quarterly Report on Form 10-Q.

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 8, 2018.

Overview

We are a clinical stage biopharmaceutical company developing an innovative pipeline of cancer therapies. We are developing our lead product candidate, entinostat, a once-weekly, oral, small molecule, Class I HDAC inhibitor, in combination with exemestane and several approved PD-1/PD-L1 antagonists. Our pipeline also includes SNDX-6352, a monoclonal antibody that blocks the colony stimulating factor 1 (CSF-1) receptor, as well as a portfolio of potent and selective inhibitors targeting the binding interaction of Menin with MLLr. We plan to continue to leverage the technical and business expertise of our management team and scientific collaborators to license, acquire and develop additional cancer therapies 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, 2018 and 2017, we reported a net loss of $55.1 million and $41.7 million, respectively. As of September 30, 2018, we had an accumulated deficit of $420.6 million, which included non-cash charges for stock-based compensation, preferred stock accretion and extinguishment charges. As of September 30, 2018, we had cash, cash equivalents and short-term investments of $89.6 million.

Clinical Developments

Entinostat

- At the International Association for the Study of Lung Cancer (IASLC) 19th World Conference on Lung Cancer (WCLC) in September, we presented data from the full cohort of PD-(L)1 refractory non-small cell lung cancer (NSCLC) patients enrolled in the ENCORE 601 trial of entinostat in combination with *Keytruda*. The data continued to support the prior observation of enhanced clinical benefit in a subpopulation of patients with elevated baseline levels of peripheral classical blood monocytes. In October, we announced plans to commence a focused, biomarker-driven, randomized registration trial comparing the entinostat-pembrolizumab combination to standard of care chemotherapy in patients whose disease has progressed after both platinum-based chemotherapy and PD-1 antagonist therapy. The trial will seek to validate peripheral classical monocytes as a marker of response to the combination and to determine whether the combination can improve progression free survival (PFS) over standard of care chemotherapy in the high monocyte population. We anticipate beginning the trial in the first half of 2019.
- In October, we announced that enrollment in E2112 has concluded, the Phase 3 registration trial of entinostat plus exemestane in advanced hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+, HER2-) breast cancer, with a total of 608 patients enrolled. ECOG-ACRIN and NCI informed us that the trial did not meet the statistical hurdle for the first primary endpoint of improving PFS, which would have provided the earliest regulatory filing opportunity. Following the most recent interim overall survival (OS) analysis conducted by the trial's Data Safety Monitoring Committee, ECOG-ACRIN also informed us that the trial is continuing as planned, with the next interim analysis for the OS primary endpoint scheduled for the second quarter of 2019. Additional interim analyses will be conducted every six months until either an OS benefit is observed, or the final target number of events occur. E2112 was designed, and obtained Breakthrough Therapy Designation for this indication, based on positive Phase 2b OS results. Any positive OS assessment would enable us to file for full regulatory approval.
- We will make a decision later this year on next steps for entinostat in combination with *Keytruda* in melanoma patients whose disease has progressed following PD-1 therapy.
- Enrollment in the expanded stage 1 ENCORE 601 cohort of patients with microsatellite stable colorectal cancer (MSS-CRC, n = 37) is now complete. A decision on whether to continue to the second stage of this cohort is expected in the first quarter of 2019.
- Target enrollment is complete in both the Phase 2 portion of ENCORE 602, the Phase 1b/2 clinical trial evaluating the combination of entinostat plus Genentech's PD-(L)1 inhibitor, *Tecentriq*, in patients with triple negative breast cancer, and the Phase 2 portion of ENCORE 603, evaluating entinostat in combination with Pfizer/Merck KGaA's PD-(L)1 inhibitor, *Bavencio*, in patients with ovarian cancer. Topline results for ENCORE 603 are expected in the first quarter of 2019, with topline results from ENCORE 602 to follow in the second quarter of 2019.

- ENCORE 606, the Phase 1b/2 trial evaluating entinostat in combination with NKTR-214, Nektar's CD122-biased agonist, is expected to begin enrolling patients with melanoma whose disease has progressed after PD-1 antagonist therapy in the second quarter of 2019.

SNDX-6352

- Enrollment has recently been initiated in the Phase 1 dose escalation trial of SNDX-6352, our anti-CSF-1R monoclonal antibody, in patients with chronic graft versus host disease (cGVHD). The objectives of this trial are to evaluate the safety and preliminary efficacy of SNDX-6352 in cGVHD and to identify a recommended Phase 2 dose and schedule. Initial results are anticipated in the second half of 2019.
- A Phase 1/1b dose escalation study evaluating the safety of SNDX-6352 remains ongoing with patients continuing to receive doses of SNDX-6352 alone or in combination with *Imfinzi*, AstraZeneca's human monoclonal antibody directed against PD-L1. We anticipate identifying the recommended Phase 2 dose and schedule for SNDX-6352 monotherapy and in combination with durvalumab in the second quarter of 2019.

Menin-MLLr Inhibitor Portfolio

- Development of our portfolio of Menin-Mixed Lineage Leukemia (MLLr) inhibitors is ongoing, and we have selected a lead compound, SNDX-5613, to continue through IND-enabling studies. We expect to file an IND with the FDA and initiate a Phase 1 clinical trial in patients with a defined subset of acute leukemias in the second quarter of 2019.
- Our Menin-MLLr program will be featured in two presentations at the upcoming 60th American Society of Hematology Annual Meeting & Exposition being held December 1-4, 2018 in San Diego.

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, 2018 and 2017 have been solely derived from our license agreement with Kyowa Hakko Kirin Co., Ltd., or KHK, under which we granted KHK an exclusive license to develop and commercialize entinostat in Japan and Korea, or the KHK license agreement. In 2015, we received a $25.0 million upfront payment from KHK, 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 KHK's purchase of shares of our convertible preferred stock.

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. From inception through September 30, 2018, we have incurred $195.9 million in research and development expenses.

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 Income, Net

Interest income consists of interest income earned on our cash, cash equivalents and short-term investment balances. Interest expense consists primarily of interest expense on capital leases.

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. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued research and development expenses and stock-based compensation. 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.

Our significant accounting policies are more fully described in Note 3 of the accompanying unaudited condensed consolidated financial statements and in Note 3 to the audited consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 8, 2018. There have been no material changes to our significant accounting policies from those described in Note 3 to the audited consolidated financial statements or 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, except as set forth below.

Revenue from Contracts with Customers

On January 1, 2018, we adopted Financial Accounting Standards Board Accounting Standards Codification Topic 606, Revenue from Contracts with Customers, or ASC 606 using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. The provisions of ASC 606 supersedes the revenue recognition requirements in Topic 605 "Revenue Recognition," and requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The adoption of ASC 606 requires us to provide expanded disclosures related to our contracts with customers but did not have a material impact on the Company's consolidated financial position, results of operations, equity or cash flows as of the adoption date or for the periods presented.

For license fee revenues, we applied and may continue to apply significant judgment to our KHK Agreement. We evaluated whether our contractual obligations represented distinct performance obligations. Such evaluation required judgment since it was made from the customer's perspective. We determined that our performance obligations under the collaboration at contract inception were not distinct and represented a single performance obligation. The KHK agreement also includes variable consideration. We assess variable consideration at each reporting period as to whether it is not subject to significant future reversal and, therefore, should be included in the transaction price. For development milestones related to the KHK Agreement, the Company does not take a substantive role or control the research, development or commercialization of any products generated by KHK. Therefore, the Company is not able to reasonably estimate when, if at all, any development milestone payments may be payable to the Company. As such, the development milestone payments associated with the KHK Agreement involve a substantial degree of uncertainty and risk that they may never be received. Sales-based milestones and royalties will be recognized as royalty revenue in the period the related sale occurred.

Results of Operations

Comparison of the three months ended September 30, 2018 and 2017:

	Three Months Ended September 30,		Increase (Decrease)	
	2018	2017	$	%
	(In thousands)			
Revenue:				
License fees	$ 379	$ 305	$ 74	24%
Total revenues	379	305	74	24%
Operating expenses:				
Research and development	14,095	12,188	1,907	16%
General and administrative	4,125	3,563	562	16%
Total operating expenses	18,220	15,751	2,469	16%
Loss from operations	(17,841)	(15,446)	2,395	16%
Other income (expense):				
Interest income, net	488	411	77	19%
Other income (expense)	15	(53)	68	-128%
Total other income	503	358	145	41%
Net loss	(17,338)	$ (15,088)	$ 2,250	15%

License Fees

For the three months ended September 30, 2018 and 2017, we recognized license fees of $0.4 million and $0.3 million respectively, derived from the KHK license agreement.

Research and Development

For the three months ended September 30, 2018, our total research and development expenses increased $1.9 million, or 16%, to $14.1 million from $12.2 million for the comparable quarter in the prior year due to an increase in development activities of $0.8 million and increased employee compensation expense of $1.2 million. The increase in development activities was primarily due to increases in spending related to the development of the Menin program and increased activities in 602 ENCORE trial partially offset by completion of Phase 1 clinical pharmacology trials and decrease in E2112 costs. The increase in employee compensation costs was primarily due to increased headcount. We expect R&D 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)	
	2018	2017	$	%
	(In thousands)			
External research and development expenses	$ 10,156	$ 10,408	$ (252)	-2%
Internal research and development expenses	3,939	1,780	2,159	121%
Total research and development expenses	$ 14,095	$ 12,188	$ 1,907	16%

General and Administrative

For the three months ended September 30, 2018, our total general and administrative expenses increased $0.6 million, or 16%, to $4.1 million from $3.6 million for the comparable period in the prior year. The increase in general and administrative expenses was primarily due to an increase employee related expenses of $0.3 million and in professional and legal fees of $0.2 million. The increase in professional fees was primarily due to pre-commercialization activities. The increase in legal fees is primarily due to an increase in patent related legal expenses.

Interest Income, Net

For the three months ended September 30, 2018, interest income, net, increased $0.1 million from the comparable period in the prior year. The increase was primarily due to increased yield on our cash, cash equivalents and short-term investments.

Comparison of the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,		Increase (Decrease)	
	2018	2017	$	%
	(In thousands)			
Revenue:				
License fees	$ 1,138	$ 915	$ 223	24%
Total revenues	1,138	915	223	24%
Operating expenses:				
Research and development	44,286	31,603	12,683	40%
General and administrative	13,395	11,777	1,618	14%
Total operating expenses	57,681	43,380	14,301	33%
Loss from operations	(56,543)	(42,465)	14,078	33%
Other income (expense):				
Interest income, net	1,422	959	463	48%
Other expense	(3)	(193)	190	-98%
Total other income	1,419	766	653	85%
Net loss	(55,124)	$ (41,699)	$ 13,425	32%

License Fees

For the nine months ended September 30, 2018 and 2017, we recognized license fees of $1.1 million and $0.9 million, respectively, derived from the KHK license agreement.

Research and Development

For the nine months ended September 30, 2018, our total research and development expenses increased $12.7 million, or 40%, to $44.3 million from $31.6 million for the comparable period in the prior year due to increases in development expenses of $6.2 million, employee compensation expense of $3.9 million, professional fees of $2.4 million and facility costs of $0.3 million. The increase in development expenses was primarily due to increases in spending related the increased manufacturing costs for SNDX-6352, development of the Menin program and increased activities in ENCORE 602 and ENCORE 603 partially offset by completion of Phase 1 clinical pharmacology trials and decrease in E2112 costs. The increase in employee compensation costs was primarily due to increased headcount. The increase in professional fees was primarily due to the increase in New Drug Application (NDA) preparation activities and medical communication. We expect R&D expenses to fluctuate from quarter to quarter depending on the timing of clinical trial activities, clinical manufacturing and other development activities.

	Nine Months Ended September 30,		Increase (Decrease)	
	2018	2017	$	%
	(In thousands)			
External research and development expenses	$ 32,571	$ 24,846	$ 7,725	31%
Internal research and development expenses	11,715	6,757	4,958	73%
Total research and development expenses	$ 44,286	$ 31,603	$ 12,683	40%

General and Administrative

For the nine months ended September 30, 2018, our total general and administrative expenses increased $1.6 million, or 14%, to $13.4 million, from $11.8 million for the comparable period in the prior year. The increase in general and administrative expenses was primarily due to increases in legal expenses and professional fees of $1.2 million and employee related expenses of $0.4 million. The increase in professional fees was primarily due to pre-commercialization activities. The increase in legal fees is primarily due to an increase in patent related legal expenses.

Interest Income, Net

For the nine months ended September 30, 2018, interest income, net, increased $0.5 million from the comparable period in the prior year. The increase was primarily due to increased yield on our cash, cash equivalents and short-term investments.

Liquidity and Capital Resources

As of September 30, 2018, we had cash, cash equivalents and short-term investments totaling $89.6 million. Since our inception, our operations have been primarily financed by net proceeds from our IPO, our follow-on stock offering, sale of convertible preferred stock and convertible debt securities and proceeds from our license agreements. 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. 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.

In March 2016, we completed our IPO whereby we sold 4,809,475 shares of our common stock at the price of $12.00 per share, resulting in total net proceeds of $50.5 million, after deducting underwriting discounts and commissions and offering expenses. In May 2017, we completed a follow-on public offering whereby we sold 3,950,190 shares of our common stock at a price of $13.25 per share, resulting in total net proceeds of $48.7 million, net of underwriting discounts and commissions and offering expenses. In October 2017, we issued to BVF 2,021,018 shares of our common stock at a price of $12.37 per share. Net proceeds after deducting expenses were approximately $24.9 million.

In April 2017, we entered into a sales agreement with Cowen under which we may issue and sell shares of our common stock having aggregate sales proceeds of up to $50.0 million from time to time pursuant to the 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-3 (Registration No. 333-217172), which was declared effective on April 20, 2017. Our common stock will be sold at prevailing market prices at the time of the sale; and as a result, prices may vary. We will pay Cowen up to 3% of the gross proceeds from any common stock sold through the sales agreement. The proceeds from the offerings, if any, will be used for general corporate purposes, including expenditures for research and development of the Company's drug products. During the nine months ended September 30, 2018, the Company sold 1,329,582 shares of common stock, with net proceeds of $9.4 million. As of September 30, 2018, $38.4 million of common stock remained available for sale under the ATM program. In the fourth quarter of 2018, up to November 2, 2018, we have sold an additional 784,587 shares of our common stock with net proceeds of approximately $6.1 million. As of November 2, 2018, we have $32.1 million of common stock available for sale under the ATM program.

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 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.

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, 2018, we had an accumulated deficit of $420.6 million. We anticipate that we will continue to incur significant losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase. As a result, we will need additional capital to fund our operations, which we may raise through a combination of the sale of equity, debt financings, or other sources, including potential collaborations. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or drug candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following is a summary of cash flows:

	Nine Months Ended September 30,	
	2018	2017
	(In thousands)	
Net cash used in operating activities	$ (53,488)	$ (34,649)
Net cash provided by (used in) investing activities	35,436	(18,622)
Net cash provided by financing activities	9,584	50,108
Net decrease in cash, cash equivalents and restricted cash	$ (8,468)	$ (3,163)

Net Cash Used in Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2018 was $53.5 million and primarily consisted of our net loss of $55.1 million adjusted for non-cash items, including stock-based compensation of $4.7 million, net decrease in operating assets and liabilities of $2.8 million and a net decrease in investment amortization of $0.3 million. The increase in our net loss was primarily due to the increase in our clinical trial activities and CMC expenses. The significant items in the decrease in operating assets and liabilities included an increase in prepaid expenses and other assets of $2.8 million and a decrease in deferred revenue of $1.1 million partially offset by an increase in accounts payable, accrued expenses and other liabilities of $1.1 million.

Net cash used in operating activities for the nine months ended September 30, 2017 was $34.6 million and primarily consisted of our net loss of $41.7 million adjusted for non-cash items including stock-based compensation of $4.2 million and a net increase in operating assets and liabilities of $2.6 million. The increase in our net loss was primarily due to the increase in our clinical trial activities and increase in headcount. The significant items in the increase in operating assets and liabilities included an increase in prepaid expenses and other assets of $0.2 million and a decrease in deferred revenue of $0.9 million offset by an increase in accrued expenses and other liabilities of $4.0 million.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2018 was $35.4 million and was primarily due to the $95.8 million of proceeds from the maturities of available-for-sale securities partially offset by the purchase of $60.1 million of available-for-sale marketable securities and purchase of equipment.

Net cash used in investing activities for the nine months ended September 30, 2017 was $18.6 million and was primarily due to the $94.4 million of proceeds from the maturities of available-for-sale securities partially offset by the purchase of $113.0 million of available-for-sale marketable securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2018 of $9.6 million was primarily due to proceeds from sales of shares of common stock under our at-the-market offering, net of discounts and commissions of $9.4 million and purchases pursuant to our 2015 Employee Stock Purchase Plan of $0.1 million.

Net cash provided by financing activities for the nine months ended September 30, 2017 of $50.1 million was primarily due to proceeds from our follow-on offering, net of underwriting discounts and commissions of $48.7 million, proceeds from sales of shares

of common stock under our at-the-market offering, net of discounts and commissions of $1.1 million, and the exercise of stock options of $0.3 million.

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations from those described in our Annual Report on Form 10-K that was filed with the SEC on March 8, 2018.

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.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. 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.

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, 2018, we had cash and cash equivalents of $26.7 million, consisting of overnight investments, interest-bearing money market funds, commercial papers and short-term corporate bonds and short-term investments of $62.9 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 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, 2018, 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, 2018, 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.

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, 2018, 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.

Risks Related to Our Business and Industry

If the Phase 3 clinical trial of entinostat in combination with exemestane in advanced HR+, HER2- breast cancer patients fails to demonstrate safety and efficacy to the satisfaction of regulatory authorities or does not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of entinostat.

Before obtaining marketing approval from regulatory authorities for the sale of entinostat, we or our collaborators must conduct extensive trials to demonstrate the safety and efficacy of entinostat in humans. We have entered into an arrangement with ECOG-ACRIN to conduct the Phase 3 clinical trial of entinostat in combination with exemestane in advanced HR+, HER2- breast cancer patients. The trial is measuring two primary endpoints of progression-free survival, or PFS, and overall survival. We received the final PFS analysis from ECOG-ACRIN in October 2018 and we expect to receive the final overall survival analysis no later than the end of 2020. In October 2018, ECOG-ACRIN informed us that the trial did not achieve the statistical hurdle for the first primary endpoint of improving PFS, which would have provided the earliest regulatory filing opportunity. In accordance with the trial protocol, ECOG-ACRIN is confidentially holding the findings from the PFS analysis until reporting final overall survival results. We will not be able to submit an NDA unless and until we receive data demonstrating that the trial has achieved the primary endpoint for overall survival. In addition, based on scientific advice that we received from the European Medicines Agency in March 2014, the current Phase 3 clinical trial is not likely to be sufficient to receive regulatory approval in Europe for entinostat to treat advanced HR+, HER2- breast cancer, and it is unclear whether we would be able to complete an alternate clinical trial that would be sufficient.

Despite the results reported in our Phase 2b clinical trial for entinostat in advanced estrogen receptor positive, or ER+, breast cancer, we do not know whether the Phase 3 clinical trial in advanced HR+, HER2- breast cancer will demonstrate adequate efficacy and safety to result in regulatory approval to market entinostat in any particular cancer indications or jurisdiction. Additionally, while we do not expect that there will be overlapping toxicities between entinostat and exemestane, we cannot be certain that we will not observe these toxicities or unexpected side effects in the Phase 3 clinical trial.

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, with the emergence of the new therapies such as *Verzenio*, *Kisqali* and *Ibrance*, patients enrolled in the Phase 3 clinical trial may be different than those enrolled in our previous Phase 2b clinical trial in that they may have received a CDK 4/6 inhibitor prior to our trial and therefore may respond differently to treatment with entinostat. 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.

The failure of ECOG-ACRIN or the NCI to adequately perform its obligations and responsibilities in the conduct of the Phase 3 clinical trial or to meet expected deadlines could substantially harm our business because we may not obtain regulatory approval for entinostat in a timely manner, or at all.

We have entered into an arrangement with ECOG-ACRIN, pursuant to which it, with sponsorship and funding support by the NCI, is conducting the Phase 3 clinical trial of entinostat in combination with exemestane in advanced HR+, HER2- breast cancer patients. While we provide operational and logistical support for the trial, we have limited control of their activities. We cannot control whether ECOG-ACRIN will devote sufficient time and resources to the trial, including as a result of any reduction or delay in government funding or sponsorship of the activities of ECOG-ACRIN or the NCI. If ECOG-ACRIN or the NCI does not successfully carry out its obligations and responsibilities or meet expected deadlines or if the quality or accuracy of the clinical data that ECOG-ACRIN obtains is compromised due to the failure to adhere to cGMPs, clinical protocols, regulatory requirements or for other reasons, the Phase 3 clinical trial may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, entinostat. As a result, our results of operations and the commercial prospects for entinostat would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Although the Phase 3 clinical trial is being conducted by ECOG-ACRIN, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on ECOG-ACRIN does not relieve us of our regulatory responsibilities. We are required to comply with Good Clinical Practice, or GCP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and foreign regulatory authorities for any product in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we fail to comply with applicable GCP, the clinical data generated in our trials may be deemed unreliable and the FDA or foreign regulatory authorities may require us to perform additional trials before approving our marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our trials comply with GCP requirements. In addition, we must conduct our trials with products produced under cGMP requirements. Failure to comply with any of these regulations may require us to repeat preclinical and clinical trials, which would delay the regulatory development process.

If there are delays in completing the Phase 3 clinical trial for entinostat in advanced HR+, HER2- breast cancer, we will be delayed in commercializing entinostat, our development costs may increase and our business may be harmed.

The Phase 3 clinical trial of entinostat in combination with exemestane in advanced HR+, HER2- breast cancer commenced in the second quarter of 2014, and we expect to receive the final overall survival analysis no later than the end of 2020. Our product development costs could increase if we experience delays in the overall number of survival events. Significant trial delays also could shorten any periods during which we may have the exclusive right to commercialize entinostat or allow our competitors to bring products to market before we do, which would impair our ability to successfully capitalize on entinostat and may harm our business, results of operations and prospects. Events that may result in a delay or unsuccessful completion of clinical development of entinostat include, among other things:

- unexpectedly high rate of patients withdrawing consent or being lost to follow-up, including patients that withdraw or are lost to follow-up following our announcement in October 2018 that the trial did not achieve the statistical hurdle for the first primary endpoint of improving PFS;
- feedback from the FDA and foreign regulatory authorities, institutional review boards, or IRBs, or the data safety monitoring board, or results from clinical trials that might require modification to a clinical trial protocol;
- imposition of a clinical hold by the FDA or other regulatory authorities, a decision by the FDA, other regulatory authorities, IRBs or the company, or a recommendation by a data safety monitoring board to suspend or terminate trials at any time for safety issues or for any other reason;
- deviations from the trial protocol by clinical trial sites and investigators or failure to conduct the trial in accordance with regulatory requirements;
- failure of third parties, such as ECOG-ACRIN or contract research organizations, or CROs, to satisfy their contractual duties or meet expected deadlines;
- withdrawal of sponsorship of the NCI because of a failure of ECOG-ACRIN to meet certain performance metrics in the clinical trial;
- delays in the testing, validation, manufacturing and delivery of entinostat to the clinical trial sites;
- delays caused by patients dropping out of a trial due to side effects or disease progression;
- unacceptable risk-benefit profile or unforeseen safety issues or adverse side effects;

- failure to demonstrate the efficacy of entinostat in this clinical trial; or
- changes in government regulations or administrative actions or lack of adequate funding to continue the trials.

An inability by us to timely complete clinical development could result in additional costs to us or impair our ability to generate product revenues or development, regulatory, commercialization and sales milestone payments and royalties on product sales.

Although the NCI has entered into a Special Protocol Assessment, or SPA, agreement with the FDA relating to the pivotal Phase 3 clinical trial of entinostat for advanced HR+, HER2- breast cancer, this agreement does not guarantee any particular outcome with respect to regulatory review of the trial or any associated NDA for entinostat.

The protocol for the pivotal Phase 3 trial of entinostat in combination with exemestane in advanced HR+, HER2- breast cancer was reviewed and agreed upon by the FDA under a SPA agreement with the NCI. The SPA agreement allows for FDA evaluation of whether a clinical trial protocol could form the primary basis of an efficacy claim in support of an NDA. The SPA is an agreement that a Phase 3 clinical trial's design, clinical endpoints, patient population and statistical analyses are sufficient to support the efficacy claim. Agreement on the SPA is not a guarantee of approval; and there is no assurance that the design of, or data collected from, the trial will be adequate to obtain the requisite regulatory approval. In October 2018, ECOG-ACRIN informed us that the trial did not achieve the statistical hurdle for the first primary endpoint of improving PFS, which would have provided the earliest regulatory filing opportunity. Further, obtaining clinical trial data meeting the overall survival endpoint in satisfaction of the SPA does not guarantee approval. The SPA is not binding on the FDA if public health concerns unrecognized at the time the SPA was entered into become evident or other new scientific concerns regarding product safety or efficacy arise. In addition, upon written agreement of both the FDA and the NCI, the SPA may be changed, and the FDA retains significant latitude and discretion in interpreting the terms of the SPA and any resulting trial data. As a result, we do not know how the FDA will interpret the parties' respective commitments under the SPA, how it will interpret the data and overall survival results from the pivotal Phase 3 clinical trial, whether the FDA will require that we conduct or complete one or more additional clinical trials to support potential approval or whether entinostat will receive any regulatory approvals. ECOG-ACRIN, with sponsorship and funding support from the NCI, is conducting the pivotal Phase 3 clinical trial, which began enrollment in the second quarter of 2014.

A breakthrough therapy designation by the FDA for entinostat may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that entinostat will receive marketing approval.

We received breakthrough therapy designation from the FDA for entinostat when used in combination with exemestane based on the overall survival results from our completed Phase 2b clinical trial in advanced HR+, HER2- breast cancer. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The Phase 2b trial showed statistically significant improvements in PFS, the primary endpoint, and overall survival, an exploratory endpoint. Receipt of a breakthrough therapy designation for a drug candidate may not result in a faster development process or review compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, the FDA may later decide that entinostat no longer meets the conditions for qualification or decide that the time period for FDA review will not be shortened. For instance, our Phase 3 trial in HR+, HER2- breast cancer patients failed to achieve one of its primary endpoints of improving PFS. We expect to receive final analysis on the second primary endpoint, overall survival, no later than the end of 2020. If the results do not confirm the improvement in overall survival observed in our Phase 2b clinical trial, the FDA may rescind our breakthrough therapy designation.

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 such 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 a significant 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 liability.

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.

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.

Entinostat, SNDX-6352 and the Menin Assets are currently our only product candidates. 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:

- timely commencement and completion of the Phase 1b/2 clinical trials of entinostat in combination with *Keytruda*, *Tecentriq*, *Bavencio*® (avelumab) and NKTR-214 and the Phase 1/1b clinical trials of SNDX-6352 as a monotherapy and in combination with durvalumab;
- timely completion of the Phase 3 clinical trial in advanced HR+, HER2- breast cancer, which has been significantly slower than we anticipated and will depend substantially upon the satisfactory performance of the ECOG-ACRIN and the NCI and other third-party contractors for entinostat;
- whether we are able to complete IND enabling studies for one of the Menin Assets and file a subsequent IND with the FDA;
- whether we are required by the FDA or foreign regulatory authorities to conduct additional clinical trials;
- the prevalence and severity of adverse side effects 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;
- achieving and maintaining compliance with all applicable regulatory requirements;
- 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 current Good Manufacturing Practices regulations, or cGMP;
- the availability of commercial supplies of therapeutics, including exemestane, *Keytruda*, *Tecentriq* and *Bavencio*, and clinical supplies of investigational drugs, to support the development and marketing of the entinostat therapy as a component of a combination drug regimen for entinostat;
- 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.

Our strategy of combining entinostat with immune checkpoint inhibitors has undergone limited clinical testing and we may fail to show that the combination is safe and well tolerated and demonstrates additional clinical benefit from the combination.

Preclinical studies conducted by us and others suggest a strong rationale for combining entinostat with immune checkpoint inhibitors, including PD1 pathway antagonists, to enhance the immune system's ability to detect and eliminate tumor cells. Our approach is to conduct Phase 1 and 2 clinical trials in patients with tumors that are known to be responsive to PD1 pathway antagonists and assess both the safety and efficacy of the combination of entinostat plus a PD1 pathway antagonist. Our initial clinical data is supportive of our hypothesis as we have seen clinical benefit from the combination of entinostat plus pembrolizumab in patients with metastatic melanoma and non-small cell lung cancer. However, we have not yet sufficiently demonstrated a favorable risk-benefit of this combination in patients, and we may be unable to establish sufficient efficacy to warrant regulatory submission and approval.

We may be unable to transfer, qualify and validate an assay for determining peripheral monocyte levels in our forthcoming NSCLC registration trial.

In October 2018, we announced that we are proceeding with a registration trial in NSCLC patients whose disease has progressed after both platinum-based combination chemotherapy and a PD1 antagonist therapy. We designed the trial to both validate a classical monocyte biomarker and demonstrate that the combination therapy of entinostat plus Keytruda is superior to standard of care chemotherapy in a high monocyte population. This trial will require testing patients for levels of circulating classical monocytes prior to treatment before assigning them to the appropriate arm of the trial. The assay that our academic collaborators have used to determine circulating levels of classical monocytes has not been developed or validated to the qualifications that the FDA may require for patient selection. We are working to measure circulating levels of cells, including monocytes, but we may not be able to successfully transfer, qualify and validate an assay for determining peripheral monocyte levels that will be acceptable to the FDA.

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:

- 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 with immuno-oncology agents;
- the size and nature of the patient population;
- 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 consents; 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 are dependent on Merck, Genentech, Merck KGaA, Pfizer, AstraZeneca, Nektar and any future collaborators to perform satisfactorily under our agreements.

Under the agreements with Merck, Genentech, Merck KGaA, Pfizer, AstraZeneca, Nektar and any future collaborations, we will be dependent on our collaborators' performance of their responsibilities and their cooperation with us. Our collaborators may not perform their obligations under our agreements with them or otherwise cooperate with us. We cannot control whether our collaborators will devote the necessary resources to the activities contemplated by our collaborative agreements, nor can we control the timing of their performance. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. Disputes may arise between us and our collaborators that delay the development and commercialization of our product candidates, disputes that may be difficult and costly to resolve, or may not be resolved. In addition, a collaborator for the potential product may have the right to terminate the collaboration at its discretion and, for example, Merck has the right to terminate the Merck agreement for any reason after a specified advance notice period. Any termination may require us to

seek a new collaborator, which we may not be able to do on a timely basis, if at all, or may require us to delay or scale back the commercialization efforts or spend additional money to complete the clinical trial. The occurrence of any of these events could adversely affect the commercialization of entinostat and materially harm our business.

If we are unable to enter into additional clinical collaborations with developers of immune checkpoint inhibitors or other combination therapies to explore the same or additional indications, the commercial potential of entinostat and SNDX-6352 could be limited. Such collaborations are complex, and any potential discussions may not result in a definitive agreement for many reasons. For example, whether we reach a definitive agreement for a clinical collaboration will depend, among other things, upon our respective assessments of the other party's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of our clinical trials, the potential market for the combination therapy, the costs and complexities of manufacturing and delivering the potential product to patients, the potential of competing products, and industry and market conditions generally.

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

We currently sublicense entinostat to third parties for development and commercialization in certain foreign jurisdictions. Specifically, we have a sublicense agreement with KHK under which we granted KHK an exclusive sublicense to develop and commercialize entinostat in Japan and Korea. It is possible that any clinical trials conducted by KHK 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 to comply with the terms of our license agreement for SNDX-6352.

Our commercial success also depends upon our ability to develop, manufacture, market and sell SNDX-6352. In July 2016, we entered into the UCB license agreement pursuant to which we obtained a worldwide, sublicenseable, exclusive license to SNDX-6352, an IND-ready anti-CSF-1R monoclonal antibody. Under the UCB license agreement, we are dependent on UCB's performance of its responsibilities and its cooperation with us. UCB may not perform its obligations under the UCB license agreement or otherwise cooperate with us. We cannot control whether UCB will devote the necessary resources to its obligations under the UCB license agreement, nor can we control the timing of its performance. For example, under the UCB license agreement, UCB has transferred to us certain data and materials, provided limited technical assistance and certain transitional services, and is manufacturing and supplying us with quantities of SNDX-6352, which we expect will assist us with the development, manufacture and commercialization of SNDX-6352. If UCB fails to supply us with sufficient quantities of SNDX-6352 to complete all planned Phase 1 and Phase 2 studies, our efforts to develop and commercialize SNDX-6352 may be delayed or may fail. Additionally, 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 SNDX-6352 may be terminated as well. The occurrence of any of these events could adversely affect the development and commercialization of SNDX-6352, and materially harm our business.

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 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.

Our product candidates could fail to receive regulatory approval from the FDA or foreign regulatory authorities for many 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 entinostat 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 entinostat, all of which could limit our ability to successfully commercialize our product candidates.

We are not developing entinostat as a monotherapy. A shortage in the supply of exemestane, Keytruda, Tecentriq, Bavencio, NKTR-214 or other drugs used in combination with entinostat or cessation of development efforts for investigational agents being studied with entinostat could increase our development costs and adversely affect our ability to commercialize entinostat, and any unexpected adverse events with any of the drugs used in combination with entinostat could halt or delay development of entinostat.

Cancer drugs have from time to time been in short supply and, because many or all of these cancer drugs are also widely used in cancer treatment currently, we will compete with a broad range of healthcare providers and other companies for availability of those drugs. Any shortage of exemestane, *Keytruda*, *Tecentriq*, *Bavencio*, NKTR-214 or other drugs that we are testing in combination with entinostat could adversely affect our ability to timely conduct the Phase 3 clinical trial in advanced HR+, HER2- breast cancer and the Phase 1b/2 clinical trials in NSCLC, melanoma, microsatellite stable colorectal cancer, ovarian cancer, and TNBC, and if entinostat receives regulatory approval, to commercialize entinostat for treatment of advanced HR+, HER2- breast cancer, NSCLC, melanoma, microsatellite stable colorectal cancer, ovarian cancer or TNBC. A shortage of supply may also result in an increase, which could be significant, in our costs of procuring exemestane.

Additionally, because entinostat is being developed for use in combination with other cancer treatments, the development of entinostat may be delayed or halted if unexpected adverse events occurring in patients are attributed to entinostat. Likewise, new adverse events emerging from commercialized or development stage drugs being administered with entinostat may limit or halt the potential of such combinations.

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;
- the availability of coverage and adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; 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. 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 closely monitor 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. 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 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. In our Phase 2b clinical trial of entinostat in advanced HR+, HER2- breast cancer, the most significant adverse events were fatigue, gastrointestinal disturbances and hematologic toxicities, all of which occurred in higher numbers than in the placebo group. 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. For example, based on scientific advice that we received from the European Medicines Agency in March 2014, the current Phase 3 clinical trial is likely to be insufficient to receive regulatory approval in Europe for entinostat to treat advanced HR+, HER2- breast cancer. 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.

The pharmacologic treatment of NSCLC, melanoma, microsatellite stable colorectal cancer, ovarian cancer and TNBC patients has included chemotherapies and therapies targeting specific gene mutations. Over the past few years, immune checkpoint inhibitors have been approved for NSCLC and melanoma and are under investigation for ovarian cancer, TNBC and microsatellite stable colorectal cancer. Currently there are few approved combination immuno-oncology therapies although numerous drugs are undergoing active clinical investigation. We believe that if entinostat in combination with either *Keytruda*, *Tecentriq* or *Bavencio* were approved for the treatment of NSCLC, melanoma, microsatellite stable colorectal cancer, ovarian cancer or TNBC, it would face competition from standard-of-care approaches and other investigational drugs being tested in combination with any of these approaches.

If entinostat in combination with exemestane were approved for treatment of advanced HR+, HER2- breast cancer, it could face competition from other therapies recently approved for use in combination with hormone therapy in this population, including *Ibrance*, *Kisqali*, *Afinitor*, *Verzenio*, and other therapies currently in Phase 3 clinical development such as alpelisib.

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

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

- the efficacy and safety profile of our product candidates relative to marketed products and product candidates in development by third parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- our ability to commercialize our product candidates if they receive regulatory approval;
- the price of our product candidates, including in comparison to branded or generic competitors;

- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- our ability to manufacture commercial quantities of our product candidates if they receive regulatory approval; and
- acceptance of entinostat in combination with exemestane, *Keytruda*, *Tecentriq*, *Bavencio* and other drugs by physicians and other healthcare providers.

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.

Adverse events in the field of immuno-oncology could damage public perception of our product candidates and negatively affect our business.

The commercial success of our product candidates will depend in part on public acceptance of the use of cancer immunotherapies. Adverse events in clinical trials of our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of immuno-oncology that may occur in the future, could result in a decrease in demand for any products that we may develop. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, our product candidates may not be accepted by the general public or the medical community.

Future adverse events in immuno-oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining regulatory approval for our product candidates.

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, 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 government healthcare programs, private health insurers, managed care plans and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Government authorities and other 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 entinostat or any other 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 the Centers for Medicare and Medicaid Services decisions 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. Some of the provisions of the Affordable Care Act have yet to be implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two 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 repealing, 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". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated by the Affordable Care Act, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the Affordable Care Act, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In addition, Congress may consider other legislation to repeal and replace elements of the Affordable Care Act. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on 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 Affordable Care Act'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 2027. 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's budget proposal for fiscal year 2019 contains additional drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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.

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.

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 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, 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 physicians, 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 and civil monetary penalties laws, including the federal civil False Claims Act, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for 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;
- HIPAA also imposes obligations on certain covered entity 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 with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, created as part of the Physician Payments Sunshine Act under Section 6002 of the Affordable Care Act and its implementing regulations, 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 the U.S. Department of Health and Human Services 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 the U.S. Department of Health and Human Services ownership and investment interests held by physicians (as defined above) and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state 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, individual 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.

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 entinostat. 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, 2018, we reported a net loss of $55.1 million; and as of September 30, 2018, we had an accumulated deficit of $420.6 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 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. 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. In addition, 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 reimbursement, 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; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems, as we grow our company.

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.

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, until such unused losses expire. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, 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, 2017 and determined that on March 30, 2007 and August 21, 2015 ownership changes had occurred. We did not experience ownership changes since August 21, 2015 but 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.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or the Tax Act, was signed into law. The Tax Act, among other things, contains significant changes to corporate taxation, including (i) reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, (ii) limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), (iii) limitation of the deduction for net operating losses to 80% of current year taxable income in respect of net operating losses generated during or after 2018 and elimination of net operating loss carrybacks, (iv) one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, (v) immediate deductions for certain new investments instead of deductions for depreciation expense over time, and (vi) modifying or repealing many business deductions and credits. Any federal net operating loss incurred in 2018 and in future years may now be carried forward indefinitely pursuant to the Tax Act. It is uncertain if and to

what extent various states will conform to the newly enacted federal tax law. We will continue to examine the impact the Tax Act may have on our business.

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 patent applications with pending claims directed to the composition of matter of SNDX-6352 (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 SNDX-6352. There is no guarantee that any 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 SNDX-6352 or methods of using SNDX-6352. Based on the priority date and filing date of the applications in the portfolio we licensed from UCB, we expect that a patent, 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, a subsidiary of Allergan, includes patent 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 patents will be granted based on the pending applications that we licensed from Allergan 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 Allergan, we expect that a patent, if any, granted based on the currently pending applications would expire in 2036. The actual term of any patents granted based on the pending applications that we licensed from Allergan 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 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.

Our commercial success depends upon our ability to develop, manufacture, market and sell 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 $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.

If we breach the UCB license agreement related to SNDX-6352 or if the UCB license agreement is otherwise terminated, we could lose the ability to continue the development and commercialization of SNDX-6352.

Our commercial success depends upon our ability to develop, manufacture, market and sell SNDX-6352. 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 SNDX-6352, 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 SNDX-6352 have occurred and the last-to-expire relevant patent covering SNDX-6352 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 SNDX-6352 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 the Menin Assets or if the license agreement is otherwise terminated, we could lose the ability to continue the development and commercialization of the Menin Assets.

Our commercial success depends upon our ability to develop, manufacture, market and sell one or more of the Menin Assets. Subject to the achievement of certain milestone events, we may be required to pay Vitae, a subsidiary of Allergan, up to $99 million in one-time development and regulatory milestone payments over the term of the Allergan license agreement. In the event that we or any of our affiliates or sublicensees commercializes any of the Menin Assets, we will also be obligated to pay Allergan low single to low double-digit royalties on sales, subject to reduction in certain circumstances, as well as up to an aggregate of $70 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 Allergan.

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. Allergan may terminate the license agreement if we seek to revoke or challenge the validity of any patent licensed to us by Allergan 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 Allergan would expire because no commercial sales of the Menin Assets have occurred and the last-to-expire relevant patent covering the Menin Assets 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 any of the Menin Assets 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.

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. 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.

Risks Related to Ownership of Our Common Stock

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.

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. Broad market and industry factors 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. In April 2017, we filed a shelf registration statement on Form S-3 (Registration No. 333-217172) that allows us to sell up to an aggregate of $200 million of our common stock, which includes up to $50.0 million designated in the prospectus supplement for an at-the-market ("ATM") offering program. As of September 30, 2018, $38.4 million of common stock remained available for sale under the at-the-market offering program. In the fourth quarter of 2018, through November 2, 2018, we sold 784,587 shares of common stock under the ATM program for net proceeds of $6.1 million. As of November 2, 2018, we have $32.1 million of common stock available for sale under the ATM program. 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. If we raise additional funds through the issuance of additional debt or equity securities, it may result in dilution to our existing stockholders and/or increased fixed payment obligations. 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. 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 will likely 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 control over matters subject to stockholder approval.

As of September 30, 2018, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own approximately 48.0% of our outstanding voting stock and options and warrants to acquire stock. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control 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 may avail ourselves of reduced disclosure requirements applicable to emerging growth 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 would cease to be an "emerging growth company" upon the earliest of: (i) the first fiscal year following the fifth anniversary of our IPO; (ii) the first fiscal year after our annual gross revenues are $1.07 billion or more; (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities; or (iv) as of the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700 million as of the end of the second quarter of that fiscal year.

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.

We will continue to incur significant costs as a result of operating as a public company, and our management will devote substantial time to compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an "emerging growth company." We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and the Nasdaq Global Select Market.

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.

Some of the holders of our securities have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act except for shares held by our affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading 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 will be 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 will need 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. However, for as long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of the exemption permitting us not to comply with the independent registered public accounting firm attestation requirement.

Our compliance with Section 404 will require 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 begin its Section 404 reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the Nasdaq Global Select Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which we may establish and shares of which we may issue without stockholder approval;
- prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

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

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

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from Initial Public Offering of Common Stock

On March 8, 2016, we completed our IPO and sold 4,400,000 shares of common stock at the initial public offering price of $12.00 per share. On March 11, 2016, we sold an additional 409,475 shares of our common stock at the initial public offering price of $12.00 per share as a result of the partial exercise by the underwriters of their option purchase additional shares of common stock. We received net proceeds from the IPO of approximately $50.5 million, after deducting underwriting discounts, commissions and offering expenses. None of these expenses consisted of payments made by us to directors, officers or persons owning 10% or more of our common stock or to their associates, or to our affiliates. The offer and sale of the shares in our IPO were registered pursuant to our Registration Statement on Form S-1 (File No. 333-208861), which was declared effective by the SEC on March 2, 2016. Morgan Stanley and Citigroup acted as joint book-running managers for the offering, and JMP Securities and Oppenheimer & Co. acted as co-managers for the offering. There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on March 3, 2016, pursuant to Rule 424. We invested the funds received in cash equivalents and other short-term investments in accordance with our investment policy. As of September 30, 2018, we have used approximately $48.1 million of the proceeds from the IPO and as such, the balance of the net proceeds is included as cash, cash equivalents and short-term investments.

Item 6. Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-37708), as filed with the SEC on March 8, 2016).
3.2	Amended and Restated Bylaws of the Company (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-37708), as filed with the SEC on March 8, 2016).
4.1	Specimen Common Stock Certificate of the Company (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A (File No. 333-208861), as filed with the SEC on February 10, 2016).
4.2	Form of Warrant to purchase Common Stock issued pursuant to the Exchange Agreement between the Company and Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P. and Biotechnology Value Trading Fund OS, L.P., dated June 18, 2018 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-37708), as filed with the SEC on June 20, 2018).
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Financial statements from the Quarterly Report on Form 10-Q of Syndax Pharmaceuticals, Inc. for the quarter ended September 30, 2018, formatted in XBRL (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.

* Furnished herewith and not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

Date: November 5, 2018

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

By: /s/ Richard P. Shea
Richard P. Shea
Chief Financial Officer and Treasurer
(Principal Executive Officer and Principal Accounting Officer)

Exhibit 31.1

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 5, 2018

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

Exhibit 31.2

CERTIFICATIONS

I, Richard P. Shea, 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 5, 2018

By: /s/ Richard P. Shea
Richard P. Shea
Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Syndax Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2018, 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 5, 2018

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

Date: November 5, 2018

By /s/ Richard P. Shea
Richard P. Shea
Chief Financial Officer and Treasurer