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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED September 30, 2019
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 001-39044

SPRINGWORKS THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	83-4066827
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
100 Washington Blvd Stamford, Connecticut	06902
(Address of principal executive offices)	**(Zip Code)**

(203) 883-9490
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	SWTX	The Nasdaq Global Select Market

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 (§ 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, a 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 financial 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 ☒

The number of outstanding shares of the Registrant's Common Stock as of November 12, 2019 was 43,006,077.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “should”, “expects”, “intends”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “potential”, “continue” or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and clinical trials, including statements regarding the timing of our ongoing Phase 3 clinical trial of nirogacestat, Phase 2b clinical trial of mirdametinib and the initiation and completion of any other clinical trials and related preparatory work, the expected timing of the availability of results of the clinical trials and the potentially registrational nature of the single Phase 3 clinical trial and the Phase 2b clinical trial;
- the potential attributes and benefits of our product candidates;
- our plans to commercialize any of our product candidates that achieve approval either alone or in partnership with others;
- our ability to obtain funding for our operations, including funding necessary to complete further development of our product candidates, and if approved, commercialization;
- the period over which we anticipate the proceeds of the initial public offering, together with our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditure requirements;
- the potential for our business development efforts to maximize the potential value of our portfolio;
- our ability to identify, in-license or acquire additional product candidates;
- the ability and willingness of our third-party collaborators to continue research and development activities relating to our product candidates that we are developing as combination therapies;
- our ability to obtain and maintain regulatory approval for our product candidates, and any related restrictions, limitations or warnings in the label of an approved product candidate;
- the potential benefit of Orphan Drug Designation, Fast Track Designation and Breakthrough Therapy Designation for nirogacestat, mirdametinib and any other of our product candidates that may receive one or more of these designations;
- our ability to compete with companies currently marketing or engaged in the development of treatments for desmoid tumors or NF1-PN;
- our expectations regarding our ability to obtain and maintain intellectual property protection or market exclusivity for our product candidates and the direction of such protection;
- our ability and the potential to successfully manufacture our product candidates for preclinical studies, clinical trials and, if approved, for commercial use, the capacity of our current contract manufacturing organizations, or CMOs, to support clinical supply and commercial-scale production for product candidates and our potential election to pursue additional CMOs for manufacturing supplies of drug substance and finished drug product in the future;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets, either alone or in partnership with others;
- the rate and degree of market acceptance of our product candidates, if approved;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the success of competing products that are or may become available;
- our ability to attract and retain key scientific, medical, commercial or management personnel;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- our use of the proceeds from the initial public offering.

Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events and with respect to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part II, Item 1A, Risk Factors and elsewhere in this Quarterly Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

We may from time to time provide estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this Quarterly Report. Unless otherwise expressly stated, we obtained this industry, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

SPRINGWORKS THERAPEUTICS, INC.
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2019
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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

SpringWorks Therapeutics, Inc.
Consolidated Balance Sheets
(in thousands, except share, unit, per-share and per-unit data)

	September 30, 2019 (unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 343,825	$ 45,648
Prepaid expenses and other current assets	689	1,382
Total current assets	344,514	47,030
Property and equipment, net	820	317
Investment in VIE (MapKure)	999	-
Other assets	2,062	1,043
Total Assets	$ 348,395	$ 48,390
Liabilities, Convertible Preferred Stock and Stockholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 2,157	$ 774
Accrued expenses	7,682	2,568
Deferred rent	356	335
Total current liabilities	10,195	3,677
Long-term portion of deferred rent	881	1,152
Total liabilities	11,076	4,829
Commitments and contingencies		
Convertible Preferred Stock:		
Series A convertible preferred stock, $0.0001 par value; no shares authorized, issued or outstanding at September 30, 2019 and December 31, 2018, respectively.	-	-
Series A convertible preferred units, no par value, net of issuance costs; no units authorized, issued and outstanding at September 30, 2019; 103,000,000 units authorized; 63,600,000 units issued and outstanding at December 31, 2018.	-	62,930
Stockholders' (deficit) equity:		
Junior Series A convertible preferred stock, no par value; no shares authorized, issued or outstanding at September 30, 2019 and December 31, 2018, respectively.	-	-
Junior Series A convertible preferred units, no par value; no units authorized, issued or outstanding at September 30, 2019; 6,437,500 units authorized, issued and outstanding at December 31, 2018.	-	2,014
Common stock, $0.0001 par value, 150,000,000 shares authorized, 43,233,387 shares issued and outstanding, at September 30, 2019; no shares authorized, issued or outstanding at December 31, 2018.	4	-
Common units, no par value; no units authorized, issued or outstanding at September 30, 2019; 195,638 units authorized, issued and outstanding at December 31, 2018.	-	-
Additional paid-in capital	394,127	1,069
Accumulated deficit	(56,812)	(22,452)
Total stockholders' (deficit) equity	337,319	(19,369)
Total liabilities, convertible preferred stock and stockholders' (deficit) equity	$ 348,395	$ 48,390

See accompanying unaudited notes to consolidated financial statements

SpringWorks Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss (unaudited)
(in thousands, except share, unit, per-share and per-unit data)

	Three Months ending September 30, 2019	Three Months ending September 30, 2018	Nine Months ending September 30, 2019	Nine Months ending September 30, 2018
Operating expenses:				
Research and development	$ 10,745	$ 3,406	$ 30,373	$ 6,192
General and administrative	4,584	1,824	11,495	5,852
Total operating expenses	15,329	5,230	41,868	12,044
Loss from operations	(15,329)	(5,230)	(41,868)	(12,044)
Other income:				
Interest income, net	997	226	2,280	450
Total other Income	997	226	2,280	450
Equity investment loss	(2,501)	-	(2,501)	-
Net loss	$ (16,833)	$ (5,004)	$ (42,089)	$ (11,594)
Reconciliation of net loss to net loss attributable to common stockholders:				
Net loss	$ (16,833)	$ (5,004)	$ (42,089)	$ (11,594)
Net gain attributable to extinguishment of Series A convertible preferred and Junior Series A convertible preferred shares	-	-	7,729	-
Net loss attributable to common stockholders, basic and diluted	$ (16,833)	$ (5,004)	$ (34,360)	$ (11,594)
Net loss per unit, basic and diluted	-	$ (11.55)	-	$ (44.20)
Net loss per share, basic and diluted	$ (1.77)	-	$ (9.24)	-
Weighted average common units outstanding, basic and diluted	-	433,401	-	262,273
Weighted average common shares outstanding, basic and diluted	9,487,329	-	3,716,877	-

See accompanying unaudited notes to consolidated financial statements

SpringWorks Therapeutics, Inc.
Consolidated Statements of Preferred Stock and Members'/Stockholders' Deficit
(unaudited)
(in thousands, except share, unit, per-share and per-unit data)

	Series A & B convertible preferred		Junior Series A convertible preferred		Common				
	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total
Balance at December 31, 2017	13,200,001	12,554	6,437,500	2,014	-	-	-	(4,639)	(2,625)
Issuance of Series A convertible preferred units, net	50,399,999	50,376	-	-	-	-	-	-	-
Issuance of common units to founders	-	-	-	-	195,638	-	-	-	-
Issuance of incentive units	-	-	-	-	1,732,491	-	609	-	609
Net loss	-	-	-	-	-	-	-	(6,590)	(6,590)
Balance at June 30, 2018	63,600,000	62,930	6,437,500	2,014	1,928,129	-	609	(11,229)	(8,606)
Issuance of incentive units	-	-	-	-	1,212,062	-	234	-	234
Net loss	-	-	-	-	-	-	-	(5,004)	(5,004)
Balance at September 30, 2018	63,600,000	62,930	6,437,500	2,014	3,140,191	-	843	(16,233)	(13,376)
Issuance of incentive units					42,725		226	(6,219)	(5,993)
Incentive units forfeited during the period	-	-	-	-	(81,710)	-	-	-	-
Balance at December 31, 2018	63,600,000	62,930	6,437,500	2,014	3,101,206	-	1,069	(22,452)	(19,369)
Issuance of Series A convertible preferred shares, net	39,400,000	39,367	-	-	-	-	-	-	-
Issuance of Series B convertible preferred shares, net of $413,063 in legal costs	86,639,279	124,590	-	-	-	-	-	-	-
Series A convertible preferred extinguishment	-	(9,597)	-	-	-	-	-	9,597	9,597
Junior Series A convertible preferred extinguishment	-	-	-	1,868	-	-	-	(1,868)	-
Stock-based compensation, net of forfeiture	-	-	-	-	(12,570)	-	1,371	-	1,371
Net loss	-	-	-	-	-	-	-	(25,256)	(25,256)
Balance at June 30, 2019	189,639,279	217,290	6,437,500	3,882	3,088,636	-	2,440	(39,979)	(33,657)
Issuance of common stock upon closing of initial public offering, net of $16,570 in issuance cost	-	-	-	-	10,350,000	1	169,729	-	169,730
Stock-based compensation	-	-	-	-	-	-	788	-	788
Conversion of convertible preferred stock into common stock	(189,639,279)	(217,290)	(6,437,500)	(3,882)	29,794,359	3	221,169	-	217,290
Exercise of stock options	-	-	-	-	392	-	1	-	1
Net loss	-	-	-	-	-	-	-	(16,833)	(16,833)
Balance at September 30, 2019	-	-	-	-	43,233,387	4	394,127	(56,812)	337,319

See accompanying unaudited notes to consolidated financial statements

SpringWorks Therapeutics, Inc.
Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Nine Months ending September 30, 2019	Nine Months ending September 30, 2018
Operating Activities		
Net loss	$ (42,089)	$ (11,594)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	127	9
Stock compensation expense	2,159	843
Equity investment loss	2,501	-
Changes in Operating Assets and Liabilities		
Prepaid expenses and other current assets	693	(1,361)
Other assets	(1,019)	(542)
Accounts payable	1,383	(44)
Accrued expenses	5,114	1,478
Deferred rent	(250)	-
Net cash used in operating activities	(31,381)	(11,211)
Investing activities		
Purchases of property and equipment	(630)	-
Investment in MapKure	(3,500)	-
Net cash used in investing activities	(4,130)	-
Financing Activities		
Proceeds from issuance of common stock, net of issuance costs	169,730	-
Proceeds from issuance of Series A convertible preferred shares, net of issuance costs	39,367	50,400
Proceeds from issuance of Series B convertible preferred shares, net of issuance costs	124,590	-
Proceeds from stock option exercises	1	-
Net cash provided by financing activities	333,688	50,400
Net increase in cash and cash equivalents	298,177	39,189
Cash and cash equivalents, beginning of period	45,648	10,271
Cash and cash equivalents, end of period	343,825	49,460

See accompanying unaudited notes to consolidated financial statements

1. Nature of Operations

SpringWorks Therapeutics, Inc. (The "Company") was formed in Delaware on August 18, 2017 ("Inception").

Prior to March 29, 2019, the Company conducted its business through SpringWorks Therapeutics, LLC, a Delaware limited liability company. On March 29, 2019, it completed a series of transactions pursuant to which SpringWorks MergerSub LLC, a wholly owned subsidiary of SpringWorks Therapeutics, Inc., merged with SpringWorks Therapeutics, LLC, with SpringWorks Therapeutics, LLC surviving the merger as a wholly owned subsidiary of SpringWorks Therapeutics, Inc. (the "Reorganization").

The Company is a clinical-stage biopharmaceutical company focused on identifying, developing and commercializing therapies for underserved patient populations suffering from severe rare diseases and cancer. The Company has a pipeline of product candidates across various stages of development, currently focused on rare disease and oncology conditions. Two of the programs are late stage clinical product candidates: nirogacestat and mirdametinib.

Initial Public Offering

On September 12, 2019, the Company completed an initial public offering (IPO) of its common stock. In connections with its IPO, the Company issued and sold 10,350,000 shares of its common stock at a price to the public of $18.00 per share. The net proceeds from the IPO were approximately $169.7 million after deducting underwriting discounts and commissions of $13.0 million and offering expenses of approximately $3.5 million.

At the closing of the IPO, 196,076,779 shares of outstanding convertible preferred stock were automatically converted into 29,794,359 shares of common stock at a conversion rate of one-for-6.5810. Following the IPO, there were no shares of preferred stock outstanding.

Reverse Stock Split

In August 2019, the Company's Board of Directors and stockholders approved a one-for-6.5810 reverse stock split of the Company's common stock. The reverse stock split became effective on August 30, 2019. Stockholders entitled to a fractional share as a result of the reverse stock split will receive a cash payment in lieu of the fractional shares at the initial public offering price.

All common stock share and per share amounts in the consolidated financial statements and notes thereto have been retroactively adjusted, where applicable for all periods presented to give effect to the reverse stock split. The shares of common stock retained a par value of $0.0001 per share.

2. Risks and Liquidity

The Company has incurred losses and negative operating cash flows since Inception and had an accumulated deficit of $56.8 million and $22.5 million and working capital of $334.3 million and $43.4 million at September 30, 2019 and December 31, 2018, respectively. The Company is subject to those risks associated with any biopharmaceutical company that has substantial expenditures for development. There can be no assurance that the Company's development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its employees, advisors, consultants and vendors.

The Company had cash and cash equivalents of $343.8 million and $45.6 million as of September 30, 2019 and December 31, 2018, respectively. In March 2019, the company received $39.4 million in net proceeds from the issuance of the third tranche of Series A convertible preferred units and raised an aggregate of $124.6 million of net proceeds from its Series B convertible preferred stock financing. In September 2019, the Company completed its IPO whereby the Company sold an aggregate of 10,350,000 shares of its common stock for aggregate net proceeds of approximately $169.7 million. Based on the Company's cash and cash equivalents balance at September 30, 2019, management estimates that its cash and cash equivalents balance will enable it to meet operations expenses through at least twelve months after the date that the financial statements were available to be issued.

3. Summary of Significant Accounting Policies

Basis of Presentation

These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The consolidated financial statements include the accounts of the Company and all subsidiaries. All intercompany accounts and transactions have been eliminated.

The Company does not have any components of other comprehensive income recorded within its consolidated financial statements, and, therefore, does not separately present a statement of comprehensive income in its consolidated financial statements.

The Company's unaudited interim financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") for interim information and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (the "SEC") for reporting on Form 10-Q. Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been or omitted pursuant to such rules and regulations. These unaudited interim financial statements should be read in conjunction with the audited financial statements and related notes included in the Company's final prospectus for its IPO, dated September 12, 2019, and filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, accrued expenses, the valuation of equity-based compensation and deferred tax asset valuation allowance. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Actual results may differ from those estimates or assumptions.

The Company utilizes significant estimates and assumptions in determining the fair value of its common and incentive units, common stock, restricted stock and stock options. The Company has utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately Held Company Equity Securities Issued as Compensation (the "Practice Aid") to estimate the fair value of its common units and common stock. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold preferred units and convertible preferred stock, the rights and preferences of securities senior to the Company's common and incentive units, and common stock and restricted stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale. Significant changes to the key assumptions used in the valuations could result in different fair values at each valuation date.

Segment Information

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment operating exclusively in the United States.

Fair Value of Financial Instruments

Management believes that the carrying amounts of the Company's financial instruments, including accounts payable and accrued expenses, approximate fair value due to the short-term nature of those instruments. The Company follows the provisions of Financial Accounting Standards Board ("FASB") ASC Topic 820, "Fair Value Measurements and Disclosures" (ASC 820), for financial assets and liabilities measured on a recurring basis. This pronouncement defines fair value, establishes a framework for measuring fair value under U.S. GAAP and requires expanded disclosures about fair value measurements. The guidance requires that fair value measurements be classified in one of the following three categories:

Level 1— Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets, or liabilities.

Level 2 — Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the instrument.

Level 3 — Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The Company considers all highly liquid instruments that have maturities of three months or less when acquired to be cash equivalents. The Company had cash and cash equivalents at September 30, 2019 of $343.8 million (unaudited) consisting of money market funds and are measured at fair value at the reporting date using quoted prices in active markets for identical assets (Level 1). The Company has no other financial assets or liabilities that are measured at fair value on a recurring basis.

Cash and Cash Equivalents

The Company considers all highly liquid instruments that have original maturities of three months or less when acquired to be cash equivalents. The Company had cash and cash equivalents at September 30, 2019 of $343.8 million. The Company maintains its bank accounts at one major financial institution.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains each of its cash and cash equivalent balances with high quality, financial institutions and, accordingly, such funds are not exposed to significant credit risk. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Research and Development Costs

Research and Development Costs consist of expenses incurred in performing development activities, including salaries and benefits, equity-based compensation expenses, materials and supplies, preclinical expenses, clinical trial and related clinical manufacturing expenses, depreciation of equipment, contract services and other outside expenses. Costs for certain development activities, such as manufacturing and clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using either time-based measures or data such as information provided to the Company by its vendors on their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued development expenses. Nonrefundable advance payments for goods or services to be received in the future for use in development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

Equity-Based Compensation

The Company accounts for employee equity-based compensation in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic (“ASC”) 718, Compensation — Stock Compensation. ASC 718 requires all equity-based awards to employees and non-employee directors to be recognized as expense in the statement of operations based on the grant date fair value of the common and incentive unit, unit option, restricted stock and stock option awards. Equity-based awards vest over a four-year period. Generally, onboarding equity-based awards vest with the first 25% vesting following 12 months of employment or service and the remaining vesting in equal quarterly installments over the following 36 months. Certain restricted stock and stock options are subject to performance conditions and/or market conditions.

Stock compensation expense is recognized using the straight-line method, based on the grant date fair value, over the requisite service period of the award, which is generally the vesting term.

For awards subject to performance conditions, as well as awards containing both market and performance conditions, the Company recognizes equity award compensation expense using an accelerated recognition method over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the expected satisfaction of the performance conditions as of the reporting date.

The Company recognizes forfeitures at the time of the actual forfeiture event in accordance with the adoption of the guidance per Accounting Standard Update ("ASU") No. 2016-09.

The grant-date fair value of performance-based awards with market conditions is estimated using a Monte Carlo simulation method that incorporates the probability of the performance conditions being met as of the grant date.

For stock options issued, the Company estimates the grant date fair value and the resulting stock-based compensation expense using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the use of subjective assumptions which determine the fair value of stock-based awards, including the expected term and the price volatility of the underlying stock. The Company lacks company specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly-traded set of peer companies and expects to continue to do so until it has adequate historical data regarding the volatility of its own traded stock price.

Net Loss per Unit and Share

Basic net loss per unit and per share is computed by dividing net loss by the weighted average number of common units and shares outstanding for the period. Diluted net loss per unit and share excludes the potential impact of convertible preferred units, unvested incentive units, convertible preferred stock, unvested restricted stock and stock options because their effect would be anti-dilutive due to the Company's net loss. Since the Company had a net loss in each of the periods presented, basic and diluted net loss per common unit and share are the same.

Income Taxes

Income taxes are accounted for using the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized as income in the period that includes the enactment date. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes.

The Company recognizes deferred tax assets to the extent that we believe that these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies and results of recent operations. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions in accordance with ASC 740 on the basis of a two-step process in which (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions. These reserves are based on a determination of whether and how much of a tax benefit taken by the Company in its filings or positions is more likely than not to be realized following resolution of any potential contingencies related to the tax benefit. Potential interest related to the underpayment of income taxes will be classified as a component of income tax expense and any related penalties will be classified in income tax expenses in the statement of operations**.**

SpringWorks Therapeutics, LLC elected to be treated under the partnership provisions of the Internal Revenue Service Code prior to the reorganization in March 29, 2019. However, its five wholly owned subsidiaries, SpringWorks Operating Company, SpringWorks Subsidiary 1, SpringWorks Subsidiary 2, SpringWorks Subsidiary 3, and SpringWorks Subsidiary 4, ("Combined Subsidiaries") are taxable corporations.

As of December 31, 2018, the Combined Subsidiaries had federal, state and city net operating loss carryforwards of $14.2 million, $0.6 million and $3.8 million, respectively, which are available to reduce future taxable income. Federal net operating loss carryforwards of $4.3 million were reported in 2017 and the state and city net operating loss carryforwards expire at various dates through 2038. Federal net operating loss carryforwards of $9.9 million reported in 2018 will be available to offset 80% of taxable income for an indefinite period of time, until fully utilized. The Combined Subsidiaries also have federal tax credits of $0.4 million, which may be used to offset future tax liabilities. These tax credit carryforwards will expire in 2038.

Recently Issued Accounting Pronouncements (not yet adopted)

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"). ASU No. 2014-09 eliminated transaction- and industry-specific revenue recognition guidance under FASB ASC Subtopic 605-15, Revenue Recognition-Products and replaced it with a principle-based approach for determining revenue recognition. The new standard requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. ASU 2014-09 defines a five-step approach for recognizing revenue, which may require a company to use more judgment and make more estimates than under the current guidance. The standard is effective for annual periods beginning after December 15, 2018. The Company is currently evaluating the impact that ASU 2014-09 will have, if any, on its financial position, results of operations or cash flows.

In February 2016, the FASB issued ASU 2016-02 “Leases (Topic 842).” This standard requires entities that lease assets to recognize on the balance sheet the assets and liabilities of the rights and obligations created by those leases. The standard is effective for annual periods beginning after December 15, 2019 and interim periods within annual periods beginning after December 15, 2020 for private companies. Early adoption is permitted. The Company will use the new transition option and is also utilizing the package of practical expedients that allows it to not reassess: (1) whether any expired or existing contracts are or contain leases, (2) lease classification for any expired or existing leases, and (3) initial direct costs for any expired or existing leases. The Company additionally expects to use the practical expedient that allows it to treat the lease and non-lease components of its leases as a single component. The Company has identified two leasing arrangements and is currently assessing the financial impact on the consolidated balance sheet. The Company qualifies as an emerging growth company (“EGC”) as defined under the Jumpstart Our Business Startups Act (the “JOBS Act”). Using exemptions provided under the JOBS Act provided to EGCs, the Company has elected to defer compliance with new or revised financial accounting standards until it is required to comply with such standards.

In June 2018, the FASB issued ASU No. 2018-07, Improvements to Nonemployee Share-Based Payment Accounting (“ASU 2018-07”). ASU 2018-07 expands the scope of Topic 718, Compensation – Stock Compensation, to include share-based payments issued to non-employees for goods or services. Consequently, non-employees and employees will be substantially aligned. ASU 2018-07 supersedes Subtopic 505-50, Equity – Equity-Based Payments to Non-Employees. The amendments are effective for fiscal years beginning after December 15, 2018. Early adoption is permitted, but not earlier than the adoption of Topic 606, Revenue from contracts with customers.

In August 2016, the FASB issued ASU 2016-15 “Statement of Cash Flows (Topic 230) — Classification of Certain Cash Receipts and Cash Payments.” This standard requires entities that must present a statement of cash flows under Topic 230 to classify certain cash receipts and cash payments using a standardized method. The standard is effective for annual periods beginning after December 15, 2018 and the interim periods within annual periods beginning after December 15, 2019. The guidance is required to be applied by the retrospective transition approach. Early adoption is permitted. The Company is currently assessing the impact of the adoption of this authoritative guidance on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract (“ASU 2018-15”). The FASB issued ASU 2018-15 to align the requirements for capitalizing implementation costs incurred in a cloud-based hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. ASU 2018-15 is effective for annual and interim reporting periods beginning after December 15, 2019, and early adoption is permitted. The amendments under ASU 2018-15 may be applied either retrospectively or prospectively to all implementation costs incurred after adoption. The Company is evaluating the impact of ASU 2018-15 on its financial statements and the timing of adoption.

4. Property and Equipment

Property and equipment, net consisted of the following:

(in thousands)	September 30, 2019	December 31, 2018
Leasehold improvements	816	293
Computer equipment	121	27
Furniture	31	18
	968	338
Less accumulated depreciation	(148)	(21)
	820	317

Depreciation expense was $126,997 and $9,325 for the nine months ended September 30, 2019 and September 30, 2018, respectively.

5. Accrued Expenses

Accrued expenses consisted of the following:

(in thousands)	September 30, 2019	December 31, 2018
Accrued professional fees	$ 850	$ 1,040
Accrued compensation and benefits	1,460	1,178
Accrued research and development	4,932	-
Accrued other	440	350
	$ 7,682	$ 2,568

6. Stockholders' Equity

In August 2017, the Company authorized the sale and issuance of up to 103,000,000 units of Series A convertible preferred units at $1.00 per unit for a total of $103 million of proceeds. The Series A convertible preferred financing was structured to close in three tranches.

The first tranche closed in August 2017, resulting in the issuance of 13,200,001 units of Series A convertible preferred units for gross cash proceeds of $13.2 million. In April 2018, the second tranche of 50,399,999 units of Series A convertible preferred were issued for $50.4 million in gross proceeds. In March 2019, the third tranche of 39,400,000 units of Series A convertible preferred units were issued for $39.4 million in gross proceeds.

In August 2017 and in conjunction with the formation of the Company and the License Agreements (see Note 8), the Company authorized and issued 6,437,500 units of Junior Series A convertible preferred units in exchange for four license agreements for the development and commercialization of products based on the inventions of Pfizer's researchers. No cash was received by the Company for these units.

In March 2019, the Company authorized the sale and issuance of up to 86,639,279 shares of convertible preferred stock. The Series B convertible preferred financing was closed in a single tranche at the price of $1.4428 per share for net proceeds of $124.6 million; issuance costs totaled $0.4 million.

The liquidation preference terms of each of the Series A convertible preferred stock and Junior Series A convertible preferred stock changed in connection with the issuance of Series B convertible preferred. Specifically, after receiving one times its original issue price, the Series A convertible preferred does not participate in the distribution with the Junior Series A convertible preferred prior to final distribution to all stockholders, and the Junior Series A convertible preferred does not participate with all other stockholders in the final distribution. The Company concluded that the changes in the Series A convertible preferred and Junior Series A convertible preferred liquidation preferences are a significant change in the economics of those instruments and therefore were accounted for as an extinguishment.

Following the reverse split of the Company's common stock in August 2019, every 6.5810 shares of Series A convertible preferred, Junior Series A convertible preferred and Series B convertible preferred became convertible into one common share at the option of the holder, subject to certain anti-dilution adjustments. The Series A convertible preferred, Junior Series A convertible preferred and Series B convertible preferred were mandatorily convertible in the event of an initial public offering, as defined. Upon completion of the Company's IPO in September 2019, all the outstanding preferred stock of the Company automatically converted into 29,794,359 shares of the Company's common stock.

On September 12, 2019, the Company completed an IPO of its common stock. In connections with its IPO, the Company issued and sold 10,350,000 shares of its common stock.

As of September 30, 2019, the Company has 150,000,000 shares authorized and 43,233,387 issued and outstanding common stock at $0.0001 par value.

7. Equity-Based Compensation

2018 Equity Plan

In January 2018, the Company adopted the 2018 Equity Incentive Plan (the "2018 Equity Plan"). There were 2,738,929 incentive units ("incentive units") initially available for issuance under the 2018 Equity Plan. The 2018 Plan was increased by 269,716 units for an aggregate of 3,008,645 as of December 31, 2018.

The Company issued 3,290,929 and cancelled 385,361 incentive units during the twelve months ended December 31, 2018. There were 103,077 incentive units available for issuance at December 31, 2018. The total unrecognized compensation related to unvested incentive units granted was $2.5 million at December 31, 2018, which the Company expects to recognize over a period of approximately 3.5 years.

On March 19, 2019, the Company modified its operating agreement to allow for the award of unit options and granted a total of 148,415 unit options to certain employees, directors and consultants.

2019 Equity Plan

On March 29, 2019, the Company adopted the 2019 Stock Option and Incentive Plan (the "2019 Private Company Plan") in connection with the Reorganization. The 2019 Private Company Plan originally had 5,292,355 shares available for issuance. In connection with the adoption of the 2019 Private Company Plan, all unit options granted on March 19, 2019 were exchanged for stock options, and all incentive units granted under the 2018 Equity Plan were exchanged for restricted stock. The restricted common stock was issued with the same vesting terms as the unvested incentive units held immediately prior to the Reorganization. On June 4, 2019, the total shares available for issuance under the 2019 Private Company Plan was increased to 5,382,828 shares. On July 29, 2019, the total shares available for issuance was increased to 6,700,197.

As of September 30, 2019 there were 2,892,998 shares of restricted stock and 3,023,714 shares of common stock issuable upon the exercise of outstanding stock option awards outstanding under the 2019 Equity Plan.

In connection with the IPO no modification was triggered for the 2019 Equity Plan and upon the effectiveness of the 2019 Public Company Plan (as defined below) no further grants will be made under the 2019 Private Company Plan. However, the shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2019 Private Company Plan will be added back to the shares of common stock available for issuance under the 2019 Public Company Plan.

2019 Equity Incentive Plan

In anticipation of the IPO, on August 30, 2019, the Company's stockholders approved the 2019 Stock Option and Equity Incentive Plan (the "2019 Public Company Plan"), which became effective upon the effectiveness of the Company's registration statement on September 12, 2019 in connection with the IPO.. The 2019 Public Company Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards and dividend equivalent rights to the Company's officers, employees, directors and other key persons (including consultants). The number of shares initially reserved for issuance under the 2019 Public Company Plan is 3,537,225 shares, which shall be cumulatively increased on January 1, 2019 and each January 1 thereafter by 5% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by the Company's compensation committee.

The terms of stock options and restricted stock awards, including vesting requirements, are determined by the Board of Directors or its delegates, subject to the provisions of the 2019 Public Company Plan. Stock options and restricted stock awards granted by the Company to employees and directors generally vest over four years.

As of September 30, 2019, there were 3,352,840 shares available for future issuance under the 2019 Plan.

2019 Employee Stock Purchase Plan

On August 30, 2019, the Company's stockholders approved the 2019 Employee Stock Purchase Plan (the "ESPP"), which became effective immediately preceding the effectiveness of the Company's registration statement on September 12, 2019 in connection with the IPO. A total of 442,153 shares of common stock were reserved for issuance under the ESPP. In addition, the number of shares of common stock that may be issued under the ESPP will automatically increase on January 1, 2019, and each January 1 thereafter through January 1, 2028, by the lesser of (i) 663,229 shares of common stock, (ii) 1% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or (iii) such lesser number of shares determined by the administrator of the Company's ESPP. No offering periods under the ESPP had been initiated as of September 30, 2019.

Stock Options

A summary of the changes in the Company's stock options during the period nine months ended September 30, 2019:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	-	-	-	-
Options granted	3,208,491	4.3	-	-
Option exercised	(392)	2.30	-	-
Options forfeited/cancelled	-	-	-	-
Outstanding at September 30, 2019	3,208,099	4.3	9.6	55,756,761
Options vested and exercisable at September 30, 2019	259,837	2.30	9.6	5,035,641

Aggregate intrinsic value is calculated by subtracting the exercise price of the option from the closing price of the Company's common stock on closing date, multiplied by the number of shares per each option.

Assumptions used in determining the fair value of the stock options granted in 2019 include risk-free interest rate 1.45% – 2.47%, expected dividend yield of 0.00%, expected Life in years of 5.75 - 6.25 and expected volatility of 68.1% - 71.0%.

Expected term — The expected term represents the period that the equity-based awards are expected to be outstanding. The expected term for our stock options was calculated based on the weighted average vesting term of the awards and the contract period, or simplified method.

Expected volatility — The Company lacks Company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until it has adequate historical data regarding the volatility of its own traded stock.

Risk-free interest rate — The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.

Expected dividend — The Company has never paid dividends on its common units or stock and has no plans to pay dividends on its common stock. Therefore, the expected dividend yield is zero.

Fair Value of Common Stock — Prior to the IPO, the fair value of the shares of common stock underlying the stock-based awards were determined by the Company's Board of Directors with input from management. Since there was no public market for the common stock prior to September 12, 2019, the Company's Board of Directors had determined the fair value of the common stock at the time of grant of the stock-based award by considering a number of objective and subjective factors, including having valuations of the common stock performed by a third-party valuation specialist. The fair value of the common stock is now determined by the public market.

At September 30, 2019, the total unrecognized compensation related to unvested stock options was $9.0 million, which the Company expects to recognize over a period of approximately 4 years. For the nine months ended September 30, 2019 the stock option compensation expense was $0.9 million.

Restricted Stock

A summary of the changes in the Company's restricted stock during the year ended December 31, 2018 and September 30th, 2019.

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2018	2,503,744	1.25
Granted	-	-
Vested	(815,493)	1.15
Forfeited	(12,570)	1.45
Unvested and outstanding at September 30, 2019	1,675,681	1.22

The Company recorded total equity-based compensation expense related to restricted stock and stock options for the periods presented as follows (in thousands):

	Three Months ending September 30, 2019	Three Months ending September 30, 2018	Nine Months ending September 30, 2019	Nine Months ending September 30, 2018
Research and development	194	56	505	102
General and administrative	594	179	1,654	741
Total equity compensation expenses	788	235	2,159	843

At September 30, 2019, the total unrecognized compensation related to unvested restricted stock was $1.2 million, which the Company expects to recognize over a period of approximately 3.0 years. For the nine months ended September 30, 2019 the restricted stock compensation expense was $1.3 million.

2019 CEO Performance Award

In June 2019, our CEO received an award of 176,411 stock options (the “2019 CEO Performance Award”) at an exercise price of $7.50 per share. The 2019 CEO Performance Award can vest over 48 monthly installments based on four years of service, a performance condition (a liquidity event, such as an IPO) and market conditions, assuming continued employment and service through each vesting date. During the vesting period of four years, the 2019 CEO Performance Award is not earned unless the market condition is achieved on each vesting date. If the market condition is not achieved on a vesting date, but is achieved on a future vesting date, the award is earned for the entire period since the last date that such market condition was achieved. All or a portion of the award can be earned following the initial four year service period if the market condition is next achieved after such four year service period and Mr. Islam remains in continuous service. The market condition and performance condition are satisfied when the Company’s common stock is listed on a U.S. national securities exchange and achieves a 60-trading day average closing price of at least $28.49 per share (as adjusted for stock splits, recapitalizations, and similar events).

As a result of the IPO, the performance conditions have been met; however the market condition is not yet satisfied as of September 30, 2019.

The Company recorded $0.2 million stock compensation expense related to this award as of September 30, 2019.

At September 30, 2019, the total unrecognized compensation related to the unvested CEO Performance Award was $1.2 million, which the Company expects to recognize over a period of approximately 3.67 years.

8. License and Collaboration Agreements

Pfizer Inc.

In August and October 2017, the Subsidiaries entered into four license agreements with Pfizer for rights to certain technologies (the “License Agreements”). Under the License Agreements, the Company obtained from Pfizer the right to use research, develop, manufacture and commercialize certain products, including nirogacestat and mirdametinib. In connection with the License Agreements, the Company issued 6,437,500 units of Junior Series A convertible preferred units to Pfizer (see Note 6). No cash was received by the Company for these units.

The Company is required to pay Pfizer milestones payments of up to an aggregate of $232.5 million for nirogacestat and up to an aggregate of $229.8 million for mirdametinib, each upon achievement of certain commercial milestone events. Royalties are also payable under each License Agreement based on a specified percentage of net sales ranging from mid-single digit percentages to the low 20s, Royalty payments under each License Agreement continue until the expiration of the last to expire licensed patent applicable to such product, but not less than ten years after the first commercial sale on a country-by-country basis.

BeiGene, Ltd. ("BeiGene")

In August 2018, the Company entered into a clinical collaboration agreement with BeiGene to conduct a clinical study of the combination of mirdametinib and a BeiGene compound designated as lifirafenib. In accordance with the terms of the agreement, the Company and BeiGene share equally the costs associated with the clinical study. BeiGene is required to supply the BeiGene compound and the Company is required to supply mirdametinib to conduct the clinical study. The collaboration is guided by a joint steering committee. Specified areas of development require unanimous agreement among all members of the joint steering committee.

The Company recorded $0.8 million and $0.4 million for the nine months ended September 30, 2019 and December 31, 2018, respectively.

GSK clinical collaboration agreement ("GSK")

In June 2019, the Company entered into a clinical collaboration agreement with GlaxoSmithKline ("GSK") (the "GSK Collaboration Agreement"), to evaluate the safety, tolerability and preliminary efficacy of nirogacestat and belantamab mafodotin. Under the terms of the GSK Collaboration Agreement, GSK will sponsor and conduct the adaptive Phase 1b study of nirogacestat, in combination with GSK's BCMA antibody-drug conjugate, belantamab mafodotin, in patients with relapsed or refractory multiple myeloma. GSK will assume all development costs associated with the study. The Company agreed to manufacture and supply the Company compound for purposes of the study.

Pursuant to the GSK Collaboration Agreement, GSK is responsible for administering the clinical trial and is responsible for all costs associated with the direct conduct of the clinical trial, other than the manufacture and supply of nirogacestat and certain expenses related to intellectual property rights. The collaboration is managed by a joint development committee of equal representation by the Company and GSK. Following completion of the clinical trial, within a specified period of time, either party may propose new agreements for the purpose of performing one or more additional clinical trials of the combination therapy for the treatment of relapsed and refractory multiple myeloma. If a party proposes to conduct an additional clinical trial, the parties will negotiate in good faith, without obligation, the details of a definitive agreement to provide for the expansion of the clinical collaboration. If the parties do not reach an agreement, and only one party wishes to proceed with an additional clinical trial, it may do so if the other party does not object to the protocol based on safety concerns.

The Company has not incurred any expense under the GSK Collaboration Agreement as of September 30, 2019.

9. Commitments and Contingencies

Leases

In August 2018, the Company entered into a five-year operating lease in Durham, NC (the location of the Company's clinical development operations), with two five-year renewal options. Rental payments under the renewal period will be at current market rates for the premises. The Company established a security deposit of $40,467 presented in other assets.

In October 2018, the Company entered into a lease for its corporate headquarters in Stamford, CT. The lease expires in November 2022. The Company received $1.5 million from the previous tenant in connection with the assumption of the lease. The Company recognizes rent expense for the office it currently occupies and records a deferred rent obligation representing the cumulative difference between actual rent payments, incentive received and rent expense recognized ratably over the lease period. The Company established a security deposit of $0.5 million in the form of a letter-of-credit, recorded in other noncurrent assets.

The Company's future minimum lease obligations as of September 30, 2019 are:

(in thousands)	Premises Operating Leases
Remainder of 2019	$ 331
2020	1,344
2021	1,372
2022	1,297
2023	135
Total Obligations	$ 4,479

The Company recorded rent expense of $0.7 million and $0.2 million for the nine months ended September 30, 2019, and September 30, 2018, respectively.

Contingencies

From time to time, the Company may be involved in disputes or regulatory inquiries that arise in the ordinary course of business. When the Company determines that a loss is both probable and reasonably estimable, a liability is recorded and disclosed if the amount is material to the financial statements taken as a whole. When a material loss contingency is only reasonably possible, the Company does not record a liability, but instead discloses the nature and the amount of the claim, and an estimate of the loss or range of loss, if such an estimate can reasonably be made.

As of September 30, 2019, there was no litigation or contingency with at least a reasonable possibility of a material loss.

10. Net Loss per Share and Unit

Basic and diluted net loss per unit is calculated as follows:

(in thousands, except unit and per unit data and share and per share data)	Three Months ending		Nine Months ending	
	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
Net Loss attributable to common stockholder - basic and diluted	(16,833)	(5,004)	(34,360)	(11,594)
Weighted average common units outstanding, basic and diluted	-	433,401	-	262,273
Weighted average common shares outstanding, basic and diluted	9,487,329	-	3,716,877	-
Net Loss per unit, basic and diluted	-	(11.55)	-	(44.20)
Net Loss per share, basic and diluted	(1.77)	-	(9.24)	-

The table below provides potential common shares not included in the calculation of the diluted net loss per share because to do so would be anti-dilutive:

	as of September 30,	
	2019	2018
Common stock options issued and outstanding	3,208,099	-
Restricted stock subject to future vesting	1,675,681	2,637,674
	4,883,780	2,637,674

11. Investment and Variable Interest Entity

MapKure

June 2019, the Company announced the formation of MapKure, an entity jointly owned by the Company and BeiGene. BeiGene licensed to MapKure exclusive rights to BGB-3245, an oral, small molecule selective inhibitor of specific BRAF driver mutations and genetic fusions. MapKure intends to advance BGB-3245 into clinical development for solid tumor patients harboring BRAF driver mutations and genetic fusions that were observed to be sensitive to the compound in preclinical studies. In addition to the Company's equity ownership in MapKure, the Company has appointed a member to each of MapKure's joint steering committee and board of directors. The Company will also contribute to clinical development and other operational activities for BGB-3245 through a service agreement with MapKure.

The Company purchased 3,500,000 Series A preferred units of MapKure, or a 25% ownership interest, of the outstanding unit for $3.5 million, and BeiGene received 10,000,000 Series A preferred units as payment for its contributed intellectual property, or a 71.4% ownership interest. Two individuals each purchased 250,000 Series A preferred units, or 1.8% ownership interest each.

Upon the first anniversary of the initial closing (the "Second Closing"), MapKure is obligated to sell another 4,000,000 Series A preferred units to the same two individuals and the Company. At the Second Closing, the Company is obligated to purchase 3,500,000 Series A preferred units, which will increase the Company's ownership to 38.9%.

The Company determined that MapKure is a variable interest entity, but the Company is not the primary beneficiary. The Company does not have the power to direct the activities that most significantly impact the economic performance of MapKure. Accordingly, the Company does not consolidate the financial statements of this entity and accounts for this investment using equity method accounting.

In accordance with ASC 323-10-35-6, the Company records MapKure's earnings or losses based on a one quarter lag.

The Company recognized $2.5 million equity loss for the nine months ended September 30, 2019. The Company's ownership interest in MapKure is included in "Equity method investments" in the Consolidated Balance Sheet as of September 30, 2019. The balance of the Company's investment was $1.0 million at September 30, 2019, representing the maximum exposure to loss as a result of the Company's involvement with MapKure.

12. Related Party Transactions

Prior to the Company becoming public, the company entered into agreements with two of its board members to provide consulting and Board of Director ("BOD") services to the Company. For the year ended December 31, 2018, the Company recorded consulting and BOD expenses totaling $287,079. The Company recorded consulting and BOD expenses totaling $216,417 to the IPO date for the nine months ended September 30, 2019 and $193,133 for the nine months ended September 30, 2018.

13. Subsequent Events

The Company has evaluated subsequent events through November 12, 2019, the date on which the financial statements were available to be issued.

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

The following discussion of the financial condition and results of operations of SpringWorks Therapeutics, Inc. should be read in conjunction with the consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q, or Quarterly Report, and the audited financial statements and notes included in our final prospectus for our initial public offering filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the Securities and Exchange Commission, on September 12, 2019. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. We caution you that forward-looking statements are not guarantees of future performance, and that our actual results of operations, financial condition and liquidity, and the developments in our business and the industry in which we operate, may differ materially from the results discussed or projected in the forward-looking statements contained in this Quarterly Report. We discuss risks and other factors that we believe could cause or contribute to these potential differences elsewhere in this Quarterly Report, including under Item 1A. "Risk Factors" and under "Special Note Regarding Forward-Looking Statements" in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and the developments in our business and the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods. We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the Securities and Exchange Commission, or SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company applying a precision medicine approach to acquiring, developing and commercializing life-changing medicines for underserved patient populations suffering from devastating rare diseases and cancer. We have a differentiated portfolio of small molecule targeted oncology product candidates and are advancing two potentially registrational clinical trials in rare tumor types, as well as several other programs addressing highly prevalent, genetically defined cancers. Our strategic approach and operational excellence in clinical development have enabled us to rapidly advance our two lead product candidates into late-stage clinical trials while simultaneously entering into multiple shared-value partnerships with industry leaders to expand our portfolio. From this foundation, we are continuing to build a differentiated global biopharmaceutical company intensely focused on understanding patients and their diseases in order to develop transformative targeted medicines.

Our most advanced product candidate, nirogacestat, is an oral, small molecule gamma secretase inhibitor, or GSI, initially in development for the treatment of desmoid tumors, a rare and often debilitating and disfiguring soft tissue tumor for which there are currently no therapies approved by the U.S. Food and Drug Administration, or FDA. We believe nirogacestat may address the significant limitations associated with existing treatment options and has the potential to become the first therapy approved by the FDA for both newly diagnosed and previously treated desmoid tumors. Since we licensed nirogacestat from Pfizer Inc., or Pfizer, in August 2017, the FDA granted nirogacestat Orphan Drug Designation, Fast Track Designation and Breakthrough Therapy Designation for this indication, and in September 2019, the European Commission granted nirogacestat Orphan Drug Designation for the treatment of soft tissue sarcoma. In May 2019, we announced the initiation of the DeFi trial, a potentially registrational Phase 3 clinical trial of nirogacestat for patients with desmoid tumors. We expect to provide an update on the DeFi trial in the second half of 2020 ahead of an anticipated top-line data readout in the second or third quarter of 2021.

Our second product candidate is mirdametinib, an oral, small molecule MEK inhibitor initially in development for the treatment of neurofibromatosis type 1-associated plexiform neurofibromas, or NF1-PN, a rare tumor of the peripheral nerve sheath that causes significant pain and disfigurement, and that most often manifests in children. We believe that mirdametinib has the potential to offer a best-in-class profile in order to enable the long-term treatment required for this patient population, as compared to other MEK inhibitors. As with nirogacestat, we licensed mirdametinib from Pfizer in August 2017; since then, the FDA has granted mirdametinib both Orphan Drug Designation and Fast Track Designation for NF1-PN, and the European Commission has granted mirdametinib Orphan Drug Designation for NF1. In the fourth quarter of 2019, we commenced the ReNeu trial, a potentially registrational Phase 2b clinical trial of mirdametinib for patients with NF1-PN. We expect to provide an update on the ReNeu trial between the fourth quarter of 2020 and the first quarter of 2021.

In addition to our late-stage programs in rare oncology indications, we have expanded our portfolio to develop targeted therapies for the treatment of highly prevalent, genetically defined cancers. To advance this strategy, we are taking a precision medicine approach in collaboration with industry leaders, including BeiGene, Ltd., or BeiGene, and GlaxoSmithKline plc, or GSK, to develop combination approaches with mirdametinib and nirogacestat, as well as new standalone medicines. The first of these efforts is our ongoing collaboration with BeiGene, under which patients with advanced or refractory solid tumors harboring RAS mutations, RAF mutations and other MAPK pathway aberrations are being enrolled in a Phase 1b clinical trial evaluating the combination of mirdametinib and BeiGene's investigational RAF dimer inhibitor lifirafenib. The second of these efforts is our collaboration with GSK, under which patients with relapsed or refractory multiple myeloma will be enrolled in an adaptive Phase 1b clinical trial evaluating the combination of nirogacestat and belantamab mafodotin, GSK's investigational antibody-drug conjugate, or ADC, targeted to B-cell maturation antigen, or BCMA.

Furthermore, we intend to continue to expand our portfolio by licensing additional programs with strong biological rationales and validated mechanisms of action. We also plan to continue using shared-value partnerships to maximize the potential of our therapies to serve patients. Since our founding, we have invested in building leading clinical development capabilities and have focused on structuring innovative partnerships that seek to align incentives and optimize business outcomes for each party involved. We believe that this approach will continue to allow us to expand our shared-value relationships with innovators, maximize the potential of our existing and future portfolio and ultimately support the building of a scalable and sustainable business focused on the efficient advancement and commercialization of product candidates that hold the potential to transform the lives of patients living with severe rare diseases and cancer.

Components of our results of operations

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future, if at all. If our development efforts for our current product candidates or additional product candidates that we may develop in the future are successful and can be commercialized, we may generate revenue in the future from product sales. Additionally, we may enter into collaboration and license agreements from time to time that provide for certain payments due to us. Accordingly, we may generate revenue from payments from such collaboration or license agreements in the future.

Operating expenses

Research and development expenses

Our research and development expenses consist of expenses incurred in connection with the development of our product candidates. These expenses include:

- employee-related expenses, which include salaries, benefits and stock-based compensation for our research and development personnel;
- fees paid to consultants for services directly related to our research and development programs;
- expenses incurred under agreements with third-party contract research organizations, investigative clinical trial sites and consultants that conduct research and development activities on our behalf;
- costs associated with preclinical studies and clinical trials;
- costs associated with the manufacture of drug substance and finished drug product for preclinical testing and clinical trials;
- costs associated with technology and intellectual property licenses; and
- an allocated portion of facilities and facility-related costs, which include expenses for rent and other facility-related costs and other supplies.

Expenditures for clinical development, including upfront licensing fees and milestone payments associated with our product candidates, are charged to research and development expense as incurred. These expenses consist of expenses incurred in performing development activities, including salaries and benefits, materials and supplies, preclinical expenses, clinical trial and related clinical manufacturing expenses, depreciation of equipment, contract services and other outside expenses. Costs for certain development activities, such as manufacturing and clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using either time-based measures or data such as information provided to us by our vendors on their actual costs incurred.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in activities related to developing our product candidates and our preclinical programs and as certain product candidates advance into later stages of development, including our ongoing potentially registrational Phase 3 clinical trial for nirogacestat and ongoing potentially registrational Phase 2b clinical trial for mirdametinib. The process of conducting the necessary clinical trials to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in executive, finance, corporate and business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs; administrative travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued development of our product candidates. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with being a public company.

Other income (expense)

Other income consists primarily of interest income. Interest income consists of interest earned on our cash equivalents, which consist of money market funds. We expect our interest income to increase due to our investment of cash received from the final closing of our last tranche of Series A convertible preferred units in March 2019 prior to the Reorganization and the sale of Series B convertible preferred stock in March 2019, as well as the net proceeds from our initial public offering.

Critical Accounting Policies and Use of Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us 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 consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Results of Operations

Comparison of the Three Months Ended September 30, 2018 and 2019

The following table summarizes our results of operations for the three months ended September 30, 2018 and 2019 (in thousands, except percentages):

	Three Months ended September 30,		2019 vs 2018	
	2019	2018	Change	Percentage
Operating Expenses:				
Research and development	$ 10,745	$ 3,406	7,339	215%
General and administrative	4,584	1,824	2,760	151%
Total Operating Loss	15,329	5,230	10,099	193%
Loss from operations	(15,329)	(5,230)	(10,099)	(193)%
Other income, net	997	226	771	341%
Equity investment loss	(2,501)	-	(2,501)	100%
Net loss	$ (16,833)	(5,004)	(11,829)	236%

Research and Development

Research and development expense increased by $7.3 million from $3.4 million for the three months ended September 30, 2018 to $10.7 million for the three months ended September 30, 2019, an increase of 216%. The following table summarizes our research and development expense for the three months ended September 30, 2018 and 2019 (in thousands, except percentages):

	Three Months ended September 30,		2019 vs 2018	
	2019	2018	Change	Percentage
Operating Expenses:				
Research and development	$ 10,745	$ 3,406	$ 7,339	215%

The increase in research and development expense was primarily attributable to the following:

- The $5.2 million increase in external costs primarily related to drug manufacturing and trial costs.
- The $2.1 million increase in internal costs was primarily driven by an increase of personnel costs due to increased number of employees.

A significant portion of our research and development costs have been external costs, which we track on a program-by-program basis after a clinical product candidate has been identified. Our internal research and development costs are primarily personnel-related costs, depreciation and other indirect costs. We do not track our internal research and development expenses on a program-by-program basis as they are deployed across multiple projects under development.

General and Administrative

General and administrative expense increased by $2.8 million from $1.8 million for the three months ended September 30, 2018 to $4.6 million for the three months ended September 30, 2019.

The increase in general and administrative expense was primarily attributable to the hiring of more personnel and an increase of $0.9 million in consulting fees and professional services primarily related to increases in legal fees related to business development, regulatory and patent costs, accounting and audit fees and public and investor relations fees due to ongoing business activities.

Interest Income, Net

The increase in interest income, net during the three months ended September 30, 2019 as compared to the three months ended September 30, 2018 was attributable to the interest earned from cash and cash equivalents which was significantly larger during the three months ended September 30, 2019 as compared to the three months ended September 30, 2018 due to the cash received for the IPO.

Equity Investment Loss

The $2.5 million Equity investment loss during the three months ended September 30, 2019 as compared to the three months ended September 30, 2018 was attributable to the pro-rata losses from the MapKure investment.

Comparison of the Nine Months Ended September 30, 2018 and 2019

The following table summarizes our results of operations for the nine months ended September 30, 2018 and 2019 (in thousands, except percentages):

	Nine Months ended September 30,		2019 vs 2018	
	2019	2018	Change	Percentage
Operating Expenses:				
Research and development	$ 30,373	$ 6,192	$ 24,181	391%
General and administrative	11,495	5,852	5,643	96%
Total Operating Loss	(41,868)	12,044	29,824	248%
Loss from operations	(41,868)	(12,044)	(29,824)	(248)%
Other income, net	2,280	450	1,830	407%
Equity investment loss	(2,501)	-	(2,501)	100%
Net loss	$ (42,089)	$ (11,594)	$ (30,495)	263%

Research and Development

Research and development expense increased by $24.2 million from $6.2 million for the nine months ended September 30, 2018 to $30.4 million for the nine months ended September 30, 2019, an increase of 391%.

The following table summarizes our research and development expense for the nine months ended September 30, 2019 and 2018 (in thousands, except percentages):

	Nine Months ended September 30,		2019 vs 2018	
	2019	2018	Change	Percentage
Operating Expenses:				
Research and development	$ 30,373	$ 6,192	$ 24,181	391%

The increase in research and development expense was primarily attributable to the following:

- The $18.6 million increase in external costs primarily related to drug manufacturing and trial costs.
- The $5.6 million increase in internal costs was primarily driven by an increase of personnel costs due to increased number of employees.

A significant portion of our research and development costs have been external costs, which we track on a program-by-program basis after a clinical product candidate has been identified. Our internal research and development costs are primarily personnel-related costs, depreciation and other indirect costs. We do not track our internal research and development expenses on a program-by-program basis as they are deployed across multiple projects under development.

General and Administrative

General and administrative expense increased by $5.6 million from $5.9 million for the nine months ended September 30, 2018 to $11.5 million for the nine months ended September 30, 2019.

The increase in general and administrative expense was primarily attributable to the hiring of more personnel and professional fees related to market research and commercial planning expenses.

Interest Income, Net

The increase in interest income, net during the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018 was attributable to the interest earned from cash and cash equivalents which was significantly larger during the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018 due to the cash received for the IPO.

Equity Investment Loss

The $2.5 million Equity investment loss during the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018 was attributable to the pro-rata losses from the MapKure investment.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have funded our operations primarily with net proceeds of $102.3 million from the sale of our Series A convertible preferred units prior to the Reorganization, with net proceeds of $124.6 million from the sale of our Series B convertible preferred stock following the Reorganization and $169.7 million from the initial public offering. At September 30, 2019, we had available cash and cash equivalents of $343.8 million.

We have incurred operating losses and experienced negative operating cash flows since our inception and anticipate that we will continue to incur losses for at least the foreseeable future. Our net loss was $42.1 million and $17.8 million for the nine months ended September 30, 2019 and December 31, 2018, respectively. We had an accumulated deficit of $56.8 million and $22.5 million at September 30, 2019 and December 31, 2018, respectively.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2018 and September 30, 2019 (in thousands):

	Nine Months ending September 30,	
	2019	**2018**
Net cash used in operating activities	(31,381)	(11,211)
Net cash used in investing activities	(4,130)	-
Net cash provided by financing activities	333,688	50,400
Net increase in cash and cash equivalents	298,177	39,189
Cash and cash equivalents, beginning of period	45,648	10,271
Cash and cash equivalents, end of period	$ 343,825	$ 49,460

Net Cash Used in Operating Activities

The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities was $31.4 million for the nine months ended September 30, 2019 compared to $11.2 million for the nine months ended September 30, 2018. The increase in cash used in operating activities was primarily due to an increase in net loss of $30.5 million and an increase of $6.4 million in cash used by operating assets and liabilities for the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018.

Net Cash Used in Investing Activities

Net cash used in investing activities was $4.1 million for the nine months ended September 30, 2019 compared to net cash provided by investing activities of $0.0 million for the nine months ended September 30, 2018. Net cash used in investing activities for the nine months ended September 30, 2019 consisted primarily of the investment in MapKure for $3.5 million. There was no net cash provided by investing activities for the nine months ended September 30, 2018.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $333.7 million during the nine months ended September 30, 2019 compared to $50.4 million provided by financing activities for the nine months ended September 30, 2018. Net cash provided by financing activities for the nine months ended September 30, 2019 consisted primarily of proceeds from Series A and B convertible preferred and the initial public offering. Net cash provided by financing activities for the nine months ended September 30, 2018 consisted primarily of Series A convertible preferred units.

Funding Requirements

Our primary use of cash is to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

Our future funding requirements will depend on many factors, including the following:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates, including our ongoing potentially registrational Phase 3 clinical trial for nirogacestat and ongoing potentially registrational Phase 2b clinical trial for mirdametinib;
- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates that we develop;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, EMA and other comparable foreign regulatory authorities;
- the terms of our existing and any future license or collaboration agreements we may choose to enter into, including the amount of upfront, milestone and royalty obligations;

- the other costs associated with in-licensing new technologies, such as any increased costs of research and development and personnel;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

We will need additional funds to meet operational needs and capital requirements for clinical trials, other research and development expenditures, and business development activities. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the common stockholders interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs 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 or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Accrued Research and Development Expenses

We record accrued expenses for estimated costs of our research and development activities conducted by third-party service providers, which include the conduct of clinical trials and preclinical studies. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in accrued liabilities in the consolidated balance sheets and within research and development expense in the consolidated statement of operations. These costs are a significant component of our research and development expenses. We record accrued expenses for these costs based on factors such as estimates of the work completed and in accordance with agreements established with these third-party service providers. Any payments made in advance of services provided are recorded as prepaid assets, which are then expensed as the contracted services are performed.

We estimate the amount of work completed based on discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed, the number of patients enrolled and the rate of patient enrollment may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers. For the periods presented, we have experienced no material differences between our accrued expenses and actual expenses.

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 under applicable SEC rules.

Contractual Obligations

During the three months ended September 30, 2019, there were no material changes to our contractual obligations and commitments from those described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations” in our final prospectus for our IPO filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on September 13, 2019.

We enter into contracts in the normal course of business with third-party contract research organizations for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice and therefore we believe that our non-cancelable obligations under these agreements are not material.

We have not recorded any reserves for uncertain tax positions as of December 31, 2017, December 31, 2018 or September 30, 2019.

JOBS Act

In April 2012, the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an emerging growth company, or EGC, can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

Subject to certain conditions, as an EGC, we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an EGC until the earlier of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) December 31, 2023; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We had cash and cash equivalents of $343.8 million and $45.6 million as of September 30, 2019 and December 31, 2018, respectively, which consisted of bank deposits and highly liquid money market funds. Historical fluctuations in interest rates have not been significant for us. We had no outstanding debt as of December 31, 2018 and September 30, 2019. Due to the short-term maturities of our cash equivalents, an immediate one percentage point change in interest rates would not have a material effect on the fair market value of our cash equivalents. To minimize the risk in the future, we intend to maintain our portfolio of cash equivalents in institutional market funds that are composed of U.S. Treasury and U.S. Treasury-backed repurchase agreements or short-term U.S. Treasury securities. We do not believe that inflation, interest rate changes or exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective at a reasonable assurance level in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms; and (ii) accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely discussions regarding required disclosure. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any material legal proceedings. The outcome of litigation cannot be predicted with certainty and some lawsuits, claims or proceedings may be disposed of unfavorably to us, which could materially affect our financial condition or results of operations.

Item 1A. Risk Factors

Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Quarterly Report on Form 10-Q and in other documents that we file with the SEC, in evaluating the Company and our business. Investing in our common stock involves a high degree of risk. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks described below are not intended to be exhaustive and are not the only risks facing the Company. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition and results of operations.

Risks related to our financial position and need for additional capital

We have incurred significant net losses since our inception and anticipate that we will continue to incur net losses in the future.

We have incurred significant net losses in each reporting period since our inception. To date, we have not generated any revenue and we have financed our operations principally through equity financings. If our product candidates are not successfully developed and approved, we may never generate any revenue. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Our net losses were $17.8 million and $42.1 million for the year ended December 31, 2018 and the nine months ended September, 2019, respectively. As of December 31, 2018 and September 30, 2019, we had an accumulated deficit of $22.5 million and $56.8 million, respectively. 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, including our lead product candidates, nirogacestat and mirdametinib, and any future product candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- advance the development of our lead product candidates, nirogacestat and mirdametinib, through potentially registrational clinical trials and potentially for other indications;
- advance our development programs for our other product candidates through clinical development and into later-stage clinical development;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- invest in or in-license other technologies or product candidates for further preclinical and clinical development;
- hire additional personnel, including clinical, quality control, scientific, medical, business development and finance personnel, and continue to build our infrastructure;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- maintain, expand and protect our intellectual property portfolio; and
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties.

To become and remain profitable, we or any potential future collaborators must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, obtaining reimbursement approval, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop, register and market additional product candidates. We may 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 revenue. 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 have a limited operating history, which may make it difficult to evaluate our prospects and likelihood of success.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were formed in August 2017 and our operations to date have been focused on preparing and executing our clinical trials for our product candidates, building our infrastructure, raising capital and executing partnerships. Consequently, we have limited operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drug products. 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 activity or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable.

Although we announced the initiation of the DeFi trial, a potentially registrational Phase 3 clinical trial of nirogacestat, in May 2019, and in October 2019 commenced a potentially registrational Phase 2b clinical trial of mirdametinib, we have not yet demonstrated the ability to successfully enroll or complete clinical trials for any product candidate, we have no products approved for commercial sale and we have not generated any revenue from product sales to date. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields.

In addition, we will need to transition at some point from a company with a development focus to a company capable of supporting commercial activities, and may not be successful in such a transition.

We will require additional capital to fund our operations and if we fail to obtain necessary capital, we will not be able to complete the development and commercialization of our product candidates.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts of cash to conduct further research and development and clinical trials of our product candidates to seek regulatory approvals for our product candidates and to launch and commercialize any products for which we receive regulatory approval. As of September 30, 2019, we had $343.8 million in cash and cash equivalents. Based on our current operating plan, we believe that the net proceeds from our initial public offering completed in September 2019, together with existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditure requirements through 2022. However, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital in order to complete clinical development and obtain regulatory approval of our product candidates. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of clinical trials for our product candidates;
- the clinical and preclinical development and manufacturing plans we establish for these product candidates;
- the number and characteristics of product candidates that we develop or in-license;
- the cost of identifying and evaluating potential product candidates for acquisition or license, including the cost of preclinical activities or clinical activities;
- the terms of any collaboration or licensing agreements we may choose to enter into;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale manufacturing activities; and
- the cost of establishing medical affairs and sales, marketing and distribution capabilities for any approved product candidates.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient product or royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek commercial or development partners for our lead products or any future product candidate at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves.

The amount of our future losses is uncertain and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- our ability to obtain marketing approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;
- the changing and volatile U.S. and global economic environments; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

Risks related to research and development and the biopharmaceutical industry

Our business is highly dependent on the success of our lead product candidates, nirogacestat and mirdametinib, as well as other product candidates we may develop. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize our product candidates, or if we experience delays in doing so, our business will be materially harmed.

To date, we have not yet completed any clinical trials or development of any product candidates. Our future success and ability to generate revenue from our product candidates, which we do not expect will occur for several years, if ever, is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more product candidates. We are currently enrolling patients in a potentially registrational Phase 3 clinical trial of nirogacestat and we commenced a potentially registrational Phase 2b clinical trial of mirdametinib in October 2019. If either of our lead product candidates encounter safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be significantly harmed.

All of our other product candidates are in earlier stages of development and will require substantial additional investment for preclinical development, clinical development, regulatory review and approval in one or more jurisdictions.

We may not have the financial resources to continue development of, or to modify existing or enter into new collaborations for, a product candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including:

- our inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective;
- insufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- negative or inconclusive results from our preclinical studies, clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon a program;
- product-related adverse events experienced by subjects in our clinical trials or by individuals using drugs or therapeutic biologics similar to our product candidates;
- delays in submitting an Investigational New Drug application, or IND, or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA, EMA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- poor effectiveness of our product candidates during clinical trials;
- better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials;
- delays in enrolling subjects in clinical trials;
- high drop-out rates of subjects from clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial or manufacturing costs;
- unfavorable FDA, EMA or comparable regulatory authority inspection and review of a clinical trial site;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular; or
- varying interpretations of data by the FDA, EMA and comparable foreign regulatory authorities.

Clinical development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing.

Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. Additionally, we plan to conduct some open-label trials, where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in those trials are aware when they are receiving treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Where a randomized, placebo-controlled clinical trial is designed to allow enrolled subjects to cross-over from the placebo arm to the treatment arm, there may be a risk of inadvertent unblinding of subjects prior to cross-over, which may limit the clinical meaningfulness of those data and may require the conduct of additional clinical trials.

Successful completion of clinical trials is a prerequisite to submitting a New Drug Application, or NDA, to the FDA, a Marketing Authorization Application, or MAA, to the EMA and similar marketing applications to comparable foreign regulatory authorities for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates.

Although we have initiated potentially registrational clinical trials for nirogacestat and mirdametinib, we do not know whether these trials or any of our clinical trials, including trials for our combination therapies using nirogacestat and mirdametinib, will be completed on schedule, if at all, or in some cases whether such clinical trials will begin.

We may experience delays in initiating or completing clinical trials and preparing for regulatory submissions. We also may experience numerous unforeseen events during, or as a result of, any future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our current product candidates or any future product candidates, including:

- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective clinical trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- clinical trials of any product candidates may fail to show acceptable safety or efficacy, or produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;

- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs or ethics committees may require, that we or our investigators suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of any product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be inadequate to initiate or complete a given clinical trial;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate the clinical trials;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates; and
- the FDA, EMA or comparable regulatory authorities may require us to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such clinical trials are being conducted, or the FDA, EMA or comparable regulatory authorities, or recommended for suspension or termination by the Data Safety Monitoring Board, or DSMB, for such clinical trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or clinical trial site by the FDA, EMA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA, EMA or comparable foreign regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Our costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be reassigned or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly. The clinical trials sponsored by our partners with our product candidates in combination with our partners' therapies pose the same development risks.

We were not involved in the early development of our lead product candidates or in the development of third-party agents used in combination with our product candidates; therefore, we are dependent on third parties having accurately generated, collected, interpreted and reported data from certain preclinical and clinical trials for our product candidates.

We had no involvement with or control over the preclinical and clinical development of any of our lead product candidates or third-party agents used in combination with our product candidates. We are dependent on third parties having conducted their research and development in accordance with the applicable protocols and legal, regulatory and scientific standards; having accurately reported the results of all preclinical studies and clinical trials conducted with respect to such product candidates; and having correctly collected and interpreted the data from these trials. If these activities were not compliant, accurate or correct, the clinical development, regulatory approval or commercialization of our product candidates will be adversely affected.

If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.

Our preclinical studies or early clinical trials of our product candidates, whether conducted by us or third parties, may not necessarily be predictive of the results of later clinical trials that we conduct. Similarly, even if we are able to complete our planned clinical trials of our product candidates, positive results from such clinical trials may not be replicated in our subsequent preclinical studies or clinical trials.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. For example, we are conducting non-clinical and clinical absorption, distribution, metabolism and excretion, or ADME, studies for each of our lead product candidates, and we cannot predict whether findings from these ADME studies will adversely affect our development plans for such product candidates. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, EMA or comparable foreign regulatory authority approval. Furthermore, the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval, which may lead to the FDA, EMA or comparable foreign regulatory authorities delaying, limiting or denying approval of our product candidates.

As an organization, we have never successfully completed any clinical trials, and we may be unable to do so for any product candidates we may develop.

We will need to successfully complete clinical trials in order to obtain the approval of the FDA, EMA or comparable foreign regulatory authorities to market any product candidates. Carrying out clinical trials, including later-stage registrational clinical trials, is a complicated process. As an organization, we have not previously completed any clinical trials. In order to do so, we will need to build and expand our clinical development and regulatory capabilities, and we may be unable to recruit and train qualified personnel. We also expect to continue to rely on third parties to conduct our clinical trials. See "-Risks related to our reliance on third parties-We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates." Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to NDA submission and approval of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approval of any product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our product candidates.

The successful development of biopharmaceuticals is highly uncertain.

Successful development of biopharmaceuticals is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons including:

- clinical trial results may show the product candidates to be less effective than expected (for example, a clinical trial could fail to meet its primary or key secondary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by patients who fail the trial screening process, slow enrollment in clinical trials, patients dropping out of trials, patients lost to follow-up;
- length of time to achieve trial endpoints, additional time requirements for data analysis or NDA preparation, discussions with the FDA, an FDA request for additional preclinical or clinical data (such as long-term toxicology studies) or unexpected safety or manufacturing issues;
- preclinical study results may show the product candidate to be less effective than desired or to have harmful side effects;
- supply issues, manufacturing costs and formulation issues, including our inability to successfully combine our product candidates with other therapies;
- post-marketing approval requirements; and
- the proprietary rights of others and their competing products and technologies that may prevent our product candidates from being commercialized.

The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product candidate to the next and from one country to the next, and may be difficult to predict.

Even if we are successful in obtaining marketing approval, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations in the United States or country specific governmental organizations in foreign countries, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide coverage and adequate reimbursement for our products once approved, market acceptance and commercial success would be reduced.

In addition, if any of our product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third-party providers comply) with current good manufacturing practices, or cGMPs, and good clinical practices, or GCPs, for any clinical trials that we conduct post-approval. In addition, there is always the risk that we, a regulatory authority or a third party might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates post-approval could adversely affect our business, financial condition and results of operations.

We expect to develop nirogacestat and mirdametinib, and potentially future product candidates, in combination with other therapies, and safety or supply issues with combination use products may delay or prevent development and approval of such product candidates.

We intend to develop nirogacestat and mirdametinib, and likely other future product candidates, in combination with one or more other approved or unapproved rational therapies to treat cancer or other diseases. For example, we are currently evaluating mirdametinib in combination with lifirafenib, BeiGene's RAF dimer inhibitor, and nirogacestat in combination with belantamab mafodotin, GSK's investigational antibody-drug conjugate, or ADC, targeted to B-cell maturation antigen, or BCMA.

Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or comparable foreign regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA, EMA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

We also may choose to evaluate nirogacestat or mirdametinib or any other future product candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell nirogacestat, mirdametinib or any product candidate we develop in combination with an unapproved cancer therapy for a combination indication if that unapproved cancer therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved cancer therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

If the FDA, EMA or comparable foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with our product candidate we develop, we may be unable to obtain approval of or market such combination therapy.

Due to our limited resources and access to additional capital, we must prioritize development of certain programs and product candidates; these decisions may prove to be wrong and may adversely affect our business.

We may fail to identify and acquire, through purchase or license, viable new product candidates for clinical development for a number of reasons. If we fail to identify and acquire additional product candidates, our business could be materially harmed.

Efforts to identify and pursue new product candidates and disease targets require substantial technical, financial and human resources, regardless of whether they are ultimately successful. We currently rely on third parties, including current and future collaborators, to perform all of our research and preclinical activities. Programs may initially show promise in preclinical studies, yet fail to yield positive results during clinical development for a number of reasons, including:

- the methodology used may not be successful in identifying potential indications and/or product candidates; or
- product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective products.

Because we have limited financial and human resources, we intend to initially focus on programs and product candidates for a limited set of indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications with our existing product candidates that may later prove to have greater commercial potential or a greater likelihood of success. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

Our future clinical trials or those of our future collaborators may reveal significant adverse events not seen in prior preclinical studies or clinical trials and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

If significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. For example, a prior Phase 2 clinical trial (A4581002) of mirdametinib was terminated and enrollment in the Phase 2 portion of a Phase 1/2 clinical trial (A4581001) was halted as a result of adverse events observed at doses of mirdametinib of 15 mg twice daily, or BID, or above using both intermittent and continuous dosing schedules. These adverse events included ocular disorders (visual disturbances, blurred vision and retinal vein occlusion), nervous system disorders (confusion, slowed ideation, slurred speech and hallucinations), musculoskeletal and connective tissue disorders (general weakness and neck muscle weakness associated with mild and moderate elevations in creatine phosphokinase) and cardiac disorders (decreased left ventricular ejection fraction and congestive heart failure). Although these doses were significantly higher than the maximum allowable dose of 4 mg BID in our ongoing Phase 2b clinical trial of mirdametinib in NF1-PN, we plan to treat patients in this trial for a period of up to 24 months, which would be longer than any subjects have been treated with mirdametinib in prior trials. In our ongoing Phase 2b clinical trial, we may observe adverse events similar to those that were seen at higher doses of mirdametinib in prior clinical trials owing to the potentially increased duration of treatment, or potentially other factors. In addition, the trial will enroll pediatric NF1-PN patients. Patients under 16 years of age have never before been exposed to mirdametinib treatment, and it is possible that there may be unanticipated adverse events observed in this patient population.

If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed or eliminated. Serious adverse events or other adverse events, as well as tolerability issues, observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue.

We, the FDA, EMA or comparable foreign regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, restrictions could be imposed on the approval or an approved product could be subject to a "black box" warning, and undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies.

If we encounter difficulties enrolling patients in any of our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the clinical trial's primary endpoints;
- the proximity of patients to clinical trial sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience, and the ability of these investigators to identify and enroll suitable patients;
- perception of the safety profile of our product candidates;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

For example, we are developing nirogacestat for the treatment of desmoid tumors and mirdametinib for the treatment of NF1-PN, both of which are rare diseases with small patient populations. As a result, we may encounter difficulties enrolling subjects in our clinical trials for these product candidates due, in part, to the small size of these patient populations. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a clinical trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. In addition, in the case of mirdametinib, we may face difficulty with enrollment due to physician or patient perception of an adverse tolerability profile.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

The target patient populations of nirogacestat for the treatment of desmoid tumors and mirdametinib for the treatment of NF1-PN are small and have not been definitively determined, and if our estimates of the number of treatable patients is lower than expected, our potential revenues from sales of our product candidates, if approved, and our ability to achieve profitability would be compromised.

Our estimates of both the number of patients who have the diseases we are targeting, as well as the subset of patients with these diseases in a position to receive our product candidates, if approved, are based on our beliefs and estimates, and these estimates may prove to be incorrect. These estimates have been derived from a variety of sources, including scientific literature, input from physicians that treat patients with the diseases we are targeting, patient foundations and secondary market research databases. Further, new studies may change the estimated incidence or prevalence of these diseases, and any regulatory approvals that we may receive for a product candidate may include limitations for use or contraindications that decrease the addressable patient population. Accordingly, the target patient populations may turn out to be lower than expected, in which case the potential revenues from sales of our product candidates, if approved, would be lower than expected.

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

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly as they develop novel approaches to treating disease indications that our product candidates are also focused on treating. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaboration partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

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 for our product candidates. 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 to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

Even if any product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any future product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to other treatments;
- the ability to offer our products, if approved, for sale at competitive prices;

- convenience and ease of administration compared to other treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage, market access and adequate reimbursement; and
- the prevalence and severity of any side effects.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, including bridging or comparability testing to demonstrate the validity of clinical data obtained in clinical trials following manufacturing changes, FDA notification or FDA approval.

Because all prior clinical trials of nirogacestat and mirdametinib were conducted by third parties, we will need to perform analytical and other tests to demonstrate that any new drug product material is comparable in all respects, including potency, to the product used in such earlier clinical trials. There is no assurance that any such product will pass the required comparability testing, that any other future third-party manufacturer that we engage will be successful in producing our product candidates or that any materials produced by any third-party manufacturer that we engage will have the same effect in patients that we have observed to date with respect to materials used in prior clinical trials.

All of the above could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

Moreover, we have not yet manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates if approved. We may make changes as we work to optimize our manufacturing processes, but we cannot be sure that even minor changes in our processes will result in therapies that are safe and effective and approved for commercial sale.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of testing our product candidates in clinical trials and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring a product candidate to the market;
- decreased demand for our products;
- harm to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to clinical trial participants or patients who receive an approved product;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and of our capital resources;
- the inability to commercialize any product candidate, if approved; and
- a decline in our stock price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. Even if our agreements with any current or future corporate collaborators entitle us to indemnification against losses, that indemnification may not be available or adequate should any claim arise. Although we currently carry $5.0 million in clinical trial insurance, that amount of insurance coverage may not be adequate, and, in the future, we may be unable to maintain this insurance coverage, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay those amounts.

Risks related to government regulation

The regulatory approval process for our product candidates in the United States, the European Union and other jurisdictions is currently uncertain and will be lengthy, time-consuming and inherently unpredictable and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products are subject to extensive regulation by the FDA in the United States, the EMA in the European Union and comparable foreign regulatory authorities. We are not permitted to market any product in any jurisdiction until we receive marketing approval from the appropriate regulatory authority. We have not previously submitted an NDA to the FDA, an MAA to the EMA or similar marketing application to comparable foreign regulatory authorities. In the United States, an NDA must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each desired indication. An NDA must also include significant information regarding the chemistry, manufacturing and controls for the product, and the manufacturing facilities must complete a successful pre-approval inspection.

The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop based on the completed clinical trials.

In addition, clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- obtaining regulatory authorization to begin a clinical trial, if applicable;
- the availability of financial resources to begin and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining approval at each clinical trial site by an independent IRB or ethics committee;
- recruiting suitable patients to participate in a clinical trial in a timely manner;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from clinical trial protocol, not complying with GCP requirements or dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a clinical trial;
- addressing any conflicts with new or existing laws or regulations;
- adding new clinical trial sites; or
- manufacturing qualified materials under cGMP regulations for use in clinical trials.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such clinical trials are being conducted, or the FDA, EMA or comparable foreign regulatory authorities, or recommended for suspension or termination by the DSMB for such clinical trial, due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or clinical trial sites by the FDA, EMA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing any clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

The FDA, EMA or comparable foreign regulatory authorities may disagree with our regulatory plan for our product candidates.

The general approach for FDA approval of a new drug is dispositive data from one or more well-controlled Phase 3 clinical trials of the product candidate in the relevant patient population. Phase 3 clinical trials typically involve a large number of patients, have significant costs and take years to complete.

Our clinical trial results may not support approval of our product candidates. In addition, our product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following:

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the dosing regimen, design or implementation of our clinical trials;

- we may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We may seek regulatory approval of our product candidates, including nirogacestat, based on an interim analysis conducted of a registrational trial, particularly if the interim analysis is statistically significant for the primary endpoint and the safety data demonstrate an acceptable safety and tolerability profile. The results of any such interim analysis would be discussed with FDA at a pre-NDA meeting to assess the adequacy of the data to support the submission of a NDA; however, if the FDA does not agree that the interim analysis provides a sufficient basis for regulatory approval, we would not submit an NDA until the conclusion of such registrational trial.

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

From time to time, we may publish interim top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

We have been granted Orphan Drug Designation for nirogacestat and mirdametinib and may seek Orphan Drug Designation for other product candidates, and we may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and therapeutic biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug or therapeutic biologic as an orphan drug if it is a drug or therapeutic biologic intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or therapeutic biologic will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA or Biologics License Application, or BLA, to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

In June 2018, the FDA granted Orphan Drug Designation to nirogacestat for the treatment of desmoid tumors and in September 2019, the European Commission granted nirogacestat Orphan Drug Designation for the treatment of soft tissue sarcoma. In October 2018, the FDA granted Orphan Drug Designation to mirdametinib for the treatment of NF1 and in July 2019 the European Commission granted mirdametinib Orphan Drug Designation for the treatment of NF1. We may seek Orphan Drug Designations for nirogacestat and mirdametinib for other indications or for our other product candidates. There can be no assurances that we will be able to obtain such designations.

Even if we obtain Orphan Drug Designation for any of our future product candidates in specific indications, we may not be the first to obtain marketing approval of nirogacestat, mirdametinib or any other such product candidates for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Further, even if we obtain orphan drug exclusivity in the United States for a product, that exclusivity may not effectively protect the product from competition because different drugs or therapeutic biologics with different active moieties can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug or therapeutic biologic with the same active moiety for the same condition if the FDA concludes that the later drug or therapeutic biologic is safer, more effective or makes a major contribution to patient care. In Europe, we could be prevented from marketing our products if a similar medicinal product is granted Orphan Drug Designation for the same indications that we are pursuing. Once authorized, with a limited number of exceptions, neither the competent authorities of the EU member states, the EMA or the European Commission are permitted to accept applications or grant marketing authorization for other similar medicinal products with the same therapeutic indication. Marketing authorization could also be granted to a similar medicinal product with the same orphan indication if the latter product is safer, more effective or otherwise clinically superior to the original orphan medicinal product. Further, the composition of matter patents for nirogacestat and mirdametinib expire in 2025 and 2021, respectively, and if orphan drug exclusivity does not protect these products from competition, our business and financial condition could be materially adversely affected. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug or therapeutic biologic nor gives the drug or therapeutic biologic any advantage in the regulatory review or approval process. In addition, while we may seek Orphan Drug Designation for our future product candidates, we may never receive such designations.

Breakthrough Therapy Designation or Fast Track Designation from the FDA may not actually lead to a faster development or regulatory review or approval process.

The FDA has granted Fast Track Designation and Breakthrough Therapy Designation for nirogacestat for the treatment of adult patients with progressive, unresectable, recurrent or refractory desmoid tumors or deep fibromatosis, and has granted Fast Track Designation for mirdametinib for the treatment of patients at least two years of age with NF1-associated inoperable PN that are progressing or causing significant morbidity. We may seek Breakthrough Therapy Designation or Fast Track Designation for our other product candidates.

If a product is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe one of our product candidates is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if a product candidate qualifies as a breakthrough therapy, the FDA may later decide that the product no longer meets the conditions for qualification and rescind the Breakthrough Therapy Designation.

The results of clinical trials conducted at clinical trial sites outside the United States might not be accepted by the FDA, and data developed outside of a foreign jurisdiction similarly might not be accepted by such foreign regulatory authority.

Some of the prior clinical trials for our product candidates were conducted outside the United States, and we intend to conduct additional clinical trials outside the United States. Although the FDA, EMA or comparable foreign regulatory authorities may accept data from clinical trials conducted outside the relevant jurisdiction, acceptance of these data is subject to certain conditions. For example, the FDA requires that the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles such as IRB or ethics committee approval and informed consent, the trial population must adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, acceptance of the data by the FDA will be dependent upon its determination that the trials were conducted consistent with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the United States as adequate support of a marketing application. Similarly, we must also ensure that any data submitted to foreign regulatory authorities adheres to their standards and requirements for clinical trials and there can be no assurance a comparable foreign regulatory authority would accept data from trials conducted outside of its jurisdiction.

Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, or FCA, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- the federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The government may deem manufacturers to have “caused” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, requirements on certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their respective business associates, independent contractors that perform services for covered entities that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended, or ACA, and its implementing regulations, which require some manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services, or CMS, of the U.S. Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians 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, and may be broader in scope than their federal equivalents; 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, marketing expenditures or drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing 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.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Pharmaceutical companies may also be subject to federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies continue to closely scrutinize interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time and resource-consuming and can divert a company's attention from the business.

It is possible that governmental and enforcement 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 any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as 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. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any action for violation of these laws, even if successfully defended, could cause a biopharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, the EMA or comparable foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. 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 products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, EMA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. Certain endpoint data we hope to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may also require a risk evaluation and mitigation strategies, or REMS, program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, EMA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The policies of the FDA, EMA and comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor’s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. Patients are unlikely to use our product candidates, once approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of their cost. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Middle Class Tax Relief and Job Creation Act of 2012 required that CMS, the agency responsible for administering the Medicare program, reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting. Additional state and federal healthcare reform measures are expected to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for certain pharmaceutical products or additional pricing pressures.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. 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, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

At the federal level, the Trump administration's budget proposals for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the legislative session 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.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry. The ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. For example, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, the Tax Reform Act includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA 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." As a result of the individual mandate repeal, subsequent litigation challenged the validity of the ACA. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, or TCJA, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. A Fifth Circuit U.S. Court of Appeals hearing to determine whether certain states and the House of Representatives have standing to appeal the lower court decision was held on July 9, 2019, but it is unclear when the court will render its decision on this hearing, and what effect it will have on the status of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Further, the Trump administration has concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Bipartisan bills to appropriate funds for CSR payments were proposed in 2017 and 2018, but the proposals have not been enacted into law. Multiple state Attorneys General filed suit to stop the administration from terminating the subsidies, but their case was dismissed by a federal judge in California on July 18, 2018. Furthermore, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace and providers, and the potential effect on our business, are not yet known.

Additionally, CMS has recently published regulations that would give states greater flexibility starting in 2020 in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. The Bipartisan Budget Act of 2018, or BBA, also amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." Moreover, in 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On May 23, 2019, CMS finalized a rule that amends the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out-of-pocket costs for plan enrollees and allows Medicare plans to negotiate lower rates for certain drugs. Among other things, the final rule allows Medicare Advantage plans the option to use step therapy, a type of prior authorization, as part of patient-centered care coordination programs for Medicare Part B drugs, beginning January 1, 2020. The proposed rule proposed to change the definition of "negotiated prices," under which plan sponsors would be required to pass through all pharmacy price concessions at the point of sale; however, CMS is still reviewing comments from stakeholders on this issue. Litigation and legislative efforts to change or repeal the ACA are likely to continue, with unpredictable and uncertain results.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs, including aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027, unless additional congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further 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.

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 federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 legislative session, 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. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. The HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. 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 have increasingly passed legislation and implemented 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.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

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

We are developing nirogacestat for the treatment of desmoid tumors and mirdametinib for the treatment of NF1-PN. If our product candidates are approved by the FDA, we may only promote or market our product candidates for their specifically approved indications. We will train our marketing and sales force against promoting our product candidates for uses outside of the approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our products off label, when in the physician's independent professional medical judgment he or she deems it appropriate. Furthermore, the use of our products for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that that might require significant financial and management resources and that could harm our reputation.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most foreign countries, including the European Economic Area, or EEA, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the Company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected.

We may incur substantial costs in our efforts to comply with evolving global data protection laws and regulations, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations.

The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about participants and healthcare providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business, affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. For example, California recently passed the California Data Privacy Protection Act, which goes into effect in January 2020 and provides broad rights to California consumers with respect to the collection and use of their information by businesses. The new California law further expands the privacy and process enhancements and commitment of resources in support of compliance with California's regulatory requirements and may lead to similar laws in other U.S. states or at a national level.

In addition to our operations in the United States, which may be subject to healthcare and other laws relating to the privacy and security of health information and other personal information, may seek to conduct clinical trials in EEA and may become subject to additional European data privacy laws, regulations and guidelines. The General Data Protection Regulation, (EU) 2016/679, or GDPR, became effective on May 25, 2018, and deals with the processing of personal data and on the free movement of such data. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. Given the limited enforcement of the GDPR to date, we face uncertainty as to the exact interpretation of the new requirements on our trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

In particular, national laws of member states of the European Union are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty. Further, the impact of the impending "Brexit", whereby the United Kingdom is planning to leave the EEA in October of 2019, either with or without a "deal" is uncertain and cannot be predicted at this time.

In the event we commence clinical trials in the EEA, we must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the United States, in compliance with European data protection laws. We expect that we will continue to face uncertainty as to whether our efforts to comply with any obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or biopharmaceutical partners. We may also experience hesitancy, reluctance or refusal by European or multi-national clients or biopharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or biopharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain or otherwise objectionable and therefore decide not to do business with us. Any of the forgoing could materially harm our business, prospects, financial condition and results of operations.

Additional laws and regulations governing international operations could negatively impact or restrict our operations.

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the Company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

A portion of our manufacturing of our lead product candidates takes place in China through third-party manufacturers. A significant disruption in the operation of those manufacturers, a trade war or political unrest in China could materially adversely affect our business, financial condition and results of operations.

We currently contract manufacturing operations to third parties, and clinical quantities of our lead product candidates are manufactured by these third parties outside the United States, including in China, and we expect to continue to use such third-party manufacturers for such product candidates. Any disruption in production or inability of our manufacturers in China to produce adequate quantities to meet our needs, whether as a result of a natural disaster or other causes, could impair our ability to operate our business on a day-to-day basis and to continue our development of our product candidates. Furthermore, since these manufacturers are located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China. For example, a trade war could lead to tariffs on the chemical intermediates we use that are manufactured in China. Any of these matters could materially and adversely affect our business and results of operations. Any recall of the manufacturing lots or similar action regarding our product candidates used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our product candidates and impair our competitive position. Further, we may be exposed to fluctuations in the value of the local currency in China. Future appreciation of the local currency could increase our costs. In addition, our labor costs could continue to rise as wage rates increase due to increased demand for skilled laborers and the availability of skilled labor declines in China.

Risks related to our intellectual property

Our success depends in part on our ability to protect our intellectual property, and patent terms may be inadequate to protect our competitive position. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is affected by the extent to which we have rights under valid and enforceable patents that cover these activities. If our patents expire, or we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions such as patent term adjustments and/or extensions, may be available, but the life of a patent, and the protection it affords, is limited. Our current composition of matter patents covering nirogacestat and mirdametinib, which we licensed from Pfizer Inc., or Pfizer, in connection with the formation of our company, are expected to expire in 2025 and 2021, respectively, not including any patent term extensions. Our earliest patents may expire before, or soon after, either product candidate achieves marketing approval in the United States or foreign jurisdictions. Upon the expiration of the current patents, we currently intend to rely on orphan drug exclusivity to market our lead products. Once the patent life has expired, we may be open to competition from competitive products, including generics. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. The expiration of the patents covering our lead product candidates, and our inability to secure additional patent protection, could also have a material adverse effect on our business, results of operations, financial condition and prospects.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. 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.

The strength of patents in the biopharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license now or in the future may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, the patents and patent applications covering our product candidates may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

Since patent applications in the United States and most other countries are confidential for a period of time after filing, there is no certainty that any patent application related to a product candidate was the first to be filed. Furthermore, for United States applications in which at least one claim is entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the U.S. Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of an application.

We cannot be certain that we are the first to invent any inventions covered by a pending patent application and, if we are not, we could 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 candidates, 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 candidates 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.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the enacted Leahy-Smith America Invents Act, or America Invents Act, enacted in 2013, the United States moved from a "first-to-invent" to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the "first-to-file" provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of any patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to the compositions of our product candidates but that are not covered by the claims of our patents;
- the active ingredients in our current product candidates will eventually become commercially available in generic drug products, and no patent protection may be available with regard to formulation or method of use;
- a company or its licensor, as the case may be, may fail to meet its obligations to the U.S. government in regard to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- such company or its licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that a pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;

- the inventors of owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past, and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

We depend on intellectual property licensed from third parties, including from Pfizer for our lead product candidates, and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. All patents covering nirogacestat and mirdametinib and any combination therapies using our product candidates are licensed from third parties. Any termination of a product license could result in the loss of significant rights and would cause material adverse harm to our ability to commercialize our product candidates.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we own, as we are for intellectual property that we license, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could materially suffer.

If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are important to our business.

We are a party to license agreements pursuant to which we in-license key patents for our product candidates. At the time we began our operations in August 2017, we entered into four license agreements with Pfizer, including a license agreement for each of our lead product candidates, nirogacestat and mirdametinib. Each of our existing licenses imposes various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property.

We may have limited control over the maintenance and prosecution of these in-licensed rights, activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and other development activities in the United States is protected under the Safe Harbor exemption as set forth in 35 U.S.C. §271. If and when any of our product candidates are approved by the FDA, that certain third-party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we do not believe that any claims of such patent that could otherwise materially adversely affect commercialization of our product candidates, if approved, are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and any patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we or our licensors may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

Third parties may assert that our employees, consultants, collaborators or partners have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants 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 our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms.

Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. We may develop products containing our compounds and pre-existing pharmaceutical compounds. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions may provide us with an option to negotiate a license to any of the institution’s rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put any patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-exam, inter partes review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the European Patent Office, or EPO, or other foreign patent offices. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent offices then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by issued patents or any pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors also may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patents or any patent applications, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or any patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology 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 a license on commercially reasonable terms. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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 such litigation. In addition, there could 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 substantial adverse effect on the price of our common stock.

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 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 provisions during the patent application process and following the issuance of a patent. 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. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Changes in patent law in the United States and in ex-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our 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 the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict how these decisions or any future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Similarly, any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world is expensive. While our licensed patents, including the patents covering our lead product candidates, have been issued in major markets and other countries, our 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 may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims 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, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us or our licensors to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and any patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Risks related to our reliance on third parties

We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for, or commercialize, any potential product candidates.

We depend upon third parties to conduct certain aspects of our preclinical studies and depend on third parties, including independent investigators, to conduct our clinical trials, under agreements with universities, medical institutions, CROs, strategic partners and others. We expect to negotiate budgets and contracts with such third parties, which may result in delays to our development timelines and increased costs.

We commenced operations in August 2017 and we continue to build our infrastructure and hire personnel necessary to execute our operational plans. We will rely especially heavily on third parties over the course of our clinical trials, and, as a result, may have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of clinical trial sponsors, clinical investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP, requirements and may require a large number of patients.

Our failure or any failure by these third parties to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting aspects of our preclinical studies or our clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed or precluded entirely.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. Though we endeavor to carefully manage our relationships with our CROs and other third parties, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Because we rely on third-party manufacturing and supply partners, our supply of preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.

We rely on third-party contract manufacturers to manufacture all of our preclinical and clinical trial product supplies. We do not own manufacturing facilities for producing any product supplies. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a product candidate is subject to FDA, EMA and comparable foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

Our or a third party's failure to execute on our manufacturing requirements and comply with cGMP could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of an existing or future collaborator;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

In addition, we contract with packaging providers with the appropriate expertise, facilities and scale to meet our needs. Failure to maintain cGMP can result in a contractor receiving FDA sanctions, which can impact our ability to operate or lead to delays in any clinical development programs. We believe that our current packaging contractors operate in accordance with cGMP, but we can give no assurance that FDA, EMA or comparable foreign regulatory authorities will not conclude that a lack of compliance exists. In addition, any delay in contracting for packaging services, or failure of the contract manufacturer to perform the services as needed, may delay any clinical trials, registration and launches, which could negatively affect our business.

Our product candidates and any drugs that we may develop may compete with other product candidates and drugs for access to manufacturing facilities. There are no assurances we would be able to enter into similar commercial arrangements with other manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

We have not yet manufactured on a commercial scale and expect to rely on third parties to produce and process commercial quantities of our product candidates, if approved.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for our product candidates. We have not yet entered into any arrangement with a third party for the manufacture and supply of commercial quantities of our product candidates. To the extent that we enter into future manufacturing arrangements with third parties for commercial supply of our product candidates, if approved, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA, EMA or comparable foreign regulatory authorities following inspections that will be conducted after we submit an application to the FDA, EMA or comparable foreign regulatory authorities. We do not directly control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with cGMP requirements for the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable foreign regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We are dependent on a small number of suppliers for some of the materials used to manufacture our product candidates, and on one company for the manufacture of the active pharmaceutical ingredient for each of our product candidates.

We currently depend on a small number of suppliers for some of the materials used in, and processes required to develop, our product candidates. We cannot ensure that these suppliers or service providers will remain in business or have sufficient capacity or supply to meet our needs, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of a small number of suppliers exposes us to several risks, including disruptions in supply, price increases or late deliveries. There are, in general, relatively few alternative sources of supply for substitute materials. Our current vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Finding suitable replacement suppliers, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption or delay in supply could compromise our ability to pursue development and eventual commercialization of our product candidates.

Our existing and future collaborations will be important to our business. If we are unable to maintain our existing collaborations or enter into new collaborations, or if these collaborations are not successful, our business could be adversely affected.

An important part of our strategy is to evaluate and, as deemed appropriate, extend our current or enter into additional partnerships in the future, including potentially with major biopharmaceutical companies. We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we have entered into collaborations with other companies to provide us with important technologies in order to more fully develop our product candidates, including mirdametinib, and we may enter into collaborations with other companies to provide us with important technologies or funding for our programs.

Any current or future collaborations we may extend or enter into may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;

- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- for collaborations involving combination therapies that have not yet been tested together, treatment emergent adverse events may be unforseen and may negatively impact the monotherapy development of our product candidates;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated by the collaborator, and, if terminated, we could lose license rights to the applicable product candidates or could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Under our collaboration agreement with BeiGene, the combination of mirdametinib and lifirafenib is being evaluated a Phase 1b clinical trial, and under our collaboration agreement with GSK, the combination of nirogacestat and belantamab mafodotin will be evaluated in a Phase 1b clinical trial that GSK plans to initiate. Under these existing collaboration arrangements, upon completion of the relevant clinical trials, we and our collaboration partner will negotiate in good faith to provide for the expansion of the respective clinical collaboration and the establishment of a commercial relationship. However, our partners have no obligation to continue development of the combination products, regardless of the applicable clinical trial results. We also jointly formed MapKure, LLC, or MapKure, with BeiGene for the development of BGB-3245, and although we will contribute to clinical development and other operational activities, we will not control the development process. MapKure may pursue a development plan that differs from our expectations, which may or may not be successful.

If our collaborations do not result in the successful discovery, development and commercialization of product candidates or if one of our collaborators elects not to enter into collaboration agreements to pursue future development, we may not receive any future funding or milestone or royalty payments under such collaborations. Risks relating to product development, regulatory approval and commercialization described in this report may also apply to the activities of our collaborators.

Additionally, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

Furthermore, we face significant competition in seeking appropriate partners for our product candidates and the negotiation process is time-consuming and complex. In order for us to successfully partner our product candidates, potential partners must view our product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies. In addition, there have been a significant number of recent business combinations among large biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or planning, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise or capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue from sales of drugs or continue to develop our technology, and our business may be materially and adversely affected. Even if we are successful in our efforts to establish new strategic partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

Risks related to managing our business and operations

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of September 30, 2019, we had 56 full-time employees. As our clinical development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect we will need additional managerial, clinical, manufacturing, medical, regulatory, sales, marketing, financial, legal and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- recruiting, integrating, retaining and motivating additional employees;
- managing our development efforts effectively, including the clinical, manufacturing and quality review process for our product candidates, while complying with our contractual obligations to contractors, collaboration partners and other third parties; and

- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on third parties, including independent organizations, advisors and consultants, to provide certain services to support and perform our operations. There can be no assurance that the services of these third parties will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, accuracy or quantity of the services provided is compromised for any reason, our clinical trials may be delayed or terminated, and we may not be able to obtain, or may be substantially delayed in obtaining, regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other suitable outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully execute the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our development and commercialization goals.

We have no history of commercializing marketed products. Building our commercialization capabilities will require a significant investment of time and money. There can be no assurance that we will successfully set up our commercialization capabilities.

We are currently in the early stages of building our commercial capabilities to allow us to market our product candidates, if approved, either alone or in combination with others. Establishing commercialization capabilities will require substantial investment of time and money and may divert significant management focus and resources. In addition, we will be competing with larger biopharmaceutical and biotechnology companies with established commercialization and marketing capabilities as we seek to recruit suitable personnel. Accordingly, there can be no assurance that our efforts to set up commercialization capabilities will be successful.

If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to pursue our business strategy will be impaired, could result in loss of markets or market share and could make us less competitive.

Our ability to compete in the highly competitive biopharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including Saqib Islam, our Chief Executive Officer, Frank Perier, our Chief Financial Officer, Badreddin Edris, our Chief Business Officer, Jens Renstrup, our Chief Medical Officer and L. Mary Smith, our Senior Vice President, Clinical Research and Development. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements for these individuals could harm our business.

Competition for skilled personnel in our industry is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, in a timely manner or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity incentive awards that vest over time. The value to employees of restricted stock awards and stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams are at-will employees and may terminate their employment with us on short notice. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. Given the stage of our programs and our plans to expand operations, our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior personnel across our organization.

We do not have the internal research capabilities required to independently discover new product candidates, and we plan to execute our growth strategy by identifying and in-licensing or acquiring additional product candidates that have been discovered and initially developed by others. We may not be successful in executing our growth strategy or such growth strategy may not deliver the anticipated results.

We do not have an internal discovery and preclinical research and development department to independently discover and initially develop new product candidates. We plan to source new product candidates, including those that may be complementary to our existing product candidates, by in-licensing or acquiring them from other companies, academic institutions or other asset originators. If we are unable to identify, in-license or acquire and integrate product candidates, our ability to pursue our growth strategy would be limited.

Research programs and business development efforts to identify new product candidates require substantial technical, financial and human resources, and we have no immediate plans to develop an internal discovery and preclinical research and development group. In-licensing and acquiring product candidates or development programs often requires significant payments and expenses and may consume valuable resources. We will need to devote a substantial amount of time and personnel to develop and commercialize any in-licensed or acquired technology or product candidate, in addition to doing so for our existing product candidates. Our business development efforts or acquisition or licensing attempts may fail to yield additional complementary or successful product candidates for clinical development and commercialization for a number of reasons, including the following:

- our identification or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates with a high probability of success for development progression;
- we may not be able or willing to assemble sufficient resources or expertise to identify and in-license or acquire additional product candidates;
- for product candidates we seek to in-license or acquire, we may not be able to agree to acceptable terms with the licensor or owner of those product candidates;
- any product candidates that we do in-license or acquire may not succeed in preclinical studies or clinical trials;
- we may not succeed in formulation or process development of such in-licensed or acquired product candidates;
- such in-licensed or acquired product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unlikely to receive regulatory approval or be unmarketable if approved;
- competitors may develop alternatives that render such in-licensed product candidates obsolete or less attractive;
- in-licensed or acquired product candidates may be covered by third parties' patents or other exclusive rights that we may not be able to access;

- in-licensed or acquired product candidates that we develop may not allow us to best make use of our expertise and our development and commercial infrastructure as currently expected;
- the market for a product candidate that we in-license or acquire may change during the course of our development of the product candidate so that such product candidate may become unreasonable to continue to develop;
- a product candidate that we in-license or acquire may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate that we in-license or acquire may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occur, we may not be successful in executing our growth strategy or our growth strategy may not deliver the anticipated results.

Our internal computer systems, or those used by our vendors, or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other third parties, including our contractors and consultants, are vulnerable to damage from computer viruses and unauthorized access. Like other companies of our size and in our industry, we have been the target of phishing attacks and attacks on our data and systems. While we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of preclinical or clinical data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of financial or confidential information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

We could also be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our contractors or consultants. In addition, outside parties may attempt to penetrate our systems or those of our contractors or consultants or fraudulently induce our personnel or the personnel of our contractors or consultants to disclose sensitive information in order to gain access to our data and/or systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our contractors or consultants occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

Our employees, independent contractors, consultants, academic collaborators, partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, academic collaborators, partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA, EMA and comparable foreign regulatory authorities, provide true, complete and accurate information to the FDA, EMA and comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In connection with our initial public offering, we have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by our employees, independent contractors, consultants, academic collaborators, partners and vendors, and the precautions we take to detect and prevent such activities 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 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 civil, criminal and administrative penalties, damages, monetary fines, imprisonment, disgorgement, possible exclusion from participation in government 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 the curtailment of our operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our development activities involve the use of biological and hazardous materials and can produce hazardous waste products. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

Our current operations are concentrated in two locations, and we or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current headquarters are located in Stamford, Connecticut. Our development operations are currently located in Durham, North Carolina. We currently outsource our manufacturing operations to third parties, and clinical quantities of our product candidates are manufactured by these third parties outside the United States, including in China and France. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters or our development operations, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. Disaster recovery and business continuity plans may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management approach, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

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

On December 22, 2017, President Trump signed into law the TCJA that significantly reforms the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from 34% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses arising in taxable years beginning after December 31, 2017 to 80% of annual taxable income and elimination of net operating loss carrybacks applying to net operating losses arising in taxable years ending after December 31, 2017, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs"). The effect of the TCJA on our business, whether adverse or favorable, is uncertain and may not become evident for some period of time. We urge investors to consult with their legal and tax advisers regarding the implications of the TCJA on an investment in our common stock.

Our ability to use our net operating loss carryforwards and certain tax credit carryforwards may be subject to limitation.

As of December 31, 2018, we had net operating loss carryforwards for federal, state and city income tax purposes of $14.2 million, $0.6 million and $3.8 million, respectively. Federal net operating loss carryforwards of $4.3 million were recorded in 2017 and the state and city net operating loss carryforwards expire at various dates through 2038. Federal net operating loss carryforwards of $9.9 million recorded in 2018 will be available to offset 80% of taxable income for an indefinite period of time, until fully utilized. As of December 31, 2018, we also had federal tax credits of $0.4 million, which may be used to offset future tax liabilities. These tax credit carryforwards will expire in 2038. Under Section 382 of the Code, changes in our ownership may limit the amount of our net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. Private placements and other transactions that have occurred since our inception, as well as our initial public offering, may trigger such an ownership change pursuant to Section 382. Any such limitation, whether as the result of the initial public offering, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us, could have a material adverse effect on our results of operations in future years. The reduction of the corporate tax rate under TCJA may cause a reduction in the economic benefit of our net operating loss carryforwards and other deferred tax assets available to us. Under the TCJA, net operating losses generated in taxable years ending after December 31, 2017 will not be subject to expiration; however, under the TCJA, net operating losses generated in taxable years beginning after December 31, 2017 will be subject to limitation on deduction.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Portions of our future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials more costly to operate. Furthermore, the most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or international trade disputes could also strain our suppliers, some of which are located outside of the United States, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Risks related to our common stock

An active trading market for our common stock may not be sustained

Our shares of common stock began trading on The Nasdaq Global Select Market on September 13, 2019. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares.

The 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 likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk factors" section and elsewhere in this report, these factors include:

- the commencement, enrollment or results of our ongoing and planned potentially registrational clinical trials for nirogacestat and mirdametinib;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results from or delays in future clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates or any future product candidate;
- changes in laws or regulations applicable to our product candidates or any future product candidate, including but not limited to clinical trial requirements for approvals;
- changes in the structure of healthcare payment systems;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations or partnerships, if needed;
- our failure to commercialize our product candidates, if approved;
- additions or departures of key medical, scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- clinical trial results for other product candidates that could compete with our product candidates;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or product candidates in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;

- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock does not exceed your purchase price, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Furthermore, future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock.

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.

Our executive officers, directors and their affiliates and certain significant stockholders beneficially hold, in the aggregate, approximately 51% of our outstanding voting stock. Therefore, these stockholders will have the ability to influence us through this ownership position. 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.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, or EGC, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this report and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an EGC for up to five years following the year in which we complete the initial public offering, although circumstances could cause us to lose that status earlier. We will remain an EGC until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of the initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this report. In particular, we have not included all of the executive compensation information that would be required if we were not an EGC. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of 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.

Under the JOBS Act, EGCs can also delay adopting new or revised accounting standards until such time as those standards apply to private companies, which may make our financial statements less comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which will require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Recent legislation permits EGCs to implement many of these requirements over a longer period and up to five years from the pricing of the initial public offering. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have an adverse effect on our business. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this report lapse, the trading price of our common stock could decline. Of the 41,882,995 shares of common stock outstanding as of September 30, 2019, only the shares of common stock sold in our initial public offering, are freely tradable without restriction in the public market.

The lock-up agreements pertaining to the initial public offering will expire on March 10, 2020; 180 days from the date of the final prospectus related to our IPO, subject to earlier release of all or a portion of the shares subject to such agreements by the representatives of the underwriters in their sole discretion. After the lock-up agreements expire, based upon the number of shares of common stock, on an as-converted basis, outstanding as of September 30, 2019, up to an additional 32,882,995 shares of common stock will be eligible for sale in the public market.

Approximately 71% of these additional shares are held by directors, executive officers and other affiliates and will be subject to certain limitations of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our existing equity compensation plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Additionally, the number of shares of our common stock reserved for issuance under the 2019 Stock Option and Equity Incentive Plan will automatically increase on January 1 of each year, beginning on January 1, 2020 and continuing through and including January 1, 2030, by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution.

Additionally, the holders of 29,794,359 shares of our common stock (including shares issued upon conversion of our outstanding convertible preferred stock upon completion of our initial public offering) will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above. 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 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.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws, contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue convertible preferred stock on terms determined by the board of directors without stockholder approval and which convertible preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an EGC, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an EGC for up to five years. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Our amended and restated bylaws will designate the Court of Chancery of the State of Delaware as the exclusive forum for certain state law litigation that may be initiated by our stockholders, which could limit our stockholders' ability to litigate disputes with us in a different judicial forum.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (v) any action asserting a claim governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. This exclusive forum provision will not apply to any causes of action arising under the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. The forum selection clause in our amended and restated bylaws may limit our stockholders' ability to litigate disputes with us in a different judicial forum.

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

Set forth below is information regarding shares of equity securities sold, and options granted, by us during the three months ended September 30, 2019 that were not registered under the Securities Act.

Recent Sales of Unregistered Equity Securities

On September 17, 2019, upon the closing of our IPO all 196,076,779 shares of our then-outstanding convertible preferred stock automatically converted into 29,794,359 shares of common stock. The issuance of such common shares was exempt from the registration requirements of the Securities Act, pursuant to Section 3(a)(9) of the Securities Act, involving an exchange of securities exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. No underwriters were involved in this issuance of shares.

During the period between July 1, 2019 and September 30, 2019, we issued to certain of our employees and advisors, options to purchase an aggregate of 718,713 shares of our common stock at a weighted average exercise price of $11.37 per share. We deemed these issuances to be exempt from registration under the Securities Act either in reliance on Rule 701 of the Securities Act as sales and offers under compensatory benefit. All recipients either received adequate information about our company or had access, through employment or other relationships, to such information. No underwriters were involved in the foregoing issuances of securities. We filed a registration statement on Form S-8 under the Securities Act on October 29, 2019 to register all of the shares of our common stock subject to outstanding options and all shares of our common stock otherwise issuable pursuant to our equity compensation plan.

Use of Proceeds from Initial Public Offering of Common Stock

On September 17, 2019, we completed the IPO of our common stock pursuant to which we issued and sold 10,350,000 shares of our common stock at a price to the public of $18.00 per share, which included the exercise in full of the underwriters' option to purchase additional shares of our common stock.

The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1, as amended (File No. 333- 233351), which was declared effective by the SEC on September 12, 2019. J.P. Morgan Securities LLC, Goldman Sachs & Co. LLC and Cowen and Company, LLC acted as joint book-running managers of our IPO.

We received aggregate gross proceeds from our IPO of $186.3 million, or aggregate net proceeds of $160.3 million after deducting underwriting discounts and commissions and other offering costs. None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

As of September 30, 2019, we have used $0 of the net proceeds from the IPO. There has been no material change in our planned use of the net proceeds from the IPO as described in the final prospectus for our initial public offering.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation, as amended, of the Registrant, as currently in effect.
3.3	Bylaws of the Registrant, as currently in effect.
4.1	Specimen Stock Certificate evidencing shares of common stock (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A (File No. 333-233351) filed with the Securities and Exchange Commission on September 12, 2019).
4.2	Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated August 30, 2018 (Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-233351) filed with the Securities and Exchange Commission on September 12, 2019).
5.1	Opinion of Goodwin Procter LLP (Incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-233351) filed with the Securities and Exchange Commission on September 12, 2019).
10.1	2019 Stock Option and Incentive Plan and forms of award agreements thereunder (Incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1/A (File No. 333-233351) filed with the Securities and Exchange Commission on September 12, 2019).
10.2	2019 Stock Option and Equity Incentive Plan and forms of award agreements thereunder (Incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1/A (File No. 333-233351) filed with the Securities and Exchange Commission on September 12, 2019).
10.3	2019 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1/A (File No. 333-233351) filed with the Securities and Exchange Commission on September 12, 2019).
10.4	Senior Executive Cash Incentive Bonus Plan (Incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1/A (File No. 333-233351) filed with the Securities and Exchange Commission on September 12, 2019).

10.5	Non-Employee Director Compensation Policy (Incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1/A (File No. 333-233351) filed with the Securities and Exchange Commission on September 12, 2019).
10.6	Form of Indemnification Agreement, by and between the Registrant and each of its Directors (Incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1/A (File No. 333-233351) filed with the Securities and Exchange Commission on September 12, 2019).
10.7	Form of Indemnification Agreement, by and between the Registrant and each of its Officers (Incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1/A (File No. 333-233351) filed with the Securities and Exchange Commission on September 12, 2019).
10.8*#	Employment Agreement between SpringWorks Therapeutics, Inc and Saqib Islam, dated October 10, 2019
10.9*#	Employment Agreement between SpringWorks Therapeutics, Inc and Francis I. Perier, Jr., dated October 10, 2019
10.10*#	Employment Agreement between SpringWorks Therapeutics, Inc and Jens Renstrup, dated October 10, 2019
10.11*#	Employment Agreement between SpringWorks Therapeutics, Inc and Badreddin Edris, dated October 10, 2019
10.12*#	Employment Agreement between SpringWorks Therapeutics, Inc and L. Mary Smith, dated October 10, 2019
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2†	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

* Filed herewith.

\# Indicates a management contract or any compensatory plan, contract or arrangement.

† This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

SIGNATURES

Pursuant to the requirements 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.

SPRINGWORKS THERAPEUTICS, INC.

Date: November 12, 2019

By: /s/ Saqib Islam
Saqib Islam
Chief Executive Officer

Date: November 12, 2019

By: /s/ Francis I. Perier, Jr.
Francis I. Perier, Jr.
Chief Financial Officer

Exhibit 10.8

SPRINGWORKS THERAPEUTICS, INC.

EMPLOYMENT AGREEMENT

This Employment Agreement ("Agreement") is made as of October 10, 2019, between SpringWorks Therapeutics, Inc., a Delaware corporation (the "Company"), and Saqib Islam (the "Employee") and is effective as of the closing of the Company's first underwritten public offering of its equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Effective Date").

WHEREAS, the Company or a subsidiary of the Company and the Employee are parties to an offer letter, dated as of July 31, 2018, and a Severance Agreement, dated as of July 31, 2018 (collectively, the "Prior Agreements"); and

WHEREAS, the parties intend to replace the Prior Agreements with this Agreement, effective as of the Effective Date.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Employment.

(a) Term. The term of this Agreement shall commence on the Effective Date and continue until terminated in accordance with the provisions hereof (the "Term"). The Employee's employment with the Company will continue to be "at will," meaning that the Employee's employment may be terminated by the Company or the Employee at any time and for any reason subject to the terms of this Agreement.

(b) Position and Duties. During the Term, the Employee shall serve as the Chief Executive Officer of the Company, and shall have such duties and authorities as may from time to time be prescribed by the Board of Directors of the Company (the "Board"). The Employee shall devote his full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, the Employee may serve on other boards of directors, with the approval of the Board of Directors, or engage in religious, charitable or other community activities as long as such services and activities do not materially interfere with the Employee's performance of his duties to the Company as provided in this Agreement.

2. Compensation and Related Matters.

(a) Base Salary. During the Term, the Employee's annual base salary shall be $515,000. The Employee's base salary shall be reviewed annually by the Compensation Committee of the Board (the "Compensation Committee"). The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices.

(b) Incentive Compensation. During the Term, the Employee shall be eligible to receive cash incentive compensation as determined by the Board or the Compensation Committee from time to time. The Employee's initial target annual incentive compensation shall be fifty percent (50%) of his Base Salary (the "Target Annual Incentive Compensation"). The actual cash incentive compensation payable to the Employee will be subject to the Board or Compensation Committee's assessment of your performance, as well as business conditions at the Company. Except as otherwise provided herein, to earn incentive compensation, the Employee must be employed by the Company on the day such incentive compensation is paid.

(c) Expenses. The Employee shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by him during the Term in performing services hereunder upon presentation of receipts and otherwise in accordance with the policies and procedures then in effect and established by the Company.

(d) Other Benefits. During the Term, the Employee shall be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, subject to the terms of such plans.

(e) Vacations. During the Term, the Employee shall be entitled to paid vacation in accordance with the Company's policies and procedures. The Employee shall also be entitled to all paid holidays given by the Company in accordance with the policies and procedures then in effect and established by the Company.

3. Termination. During the Term, the Employee's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. The Employee's employment shall terminate upon his death.

(b) Termination by Company for Cause. The Company may terminate the Employee's employment for Cause. For purposes of this Agreement, "Cause" shall mean that the Company has complied with the "Cause Process" (hereinafter defined) following the occurrence of one of the following events: (i) conduct by the Employee constituting a material act of misconduct in connection with the performance of his duties, including, without limitation, misappropriation of funds or property of the Company or any of its subsidiaries or affiliates other than the occasional, customary and de minimis use of Company property for personal purposes; (ii) the commission by the Employee of any felony or a misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) any conduct by the Employee that would result in material economic harm to the Company or any of its subsidiaries if he were retained in his position; (iv); a material breach by the Employee of any provisions of this Agreement, including without limitation continued non-performance by the Employee of his duties under this Agreement (other than by reason of the Employee's physical or mental illness, incapacity or disability) which has continued for more than 30 days following written notice of such non-performance from the Board; (v) a material violation by the Employee of the Company's employment policies provided to the Employee in writing; or (vi) material failure to cooperate with a bona fide internal investigation by the Board or an investigation by regulatory or law enforcement authorities, after being instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation (subject to the limitations in the final sentence of Section 7(a)). If the Employee rebuts or cures the applicable finding of Cause within the applicable cure period, Cause shall be deemed not to have occurred. "Cause Process" shall mean that: (A) the Board reasonably determines in good faith that a "Cause" condition has occurred; and (B) with regard to any termination of the Employee for Cause under items (i), (iii), (iv), (v) or (vi) above, (1) the Company will provide the Employee with written notice of its intention to terminate the Employee's employment hereunder setting forth with reasonable particularity the basis for Cause and will provide the Employee with a thirty (30) day opportunity to rebut or cure such finding of Cause and (2) the Company cooperates in good faith with the Employee's efforts, for a period of not less than 30 days following such notice to remedy the condition.

(c) Termination Without Cause. The Company may terminate the Employee's employment at any time without Cause. Any termination by the Company of the Employee's employment which does not constitute a termination for Cause under Section 3(b) and does not result from the death of the Employee under Section 3(a) shall be deemed a termination without Cause.

(d) Termination by the Employee. The Employee may terminate his employment at any time for any reason, including but not limited to Good Reason. For purposes of this Agreement, "Good Reason" shall mean that the Employee has complied with the "Good Reason Process" (hereinafter defined) following the occurrence of any of the following events: (i) a material diminution in the Employee's title, responsibilities, authority or duties; (ii) a diminution in the Employee's base salary except for across-the-board salary reductions based on the Company's financial performance similarly affecting all senior management employees of the Company; (iii) a greater than fifty (50) mile change in the principal office location at which the Employee provides services to the Company; or (iv) the material breach of any provisions of this Agreement by the Company. "Good Reason Process" shall mean that (i) the Employee reasonably determines in good faith that a "Good Reason" condition has occurred; (ii) the Employee notifies the Company in writing of the occurrence of the Good Reason condition within 60 days of the Employee obtaining knowledge of the occurrence of such condition; (iii) the Employee cooperates in good faith with the Company's efforts, for a period not less than 30 days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) the Employee terminates his employment within 60 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

(e) Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Employee's employment by the Company or any such termination by the Employee shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a written notice which shall indicate the specific termination provision in this Agreement relied upon Employee.

(f) Date of Termination. "Date of Termination" shall mean: (i) if the Employee's employment is terminated by his death, the date of his death; (ii) if the Employee's employment is terminated by the Company under Section 3(c), the date on which a Notice of Termination is given; (iii) if the Employee's employment is terminated by the Employee under Section 3(d) without Good Reason, the date on which a Notice of Termination is given, and (iv) if the Employee's employment is terminated by the Employee under Section 3(d) with Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period.

4. Compensation Upon Termination.

(a) Termination Generally. If the Employee's employment with the Company is terminated for any reason, the Company shall pay or provide to the Employee (or to his authorized representative or estate) (i) any base salary earned through the Date of Termination, unpaid expense reimbursements (subject to, and in accordance with, Section 3(c) of this Agreement) and unused vacation that accrued through the Date of Termination on or before the time required by law but in no event more than 30 days after the Employee's Date of Termination; and (ii) any vested benefits the Employee may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans (collectively, the "Accrued Benefit").

(b) Termination by the Company Without Cause or by the Employee with Good Reason. If the Employee's employment is terminated by the Company without Cause as provided in Section 3(c), or the Employee terminates his employment for Good Reason as provided in Section 3(d), then the Company shall pay the Employee his Accrued Benefit. In addition, subject to the Employee signing a customary separation agreement containing, among other provisions, a general release of claims in favor of the Company, its subsidiaries and affiliates, confidentiality, return of property and non-disparagement, in a form and substance mutually satisfactory to the Company and the Employee (the "Separation Agreement and Release") and the Separation Agreement and Release becoming irrevocable and fully effective, all within 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

(i) the Company shall pay the Employee an amount equal to twelve (12) months of the Employee's Base Salary plus a pro-rata payment (based on the number of days of the applicable fiscal year Employee was employed prior to termination) of the Employee's Target Annual Incentive Compensation (the "Severance Amount"). Notwithstanding the foregoing, if the Employee breaches any of the provisions contained in Section 7 of this Agreement, all payments of the Severance Amount shall immediately cease;

(ii) RESERVED;

(iii) if the Employee was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Employee a monthly cash payment for twelve (12) months or the Employee's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Employee if the Employee had remained employed by the Company; and

(iv) the amounts payable under Section 4(b)(i) and (iii) shall be paid out in substantially equal installments in accordance with the Company's payroll practice commencing within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

(c) The amounts payable pursuant to Section 4(a) and 4(b) are in addition to the provisions contained within any equity agreement between the Company and the Employee, if applicable.

5. Change in Control Payment. The provisions of this Section 5 set forth certain terms of an agreement reached between the Employee and the Company regarding the Employee's rights and obligations upon the occurrence of a Change in Control of the Company. These provisions are intended to assure and encourage in advance the Employee's continued attention and dedication to his assigned duties and his objectivity during the pendency and after the occurrence of any such event. These provisions shall apply in lieu of, and expressly supersede, the provisions of Section 4(b) regarding severance pay and benefits upon a termination of employment, if such termination of employment occurs within 18 months after the occurrence of the first event constituting a Change in Control. These provisions shall terminate and be of no further force or effect beginning 18 months after the occurrence of a Change in Control.

(a) Change in Control. During the Term, if the Employee's employment is terminated by the Company without Cause as provided in Section 3(c) or the Employee terminates his employment for Good Reason as provided in Section 3(d), within three (3) months prior to a Change in Control or within 18 months after a Change in Control, then, subject to the signing of the Separation Agreement and Release by the Employee and the Separation Agreement and Release becoming irrevocable and fully effective, all within 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

(i) the Company shall pay the Employee a lump sum in cash in an amount equal to the sum of (A) eighteen (18) months of the Employee's Base Salary (or the Employee's Base Salary in effect immediately prior to the Change in Control, if higher) plus (B) one and one-half (1.5) times the Employee's Target Annual Incentive Compensation (or the Employee's Target Annual Incentive Compensation in effect immediately prior to the Change in Control, if higher);

(ii) notwithstanding anything to the contrary in any applicable option agreement or stock-based award agreement, all time-based stock options and other time-based stock-based awards held by the Employee shall immediately accelerate and become fully exercisable or nonforfeitable as of the Date of Termination;

(iii) if the Employee was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Employee a monthly cash payment for eighteen (18) months or the Employee's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Employee if the Employee had remained employed by the Company; and

(iv) The amounts payable under Section 5(a)(i) and (iii) shall be paid or commence to be paid within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payment shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period.

(b) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Employee, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Internal Revenue Code of 1986, as amended (the "Code") and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Employee becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Employee receiving a higher After Tax Amount (as defined below) than the Employee would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ii) For purposes of this Section 5(b), the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Employee as a result of the Employee's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Employee shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 5(b)(i) shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Employee within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Employee. Any determination by the Accounting Firm shall be binding upon the Company and the Employee.

(c) Definitions. For purposes of this Section 5, the following terms shall have the following meanings:

"Change in Control" shall mean any of the following:

(i) any "person," as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Act") (other than the Company, any of its subsidiaries, or any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of the Company or any of its subsidiaries), together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Act) of such person, shall become the "beneficial owner" (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities of the Company representing 50 percent or more of the combined voting power of the Company's then outstanding securities having the right to vote in an election of the Board ("Voting Securities") (in such case other than as a result of an acquisition of securities directly from the Company); or

(ii) the date a majority of the members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election; or

(iii) the consummation of (A) any consolidation or merger of the Company where the stockholders of the Company, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing in the aggregate more than 50 percent of the voting shares of the Company issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), or (B) any sale or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of the Company and its affiliates on a consolidated basis.

Notwithstanding the foregoing, a "Change in Control" shall not be deemed to have occurred for purposes of the foregoing clause (i) solely as the result of an acquisition of securities by the Company which, by reducing the number of shares of Voting Securities outstanding, increases the proportionate number of Voting Securities beneficially owned by any person to 50 percent or more of the combined voting power of all of the then outstanding Voting Securities; provided, however, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from the Company) and immediately thereafter beneficially owns 50 percent or more of the combined voting power of all of the then outstanding Voting Securities, then a "Change in Control" shall be deemed to have occurred for purposes of the foregoing clause (i).

6. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Employee's separation from service within the meaning of Section 409A of the Code, the Company determines that the Employee is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Employee becomes entitled to under this Agreement on account of the Employee's separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after the Employee's separation from service, or (B) the Employee's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Employee during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Employee's termination of employment, then such payments or benefits shall be payable only upon the Employee's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to the Employee or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

7. Confidential Information, Noncompetition and Cooperation. The terms of the Confidentiality and Proprietary Rights Agreement (the "Restrictive Covenant Agreement"), between the Company or a subsidiary thereof and the Employee, attached hereto as Exhibit A, shall continue to be in full force and effect and are incorporated by reference in this Agreement. The Employee hereby reaffirms the terms of the Restrictive Covenant Agreement as material terms of this Agreement.

(a) Litigation and Regulatory Cooperation. During and after the Employee's employment, the Employee shall reasonably cooperate with the Company in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while the Employee was employed by the Company. The Employee's cooperation in connection with such claims or actions shall include, but not be limited to, being reasonably available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after the Employee's employment, the Employee also shall cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Employee was employed by the Company. The Company shall reimburse the Employee for any reasonable out-of-pocket expenses incurred in connection with the Employee's performance of obligations pursuant to this Section 7(a) upon presentation of receipts. Nothing about the foregoing shall preclude the Employee from testifying truthfully in any forum or from providing truthful information to any regulatory authority or require the Employee to waive any attorney-client privilege or protection or violate any applicable law.

(b) Relief. The Employee agrees that it would be difficult to measure any damages caused to the Company which might result from any breach by the Employee of the promises set forth in this Section 7, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, subject to Section 8 of this Agreement, the Employee agrees that if the Employee breaches, or proposes to breach, any portion of this Agreement, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company. In addition, in the event the Employee breaches this Section 7 during a period when he is receiving severance payments pursuant to Section 4 or Section 5 hereof, the Company shall have the right to suspend or terminate such severance payments. Such suspension or termination shall not limit the Company's other options with respect to relief for such breach and shall not relieve the Employee of his duties under this Agreement.

(c) Protected Disclosures and Other Protected Action. Nothing contained in this Agreement limits the Employee's ability to communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company.

8. Arbitration of Disputes. Any controversy or claim arising out of or relating to this Agreement or the breach thereof or otherwise arising out of the Employee's employment or the termination of that employment (including, without limitation, any claims of unlawful employment discrimination whether based on age or otherwise) shall, to the fullest extent permitted by law, be settled by arbitration in any forum and form agreed upon by the parties or, in the absence of such an agreement, under the auspices of the American Arbitration Association ("AAA") in Stamford, Connecticut, in accordance with the Employment Dispute Resolution Rules of the AAA, including, but not limited to, the rules and procedures applicable to the selection of arbitrators. In the event that any person or entity other than the Employee or the Company may be a party with regard to any such controversy or claim, such controversy or claim shall be submitted to arbitration subject to such other person or entity's agreement. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. This Section 8 shall be specifically enforceable. Notwithstanding the foregoing, this Section 8 shall not preclude either party from pursuing a court action for the sole purpose of obtaining a temporary restraining order or a preliminary injunction in circumstances in which such relief is appropriate; provided that any other relief shall be pursued through an arbitration proceeding pursuant to this Section 8.

9. Consent to Jurisdiction. To the extent that any court action is permitted consistent with or to enforce Section 8 of this Agreement, the parties hereby consent to the jurisdiction of the courts of the State of Connecticut and the United States District Court for the District of Connecticut. Accordingly, with respect to any such court action, the Employee (a) submits to the personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

10. Integration. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements between the parties concerning such subject matter, including the Prior Agreement.

11. Withholding. All payments made by the Company to the Employee under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law.

12. Successor to the Employee. This Agreement shall inure to the benefit of and be enforceable by the Employee's personal representatives, executors, administrators, heirs, distributees, devisees and legatees. In the event of the Employee's death after his termination of employment but prior to the completion by the Company of all payments due to him under this Agreement, the Company shall continue such payments to the Employee's beneficiary designated in writing to the Company prior to his death (or to his estate, if the Employee fails to make such designation).

13. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

14. Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of the Employee's employment to the extent necessary to effectuate the terms contained herein.

15. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

16. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Employee at the last address the Employee has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

17. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Employee and by a duly authorized representative of the Company.

18. Governing Law. This is a Connecticut contract and shall be construed under and be governed in all respects by the laws of the State of Connecticut without giving effect to the conflict of laws principles thereof.

19. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

20. Successor to Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company expressly to assume and agree to perform this Agreement to the same extent that the Company would be required to perform it if no succession had taken place. Failure of the Company to obtain an assumption of this Agreement at or prior to the effectiveness of any succession shall be a material breach of this Agreement.

21. Gender Neutral. Wherever used herein, a pronoun in the masculine gender shall be considered as including the feminine gender unless the context clearly indicates otherwise.

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the date and year first above written.

SPRINGWORKS THERAPEUTICS, INC.

By: /s/ Daniel Lynch
Its: Chairman

EMPLOYEE

/s/ Saqib Islam
Saqib Islam

Exhibit 10.9

SPRINGWORKS THERAPEUTICS, INC.

EMPLOYMENT AGREEMENT

This Employment Agreement ("Agreement") is made as of October 10, 2019, between SpringWorks Therapeutics, Inc., a Delaware corporation (the "Company"), and Francis I. Perier, Jr. (the "Employee") and is effective as of the closing of the Company's first underwritten public offering of its equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Effective Date").

WHEREAS, the Company or a subsidiary of the Company and the Employee are parties to an offer letter, dated as of July 25, 2019 and a Severance Agreement, dated as of August 15, 2019 (collectively, the "Prior Agreements"); and

WHEREAS, the parties intend to replace the Prior Agreements with this Agreement, effective as of the Effective Date.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Employment.

(a) Term. The term of this Agreement shall commence on the Effective Date and continue until terminated in accordance with the provisions hereof (the "Term"). The Employee's employment with the Company will continue to be "at will," meaning that the Employee's employment may be terminated by the Company or the Employee at any time and for any reason subject to the terms of this Agreement.

(b) Position and Duties. During the Term, the Employee shall serve as the Chief Financial Officer of the Company, and shall have such duties and authorities as may from time to time be prescribed by the Chief Executive Officer of the Company (the "CEO"). The Employee shall devote his full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, the Employee may serve on other boards of directors, with the approval of the CEO, or engage in religious, charitable or other community activities as long as such services and activities do not materially interfere with the Employee's performance of his duties to the Company as provided in this Agreement.

2. Compensation and Related Matters.

(a) Base Salary. During the Term, the Employee's annual base salary shall be $370,000. The Employee's base salary shall be reviewed annually by the Compensation Committee of the Board (the "Compensation Committee"). The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices.

(b) Incentive Compensation. During the Term, the Employee shall be eligible to receive cash incentive compensation as determined by the Board or the Compensation Committee from time to time. The Employee's initial target annual incentive compensation shall be thirty-five percent (35%) of his Base Salary (the "Target Annual Incentive Compensation"). The Employee will receive guaranteed cash incentive compensation for 2019, prorated based on the portion of 2019 during which the Employee is employed by the Company (the "2019 Annual Incentive Compensation"). For example, if the Employee works through December 31, 2019, the 2019 Annual Incentive Compensation will be $48,562.50. The 2019 Annual Incentive Compensation will be paid no later than December 31, 2019. Following 2019, the actual cash incentive compensation payable to the Employee will be subject to the Board or Compensation Committee's assessment of the Employee's performance, as well as business conditions at the Company. Except as otherwise provided herein, to earn incentive compensation, the Employee must be employed by the Company on the day such incentive compensation is paid.

(c) Expenses. The Employee shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by him during the Term in performing services hereunder upon presentation of receipts and otherwise in accordance with the policies and procedures then in effect and established by the Company.

(d) Other Benefits. During the Term, the Employee shall be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, subject to the terms of such plans.

(e) Vacations. During the Term, the Employee shall be entitled to paid vacation in accordance with the Company's policies and procedures. The Employee shall also be entitled to all paid holidays given by the Company in accordance with the policies and procedures then in effect and established by the Company.

3. Termination. During the Term, the Employee's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. The Employee's employment shall terminate upon his death.

(b) Termination by Company for Cause. The Company may terminate the Employee's employment for Cause. For purposes of this Agreement, "Cause" shall mean that the Company has complied with the "Cause Process" (hereinafter defined) following the occurrence of one of the following events: (i) conduct by the Employee constituting a material act of misconduct in connection with the performance of his duties, including, without limitation, misappropriation of funds or property of the Company or any of its subsidiaries or affiliates other than the occasional, customary and de minimis use of Company property for personal purposes; (ii) the commission by the Employee of any felony or a misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) any conduct by the Employee that would result in material economic harm to the Company or any of its subsidiaries if he were retained in his position; (iv); a material breach by the Employee of any provisions of this Agreement, including without limitation continued non-performance by the Employee of his duties under this Agreement (other than by reason of the Employee's physical or mental illness, incapacity or disability) which has continued for more than 30 days following written notice of such non-performance from the Board; (v) a material violation by the Employee of the Company's employment policies provided to the Employee in writing; or (vi) material failure to cooperate with a bona fide internal investigation by the Board or an investigation by regulatory or law enforcement authorities, after being instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation (subject to the limitations in the final sentence of Section 7(a)). If the Employee rebuts or cures the applicable finding of Cause within the applicable cure period, Cause shall be deemed not to have occurred. "Cause Process" shall mean that: (A) the Board reasonably determines in good faith that a "Cause" condition has occurred; and (B) with regard to any termination of the Employee for Cause under items (i), (iii), (iv), (v) or (vi) above, (1) the Company will provide the Employee with written notice of its intention to terminate the Employee's employment hereunder setting forth with reasonable particularity the basis for Cause and will provide the Employee with a thirty (30) day opportunity to rebut or cure such finding of Cause and (2) the Company cooperates in good faith with the Employee's efforts, for a period of not less than 30 days following such notice to remedy the condition.

(c) Termination Without Cause. The Company may terminate the Employee's employment at any time without Cause. Any termination by the Company of the Employee's employment which does not constitute a termination for Cause under Section 3(b) and does not result from the death of the Employee under Section 3(a) shall be deemed a termination without Cause.

(d) Termination by the Employee. The Employee may terminate his employment at any time for any reason, including but not limited to Good Reason. For purposes of this Agreement, "Good Reason" shall mean that the Employee has complied with the "Good Reason Process" (hereinafter defined) following the occurrence of any of the following events: (i) a material diminution in the Employee's title, responsibilities, authority or duties; (ii) a diminution in the Employee's base salary except for across-the-board salary reductions based on the Company's financial performance similarly affecting all senior management employees of the Company; (iii) a greater than fifty (50) mile change in the principal office location at which the Employee provides services to the Company; or (iv) the material breach of any provisions of this Agreement by the Company. "Good Reason Process" shall mean that (i) the Employee reasonably determines in good faith that a "Good Reason" condition has occurred; (ii) the Employee notifies the Company in writing of the occurrence of the Good Reason condition within 60 days of the Employee obtaining knowledge of the occurrence of such condition; (iii) the Employee cooperates in good faith with the Company's efforts, for a period not less than 30 days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) the Employee terminates his employment within 60 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

(e) Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Employee's employment by the Company or any such termination by the Employee shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a written notice which shall indicate the specific termination provision in this Agreement relied upon Employee.

(f) Date of Termination. "Date of Termination" shall mean: (i) if the Employee's employment is terminated by his death, the date of his death; (ii) if the Employee's employment is terminated by the Company under Section 3(c), the date on which a Notice of Termination is given; (iii) if the Employee's employment is terminated by the Employee under Section 3(d) without Good Reason, the date on which a Notice of Termination is given, and (iv) if the Employee's employment is terminated by the Employee under Section 3(d) with Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period.

4. Compensation Upon Termination.

(a) Termination Generally. If the Employee's employment with the Company is terminated for any reason, the Company shall pay or provide to the Employee (or to his authorized representative or estate) (i) any base salary earned through the Date of Termination, unpaid expense reimbursements (subject to, and in accordance with, Section 3(c) of this Agreement) and unused vacation that accrued through the Date of Termination on or before the time required by law but in no event more than 30 days after the Employee's Date of Termination; and (ii) any vested benefits the Employee may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans (collectively, the "Accrued Benefit").

(b) Termination by the Company Without Cause or by the Employee with Good Reason. If the Employee's employment is terminated by the Company without Cause as provided in Section 3(c), or the Employee terminates his employment for Good Reason as provided in Section 3(d), then the Company shall pay the Employee his Accrued Benefit. In addition, subject to the Employee signing a customary separation agreement containing, among other provisions, a general release of claims in favor of the Company, its subsidiaries and affiliates, confidentiality, return of property and non-disparagement, in a form and substance mutually satisfactory to the Company and the Employee (the "Separation Agreement and Release") and the Separation Agreement and Release becoming irrevocable and fully effective, all within 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

(i) the Company shall pay the Employee an amount equal to nine (9) months of the Employee's Base Salary plus a pro-rata payment (based on the number of days of the applicable fiscal year Employee was employed prior to termination) of the Employee's Target Annual Incentive Compensation (the "Severance Amount"). Notwithstanding the foregoing, if the Employee breaches any of the provisions contained in Section 7 of this Agreement, all payments of the Severance Amount shall immediately cease;

(ii) RESERVED;

(iii) if the Employee was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Employee a monthly cash payment for nine (9) months or the Employee's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Employee if the Employee had remained employed by the Company; and

(iv) the amounts payable under Section 4(b)(i) and (iii) shall be paid out in substantially equal installments in accordance with the Company's payroll practice commencing within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

(c) The amounts payable pursuant to Section 4(a) and 4(b) are in addition to the provisions contained within any equity agreement between the Company and the Employee, if applicable.

5. Change in Control Payment. The provisions of this Section 5 set forth certain terms of an agreement reached between the Employee and the Company regarding the Employee's rights and obligations upon the occurrence of a Change in Control of the Company. These provisions are intended to assure and encourage in advance the Employee's continued attention and dedication to his assigned duties and his objectivity during the pendency and after the occurrence of any such event. These provisions shall apply in lieu of, and expressly supersede, the provisions of Section 4(b) regarding severance pay and benefits upon a termination of employment, if such termination of employment occurs within 18 months after the occurrence of the first event constituting a Change in Control. These provisions shall terminate and be of no further force or effect beginning 18 months after the occurrence of a Change in Control.

(a) Change in Control. During the Term, if the Employee's employment is terminated by the Company without Cause as provided in Section 3(c) or the Employee terminates his employment for Good Reason as provided in Section 3(d), within three (3) months prior to a Change in Control or within 18 months after a Change in Control, then, subject to the signing of the Separation Agreement and Release by the Employee and the Separation Agreement and Release becoming irrevocable and fully effective, all within 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

(i) the Company shall pay the Employee a lump sum in cash in an amount equal to the sum of (A) twelve (12) months of the Employee's Base Salary (or the Employee's Base Salary in effect immediately prior to the Change in Control, if higher) plus (B) one (1) times the Employee's Target Annual Incentive Compensation (or the Employee's Target Annual Incentive Compensation in effect immediately prior to the Change in Control, if higher);

(ii) notwithstanding anything to the contrary in any applicable option agreement or stock-based award agreement, all time-based stock options and other time-based stock-based awards held by the Employee shall immediately accelerate and become fully exercisable or nonforfeitable as of the Date of Termination;

(iii) if the Employee was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Employee a monthly cash payment for twelve (12) months or the Employee's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Employee if the Employee had remained employed by the Company; and

(iv) The amounts payable under Section 5(a)(i) and (iii) shall be paid or commence to be paid within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payment shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period.

(b) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Employee, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Internal Revenue Code of 1986, as amended (the "Code") and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Employee becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Employee receiving a higher After Tax Amount (as defined below) than the Employee would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ii) For purposes of this Section 5(b), the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Employee as a result of the Employee's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Employee shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 5(b)(i) shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Employee within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Employee. Any determination by the Accounting Firm shall be binding upon the Company and the Employee.

(c) Definitions. For purposes of this Section 5, the following terms shall have the following meanings:

"Change in Control" shall mean any of the following:

(i) any "person," as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Act") (other than the Company, any of its subsidiaries, or any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of the Company or any of its subsidiaries), together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Act) of such person, shall become the "beneficial owner" (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities of the Company representing 50 percent or more of the combined voting power of the Company's then outstanding securities having the right to vote in an election of the Board ("Voting Securities") (in such case other than as a result of an acquisition of securities directly from the Company); or

(ii) the date a majority of the members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election; or

(iii) the consummation of (A) any consolidation or merger of the Company where the stockholders of the Company, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing in the aggregate more than 50 percent of the voting shares of the Company issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), or (B) any sale or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of the Company and its affiliates on a consolidated basis.

Notwithstanding the foregoing, a "Change in Control" shall not be deemed to have occurred for purposes of the foregoing clause (i) solely as the result of an acquisition of securities by the Company which, by reducing the number of shares of Voting Securities outstanding, increases the proportionate number of Voting Securities beneficially owned by any person to 50 percent or more of the combined voting power of all of the then outstanding Voting Securities; provided, however, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from the Company) and immediately thereafter beneficially owns 50 percent or more of the combined voting power of all of the then outstanding Voting Securities, then a "Change in Control" shall be deemed to have occurred for purposes of the foregoing clause (i).

6. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Employee's separation from service within the meaning of Section 409A of the Code, the Company determines that the Employee is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Employee becomes entitled to under this Agreement on account of the Employee's separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after the Employee's separation from service, or (B) the Employee's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Employee during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Employee's termination of employment, then such payments or benefits shall be payable only upon the Employee's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to the Employee or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

7. Confidential Information, Noncompetition and Cooperation. The terms of the Confidentiality and Proprietary Rights Agreement (the "Restrictive Covenant Agreement"), between the Company or a subsidiary thereof and the Employee, attached hereto as Exhibit A, shall continue to be in full force and effect and are incorporated by reference in this Agreement. The Employee hereby reaffirms the terms of the Restrictive Covenant Agreement as material terms of this Agreement.

(a) Litigation and Regulatory Cooperation. During and after the Employee's employment, the Employee shall reasonably cooperate with the Company in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while the Employee was employed by the Company. The Employee's cooperation in connection with such claims or actions shall include, but not be limited to, being reasonably available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after the Employee's employment, the Employee also shall cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Employee was employed by the Company. The Company shall reimburse the Employee for any reasonable out-of-pocket expenses incurred in connection with the Employee's performance of obligations pursuant to this Section 7(a) upon presentation of receipts. Nothing about the foregoing shall preclude the Employee from testifying truthfully in any forum or from providing truthful information to any regulatory authority or require the Employee to waive any attorney-client privilege or protection or violate any applicable law.

(b) Relief. The Employee agrees that it would be difficult to measure any damages caused to the Company which might result from any breach by the Employee of the promises set forth in this Section 7, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, subject to Section 8 of this Agreement, the Employee agrees that if the Employee breaches, or proposes to breach, any portion of this Agreement, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company. In addition, in the event the Employee breaches this Section 7 during a period when he is receiving severance payments pursuant to Section 4 or Section 5 hereof, the Company shall have the right to suspend or terminate such severance payments. Such suspension or termination shall not limit the Company's other options with respect to relief for such breach and shall not relieve the Employee of his duties under this Agreement.

(c) Protected Disclosures and Other Protected Action. Nothing contained in this Agreement limits the Employee's ability to communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company.

8. Arbitration of Disputes. Any controversy or claim arising out of or relating to this Agreement or the breach thereof or otherwise arising out of the Employee's employment or the termination of that employment (including, without limitation, any claims of unlawful employment discrimination whether based on age or otherwise) shall, to the fullest extent permitted by law, be settled by arbitration in any forum and form agreed upon by the parties or, in the absence of such an agreement, under the auspices of the American Arbitration Association ("AAA") in Stamford, Connecticut, in accordance with the Employment Dispute Resolution Rules of the AAA, including, but not limited to, the rules and procedures applicable to the selection of arbitrators. In the event that any person or entity other than the Employee or the Company may be a party with regard to any such controversy or claim, such controversy or claim shall be submitted to arbitration subject to such other person or entity's agreement. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. This Section 8 shall be specifically enforceable. Notwithstanding the foregoing, this Section 8 shall not preclude either party from pursuing a court action for the sole purpose of obtaining a temporary restraining order or a preliminary injunction in circumstances in which such relief is appropriate; provided that any other relief shall be pursued through an arbitration proceeding pursuant to this Section 8.

9. Consent to Jurisdiction. To the extent that any court action is permitted consistent with or to enforce Section 8 of this Agreement, the parties hereby consent to the jurisdiction of the courts of the State of Connecticut and the United States District Court for the District of Connecticut. Accordingly, with respect to any such court action, the Employee (a) submits to the personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

10. Integration. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements between the parties concerning such subject matter, including the Prior Agreement.

11. Withholding. All payments made by the Company to the Employee under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law.

12. Successor to the Employee. This Agreement shall inure to the benefit of and be enforceable by the Employee's personal representatives, executors, administrators, heirs, distributees, devisees and legatees. In the event of the Employee's death after his termination of employment but prior to the completion by the Company of all payments due to him under this Agreement, the Company shall continue such payments to the Employee's beneficiary designated in writing to the Company prior to his death (or to his estate, if the Employee fails to make such designation).

13. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

14. Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of the Employee's employment to the extent necessary to effectuate the terms contained herein.

15. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

16. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Employee at the last address the Employee has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

17. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Employee and by a duly authorized representative of the Company.

18. Governing Law. This is a Connecticut contract and shall be construed under and be governed in all respects by the laws of the State of Connecticut without giving effect to the conflict of laws principles thereof.

19. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

20. Successor to Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company expressly to assume and agree to perform this Agreement to the same extent that the Company would be required to perform it if no succession had taken place. Failure of the Company to obtain an assumption of this Agreement at or prior to the effectiveness of any succession shall be a material breach of this Agreement.

21. Gender Neutral. Wherever used herein, a pronoun in the masculine gender shall be considered as including the feminine gender unless the context clearly indicates otherwise.

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the date and year first above written.

SPRINGWORKS THERAPEUTICS, INC.

By: Saqib Islam
Its: Chief Executive Officer

EMPLOYEE

/s/ Francis I. Perier, Jr.
Francis I. Perier, Jr.

Exhibit 10.10

SPRINGWORKS THERAPEUTICS, INC.

EMPLOYMENT AGREEMENT

This Employment Agreement ("Agreement") is made as of September 11, 2019, between SpringWorks Therapeutics, Inc., a Delaware corporation (the "Company"), and Jens Renstrup (the "Employee") and is effective as of the closing of the Company's first underwritten public offering of its equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Effective Date").

WHEREAS, the Company or a subsidiary of the Company and the Employee are parties to an offer letter, dated as of July 13, 2018 and a Severance Agreement, dated as of July 16, 2018 (collectively, the "Prior Agreements"); and

WHEREAS, the parties intend to replace the Prior Agreements with this Agreement, effective as of the Effective Date.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Employment.

(a) Term. The term of this Agreement shall commence on the Effective Date and continue until terminated in accordance with the provisions hereof (the "Term"). The Employee's employment with the Company will continue to be "at will," meaning that the Employee's employment may be terminated by the Company or the Employee at any time and for any reason subject to the terms of this Agreement.

(b) Position and Duties. During the Term, the Employee shall serve as the Chief Medical Officer of the Company, and shall have such duties and authorities as may from time to time be prescribed by the Chief Executive Officer of the Company (the "CEO"). The Employee shall devote his full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, the Employee may serve on other boards of directors, with the approval of the CEO, or engage in religious, charitable or other community activities as long as such services and activities do not materially interfere with the Employee's performance of his duties to the Company as provided in this Agreement.

2. Compensation and Related Matters.

(a) Base Salary. During the Term, the Employee's annual base salary shall be $410,000. The Employee's base salary shall be reviewed annually by the Compensation Committee of the Board (the "Compensation Committee"). The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices.

(b) Incentive Compensation. During the Term, the Employee shall be eligible to receive cash incentive compensation as determined by the Board or the Compensation Committee from time to time. The Employee's initial target annual incentive compensation shall be forty percent (40%) of his Base Salary (the "Target Annual Incentive Compensation"). The actual cash incentive compensation payable to the Employee will be subject to the Board or Compensation Committee's assessment of your performance, as well as business conditions at the Company. Except as otherwise provided herein, to earn incentive compensation, the Employee must be employed by the Company on the day such incentive compensation is paid.

(c) Expenses. The Employee shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by him during the Term in performing services hereunder upon presentation of receipts and otherwise in accordance with the policies and procedures then in effect and established by the Company.

(d) Other Benefits. During the Term, the Employee shall be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, subject to the terms of such plans.

(e) Vacations. During the Term, the Employee shall be entitled to paid vacation in accordance with the Company's policies and procedures. The Employee shall also be entitled to all paid holidays given by the Company in accordance with the policies and procedures then in effect and established by the Company.

3. Termination. During the Term, the Employee's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. The Employee's employment shall terminate upon his death.

(b) Termination by Company for Cause. The Company may terminate the Employee's employment for Cause. For purposes of this Agreement, "Cause" shall mean that the Company has complied with the "Cause Process" (hereinafter defined) following the occurrence of one of the following events: (i) conduct by the Employee constituting a material act of misconduct in connection with the performance of his duties, including, without limitation, misappropriation of funds or property of the Company or any of its subsidiaries or affiliates other than the occasional, customary and de minimis use of Company property for personal purposes; (ii) the commission by the Employee of any felony or a misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) any conduct by the Employee that would result in material economic harm to the Company or any of its subsidiaries if he were retained in his position; (iv); a material breach by the Employee of any provisions of this Agreement, including without limitation continued non-performance by the Employee of his duties under this Agreement (other than by reason of the Employee's physical or mental illness, incapacity or disability) which has continued for more than 30 days following written notice of such non-performance from the Board; (v) a material violation by the Employee of the Company's employment policies provided to the Employee in writing; or (vi) material failure to cooperate with a bona fide internal investigation by the Board or an investigation by regulatory or law enforcement authorities, after being instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation (subject to the limitations in the final sentence of Section 7(a)). If the Employee rebuts or cures the applicable finding of Cause within the applicable cure period, Cause shall be deemed not to have occurred. "Cause Process" shall mean that: (A) the Board reasonably determines in good faith that a "Cause" condition has occurred; and (B) with regard to any termination of the Employee for Cause under items (i), (iii), (iv), (v) or (vi) above, (1) the Company will provide the Employee with written notice of its intention to terminate the Employee's employment hereunder setting forth with reasonable particularity the basis for Cause and will provide the Employee with a thirty (30) day opportunity to rebut or cure such finding of Cause and (2) the Company cooperates in good faith with the Employee's efforts, for a period of not less than 30 days following such notice to remedy the condition.

(c) Termination Without Cause. The Company may terminate the Employee's employment at any time without Cause. Any termination by the Company of the Employee's employment which does not constitute a termination for Cause under Section 3(b) and does not result from the death of the Employee under Section 3(a) shall be deemed a termination without Cause.

(d) Termination by the Employee. The Employee may terminate his employment at any time for any reason, including but not limited to Good Reason. For purposes of this Agreement, "Good Reason" shall mean that the Employee has complied with the "Good Reason Process" (hereinafter defined) following the occurrence of any of the following events: (i) a material diminution in the Employee's title, responsibilities, authority or duties; (ii) a diminution in the Employee's base salary except for across-the-board salary reductions based on the Company's financial performance similarly affecting all senior management employees of the Company; (iii) a greater than fifty (50) mile change in the principal office location at which the Employee provides services to the Company; or (iv) the material breach of any provisions of this Agreement by the Company. "Good Reason Process" shall mean that (i) the Employee reasonably determines in good faith that a "Good Reason" condition has occurred; (ii) the Employee notifies the Company in writing of the occurrence of the Good Reason condition within 60 days of the Employee obtaining knowledge of the occurrence of such condition; (iii) the Employee cooperates in good faith with the Company's efforts, for a period not less than 30 days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) the Employee terminates his employment within 60 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

(e) Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Employee's employment by the Company or any such termination by the Employee shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a written notice which shall indicate the specific termination provision in this Agreement relied upon Employee.

(f) Date of Termination. "Date of Termination" shall mean: (i) if the Employee's employment is terminated by his death, the date of his death; (ii) if the Employee's employment is terminated by the Company under Section 3(c), the date on which a Notice of Termination is given; (iii) if the Employee's employment is terminated by the Employee under Section 3(d) without Good Reason, the date on which a Notice of Termination is given, and (iv) if the Employee's employment is terminated by the Employee under Section 3(d) with Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period.

4. Compensation Upon Termination.

(a) Termination Generally. If the Employee's employment with the Company is terminated for any reason, the Company shall pay or provide to the Employee (or to his authorized representative or estate) (i) any base salary earned through the Date of Termination, unpaid expense reimbursements (subject to, and in accordance with, Section 3(c) of this Agreement) and unused vacation that accrued through the Date of Termination on or before the time required by law but in no event more than 30 days after the Employee's Date of Termination; and (ii) any vested benefits the Employee may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans (collectively, the "Accrued Benefit").

(b) Termination by the Company Without Cause or by the Employee with Good Reason. If the Employee's employment is terminated by the Company without Cause as provided in Section 3(c), or the Employee terminates his employment for Good Reason as provided in Section 3(d), then the Company shall pay the Employee his Accrued Benefit. In addition, subject to the Employee signing a customary separation agreement containing, among other provisions, a general release of claims in favor of the Company, its subsidiaries and affiliates, confidentiality, return of property and non-disparagement, in a form and substance mutually satisfactory to the Company and the Employee (the "Separation Agreement and Release") and the Separation Agreement and Release becoming irrevocable and fully effective, all within 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

(i) the Company shall pay the Employee an amount equal to nine (9) months of the Employee's Base Salary plus a pro-rata payment (based on the number of days of the applicable fiscal year Employee was employed prior to termination) of the Employee's Target Annual Incentive Compensation (the "Severance Amount"). Notwithstanding the foregoing, if the Employee breaches any of the provisions contained in Section 7 of this Agreement, all payments of the Severance Amount shall immediately cease;

(ii) RESERVED;

(iii) if the Employee was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Employee a monthly cash payment for nine (9) months or the Employee's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Employee if the Employee had remained employed by the Company; and

(iv) the amounts payable under Section 4(b)(i) and (iii) shall be paid out in substantially equal installments in accordance with the Company's payroll practice commencing within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

(c) The amounts payable pursuant to Section 4(a) and 4(b) are in addition to the provisions contained within any equity agreement between the Company and the Employee, if applicable.

5. Change in Control Payment. The provisions of this Section 5 set forth certain terms of an agreement reached between the Employee and the Company regarding the Employee's rights and obligations upon the occurrence of a Change in Control of the Company. These provisions are intended to assure and encourage in advance the Employee's continued attention and dedication to his assigned duties and his objectivity during the pendency and after the occurrence of any such event. These provisions shall apply in lieu of, and expressly supersede, the provisions of Section 4(b) regarding severance pay and benefits upon a termination of employment, if such termination of employment occurs within 18 months after the occurrence of the first event constituting a Change in Control. These provisions shall terminate and be of no further force or effect beginning 18 months after the occurrence of a Change in Control.

(a) Change in Control. During the Term, if the Employee's employment is terminated by the Company without Cause as provided in Section 3(c) or the Employee terminates his employment for Good Reason as provided in Section 3(d), within three (3) months prior to a Change in Control or within 18 months after a Change in Control, then, subject to the signing of the Separation Agreement and Release by the Employee and the Separation Agreement and Release becoming irrevocable and fully effective, all within 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

(i) the Company shall pay the Employee a lump sum in cash in an amount equal to the sum of (A) twelve (12) months of the Employee's Base Salary (or the Employee's Base Salary in effect immediately prior to the Change in Control, if higher) plus (B) one (1) times the Employee's Target Annual Incentive Compensation (or the Employee's Target Annual Incentive Compensation in effect immediately prior to the Change in Control, if higher);

(ii) notwithstanding anything to the contrary in any applicable option agreement or stock-based award agreement, all time-based stock options and other time-based stock-based awards held by the Employee shall immediately accelerate and become fully exercisable or nonforfeitable as of the Date of Termination;

(iii) if the Employee was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Employee a monthly cash payment for twelve (12) months or the Employee's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Employee if the Employee had remained employed by the Company; and

(iv) The amounts payable under Section 5(a)(i) and (iii) shall be paid or commence to be paid within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payment shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period.

(b) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Employee, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Internal Revenue Code of 1986, as amended (the "Code") and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Employee becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Employee receiving a higher After Tax Amount (as defined below) than the Employee would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ii) For purposes of this Section 5(b), the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Employee as a result of the Employee's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Employee shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 5(b)(i) shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Employee within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Employee. Any determination by the Accounting Firm shall be binding upon the Company and the Employee.

(c) Definitions. For purposes of this Section 5, the following terms shall have the following meanings:

"Change in Control" shall mean any of the following:

(i) any "person," as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Act") (other than the Company, any of its subsidiaries, or any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of the Company or any of its subsidiaries), together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Act) of such person, shall become the "beneficial owner" (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities of the Company representing 50 percent or more of the combined voting power of the Company's then outstanding securities having the right to vote in an election of the Board ("Voting Securities") (in such case other than as a result of an acquisition of securities directly from the Company); or

(ii) the date a majority of the members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election; or

(iii) the consummation of (A) any consolidation or merger of the Company where the stockholders of the Company, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing in the aggregate more than 50 percent of the voting shares of the Company issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), or (B) any sale or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of the Company and its affiliates on a consolidated basis.

Notwithstanding the foregoing, a "Change in Control" shall not be deemed to have occurred for purposes of the foregoing clause (i) solely as the result of an acquisition of securities by the Company which, by reducing the number of shares of Voting Securities outstanding, increases the proportionate number of Voting Securities beneficially owned by any person to 50 percent or more of the combined voting power of all of the then outstanding Voting Securities; provided, however, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from the Company) and immediately thereafter beneficially owns 50 percent or more of the combined voting power of all of the then outstanding Voting Securities, then a "Change in Control" shall be deemed to have occurred for purposes of the foregoing clause (i).

6. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Employee's separation from service within the meaning of Section 409A of the Code, the Company determines that the Employee is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Employee becomes entitled to under this Agreement on account of the Employee's separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after the Employee's separation from service, or (B) the Employee's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Employee during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Employee's termination of employment, then such payments or benefits shall be payable only upon the Employee's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to the Employee or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

7. Confidential Information, Noncompetition and Cooperation. The terms of the Confidentiality and Proprietary Rights Agreement (the "Restrictive Covenant Agreement"), between the Company or a subsidiary thereof and the Employee, attached hereto as Exhibit A, shall continue to be in full force and effect and are incorporated by reference in this Agreement. The Employee hereby reaffirms the terms of the Restrictive Covenant Agreement as material terms of this Agreement.

(a) Litigation and Regulatory Cooperation. During and after the Employee's employment, the Employee shall reasonably cooperate with the Company in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while the Employee was employed by the Company. The Employee's cooperation in connection with such claims or actions shall include, but not be limited to, being reasonably available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after the Employee's employment, the Employee also shall cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Employee was employed by the Company. The Company shall reimburse the Employee for any reasonable out-of-pocket expenses incurred in connection with the Employee's performance of obligations pursuant to this Section 7(a) upon presentation of receipts. Nothing about the foregoing shall preclude the Employee from testifying truthfully in any forum or from providing truthful information to any regulatory authority or require the Employee to waive any attorney-client privilege or protection or violate any applicable law.

(b) Relief. The Employee agrees that it would be difficult to measure any damages caused to the Company which might result from any breach by the Employee of the promises set forth in this Section 7, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, subject to Section 8 of this Agreement, the Employee agrees that if the Employee breaches, or proposes to breach, any portion of this Agreement, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company. In addition, in the event the Employee breaches this Section 7 during a period when he is receiving severance payments pursuant to Section 4 or Section 5 hereof, the Company shall have the right to suspend or terminate such severance payments. Such suspension or termination shall not limit the Company's other options with respect to relief for such breach and shall not relieve the Employee of his duties under this Agreement.

(c) Protected Disclosures and Other Protected Action. Nothing contained in this Agreement limits the Employee's ability to communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company.

8. Arbitration of Disputes. Any controversy or claim arising out of or relating to this Agreement or the breach thereof or otherwise arising out of the Employee's employment or the termination of that employment (including, without limitation, any claims of unlawful employment discrimination whether based on age or otherwise) shall, to the fullest extent permitted by law, be settled by arbitration in any forum and form agreed upon by the parties or, in the absence of such an agreement, under the auspices of the American Arbitration Association ("AAA") in Stamford, Connecticut, in accordance with the Employment Dispute Resolution Rules of the AAA, including, but not limited to, the rules and procedures applicable to the selection of arbitrators. In the event that any person or entity other than the Employee or the Company may be a party with regard to any such controversy or claim, such controversy or claim shall be submitted to arbitration subject to such other person or entity's agreement. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. This Section 8 shall be specifically enforceable. Notwithstanding the foregoing, this Section 8 shall not preclude either party from pursuing a court action for the sole purpose of obtaining a temporary restraining order or a preliminary injunction in circumstances in which such relief is appropriate; provided that any other relief shall be pursued through an arbitration proceeding pursuant to this Section 8.

9. Consent to Jurisdiction. To the extent that any court action is permitted consistent with or to enforce Section 8 of this Agreement, the parties hereby consent to the jurisdiction of the courts of the State of Connecticut and the United States District Court for the District of Connecticut. Accordingly, with respect to any such court action, the Employee (a) submits to the personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

10. Integration. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements between the parties concerning such subject matter, including the Prior Agreement.

11. Withholding. All payments made by the Company to the Employee under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law.

12. Successor to the Employee. This Agreement shall inure to the benefit of and be enforceable by the Employee's personal representatives, executors, administrators, heirs, distributees, devisees and legatees. In the event of the Employee's death after his termination of employment but prior to the completion by the Company of all payments due to him under this Agreement, the Company shall continue such payments to the Employee's beneficiary designated in writing to the Company prior to his death (or to his estate, if the Employee fails to make such designation).

13. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

14. Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of the Employee's employment to the extent necessary to effectuate the terms contained herein.

15. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

16. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Employee at the last address the Employee has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

17. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Employee and by a duly authorized representative of the Company.

18. Governing Law. This is a Connecticut contract and shall be construed under and be governed in all respects by the laws of the State of Connecticut without giving effect to the conflict of laws principles thereof.

19. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

20. Successor to Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company expressly to assume and agree to perform this Agreement to the same extent that the Company would be required to perform it if no succession had taken place. Failure of the Company to obtain an assumption of this Agreement at or prior to the effectiveness of any succession shall be a material breach of this Agreement.

21. Gender Neutral. Wherever used herein, a pronoun in the masculine gender shall be considered as including the feminine gender unless the context clearly indicates otherwise.

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the date and year first above written.

SPRINGWORKS THERAPEUTICS, INC.

By: _____

Its: _____

EMPLOYEE

_____

Jens Renstrup

Exhibit 10.11

SPRINGWORKS THERAPEUTICS, INC.

EMPLOYMENT AGREEMENT

This Employment Agreement ("Agreement") is made as of October 10, 2019, between SpringWorks Therapeutics, Inc., a Delaware corporation (the "Company"), and Badreddin Edris (the "Employee") and is effective as of the closing of the Company's first underwritten public offering of its equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Effective Date").

WHEREAS, the Company or a subsidiary of the Company and the Employee are parties to an offer letter, dated as of September 4, 2018, and a Severance Agreement, dated as of September 10, 2018 (collectively, the "Prior Agreements"); and

WHEREAS, the parties intend to replace the Prior Agreements with this Agreement, effective as of the Effective Date.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Employment.

(a) Term. The term of this Agreement shall commence on the Effective Date and continue until terminated in accordance with the provisions hereof (the "Term"). The Employee's employment with the Company will continue to be "at will," meaning that the Employee's employment may be terminated by the Company or the Employee at any time and for any reason subject to the terms of this Agreement.

(b) Position and Duties. During the Term, the Employee shall serve as the Chief Business Officer of the Company, and shall have such duties and authorities as may from time to time be prescribed by the Chief Executive Officer of the Company (the "CEO"). The Employee shall devote his full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, the Employee may serve on other boards of directors, with the approval of the CEO, or engage in religious, charitable or other community activities as long as such services and activities do not materially interfere with the Employee's performance of his duties to the Company as provided in this Agreement.

2. Compensation and Related Matters.

(a) Base Salary. During the Term, the Employee's annual base salary shall be $390,000. The Employee's base salary shall be reviewed annually by the Compensation Committee of the Board (the "Compensation Committee"). The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices.

(b) Incentive Compensation. During the Term, the Employee shall be eligible to receive cash incentive compensation as determined by the Board or the Compensation Committee from time to time. The Employee's initial target annual incentive compensation shall be forty percent (40%) of his Base Salary (the "Target Annual Incentive Compensation"). The actual cash incentive compensation payable to the Employee will be subject to the Board or Compensation Committee's assessment of your performance, as well as business conditions at the Company. Except as otherwise provided herein, to earn incentive compensation, the Employee must be employed by the Company on the day such incentive compensation is paid.

(c) Expenses. The Employee shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by him during the Term in performing services hereunder upon presentation of receipts and otherwise in accordance with the policies and procedures then in effect and established by the Company.

(d) Other Benefits. During the Term, the Employee shall be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, subject to the terms of such plans.

(e) Vacations. During the Term, the Employee shall be entitled to paid vacation in accordance with the Company's policies and procedures. The Employee shall also be entitled to all paid holidays given by the Company in accordance with the policies and procedures then in effect and established by the Company.

3. Termination. During the Term, the Employee's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. The Employee's employment shall terminate upon his death.

(b) Termination by Company for Cause. The Company may terminate the Employee's employment for Cause. For purposes of this Agreement, "Cause" shall mean that the Company has complied with the "Cause Process" (hereinafter defined) following the occurrence of one of the following events: (i) conduct by the Employee constituting a material act of misconduct in connection with the performance of his duties, including, without limitation, misappropriation of funds or property of the Company or any of its subsidiaries or affiliates other than the occasional, customary and de minimis use of Company property for personal purposes; (ii) the commission by the Employee of any felony or a misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) any conduct by the Employee that would result in material economic harm to the Company or any of its subsidiaries if he were retained in his position; (iv); a material breach by the Employee of any provisions of this Agreement, including without limitation continued non-performance by the Employee of his duties under this Agreement (other than by reason of the Employee's physical or mental illness, incapacity or disability) which has continued for more than 30 days following written notice of such non-performance from the Board; (v) a material violation by the Employee of the Company's employment policies provided to the Employee in writing; or (vi) material failure to cooperate with a bona fide internal investigation by the Board or an investigation by regulatory or law enforcement authorities, after being instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation (subject to the limitations in the final sentence of Section 7(a)). If the Employee rebuts or cures the applicable finding of Cause within the applicable cure period, Cause shall be deemed not to have occurred. "Cause Process" shall mean that: (A) the Board reasonably determines in good faith that a "Cause" condition has occurred; and (B) with regard to any termination of the Employee for Cause under items (i), (iii), (iv), (v) or (vi) above, (1) the Company will provide the Employee with written notice of its intention to terminate the Employee's employment hereunder setting forth with reasonable particularity the basis for Cause and will provide the Employee with a thirty (30) day opportunity to rebut or cure such finding of Cause and (2) the Company cooperates in good faith with the Employee's efforts, for a period of not less than 30 days following such notice to remedy the condition.

(c) Termination Without Cause. The Company may terminate the Employee's employment at any time without Cause. Any termination by the Company of the Employee's employment which does not constitute a termination for Cause under Section 3(b) and does not result from the death of the Employee under Section 3(a) shall be deemed a termination without Cause.

(d) Termination by the Employee. The Employee may terminate his employment at any time for any reason, including but not limited to Good Reason. For purposes of this Agreement, "Good Reason" shall mean that the Employee has complied with the "Good Reason Process" (hereinafter defined) following the occurrence of any of the following events: (i) a material diminution in the Employee's title, responsibilities, authority or duties; (ii) a diminution in the Employee's base salary except for across-the-board salary reductions based on the Company's financial performance similarly affecting all senior management employees of the Company; (iii) a greater than fifty (50) mile change in the principal office location at which the Employee provides services to the Company; or (iv) the material breach of any provisions of this Agreement by the Company. "Good Reason Process" shall mean that (i) the Employee reasonably determines in good faith that a "Good Reason" condition has occurred; (ii) the Employee notifies the Company in writing of the occurrence of the Good Reason condition within 60 days of the Employee obtaining knowledge of the occurrence of such condition; (iii) the Employee cooperates in good faith with the Company's efforts, for a period not less than 30 days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) the Employee terminates his employment within 60 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

(e) Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Employee's employment by the Company or any such termination by the Employee shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a written notice which shall indicate the specific termination provision in this Agreement relied upon Employee.

(f) Date of Termination. "Date of Termination" shall mean: (i) if the Employee's employment is terminated by his death, the date of his death; (ii) if the Employee's employment is terminated by the Company under Section 3(c), the date on which a Notice of Termination is given; (iii) if the Employee's employment is terminated by the Employee under Section 3(d) without Good Reason, the date on which a Notice of Termination is given, and (iv) if the Employee's employment is terminated by the Employee under Section 3(d) with Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period.

4. Compensation Upon Termination.

(a) Termination Generally. If the Employee's employment with the Company is terminated for any reason, the Company shall pay or provide to the Employee (or to his authorized representative or estate) (i) any base salary earned through the Date of Termination, unpaid expense reimbursements (subject to, and in accordance with, Section 3(c) of this Agreement) and unused vacation that accrued through the Date of Termination on or before the time required by law but in no event more than 30 days after the Employee's Date of Termination; and (ii) any vested benefits the Employee may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans (collectively, the "Accrued Benefit").

(b) Termination by the Company Without Cause or by the Employee with Good Reason. If the Employee's employment is terminated by the Company without Cause as provided in Section 3(c), or the Employee terminates his employment for Good Reason as provided in Section 3(d), then the Company shall pay the Employee his Accrued Benefit. In addition, subject to the Employee signing a customary separation agreement containing, among other provisions, a general release of claims in favor of the Company, its subsidiaries and affiliates, confidentiality, return of property and non-disparagement, in a form and substance mutually satisfactory to the Company and the Employee (the "Separation Agreement and Release") and the Separation Agreement and Release becoming irrevocable and fully effective, all within 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

(i) the Company shall pay the Employee an amount equal to nine (9) months of the Employee's Base Salary plus a pro-rata payment (based on the number of days of the applicable fiscal year Employee was employed prior to termination) of the Employee's Target Annual Incentive Compensation (the "Severance Amount"). Notwithstanding the foregoing, if the Employee breaches any of the provisions contained in Section 7 of this Agreement, all payments of the Severance Amount shall immediately cease;

(ii) RESERVED;

(iii) if the Employee was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Employee a monthly cash payment for nine (9) months or the Employee's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Employee if the Employee had remained employed by the Company; and

(iv) the amounts payable under Section 4(b)(i) and (iii) shall be paid out in substantially equal installments in accordance with the Company's payroll practice commencing within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

(c) The amounts payable pursuant to Section 4(a) and 4(b) are in addition to the provisions contained within any equity agreement between the Company and the Employee, if applicable.

5. Change in Control Payment. The provisions of this Section 5 set forth certain terms of an agreement reached between the Employee and the Company regarding the Employee's rights and obligations upon the occurrence of a Change in Control of the Company. These provisions are intended to assure and encourage in advance the Employee's continued attention and dedication to his assigned duties and his objectivity during the pendency and after the occurrence of any such event. These provisions shall apply in lieu of, and expressly supersede, the provisions of Section 4(b) regarding severance pay and benefits upon a termination of employment, if such termination of employment occurs within 18 months after the occurrence of the first event constituting a Change in Control. These provisions shall terminate and be of no further force or effect beginning 18 months after the occurrence of a Change in Control.

(a) Change in Control. During the Term, if the Employee's employment is terminated by the Company without Cause as provided in Section 3(c) or the Employee terminates his employment for Good Reason as provided in Section 3(d), within three (3) months prior to a Change in Control or within 18 months after a Change in Control, then, subject to the signing of the Separation Agreement and Release by the Employee and the Separation Agreement and Release becoming irrevocable and fully effective, all within 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

(i) the Company shall pay the Employee a lump sum in cash in an amount equal to the sum of (A) twelve (12) months of the Employee's Base Salary (or the Employee's Base Salary in effect immediately prior to the Change in Control, if higher) plus (B) one (1) times the Employee's Target Annual Incentive Compensation (or the Employee's Target Annual Incentive Compensation in effect immediately prior to the Change in Control, if higher);

(ii) notwithstanding anything to the contrary in any applicable option agreement or stock-based award agreement, all time-based stock options and other time-based stock-based awards held by the Employee shall immediately accelerate and become fully exercisable or nonforfeitable as of the Date of Termination;

(iii) if the Employee was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Employee a monthly cash payment for twelve (12) months or the Employee's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Employee if the Employee had remained employed by the Company; and

(iv) The amounts payable under Section 5(a)(i) and (iii) shall be paid or commence to be paid within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payment shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period.

(b) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Employee, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Internal Revenue Code of 1986, as amended (the "Code") and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Employee becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Employee receiving a higher After Tax Amount (as defined below) than the Employee would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ii) For purposes of this Section 5(b), the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Employee as a result of the Employee's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Employee shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 5(b)(i) shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Employee within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Employee. Any determination by the Accounting Firm shall be binding upon the Company and the Employee.

(c) Definitions. For purposes of this Section 5, the following terms shall have the following meanings:

"Change in Control" shall mean any of the following:

(i) any "person," as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Act") (other than the Company, any of its subsidiaries, or any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of the Company or any of its subsidiaries), together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Act) of such person, shall become the "beneficial owner" (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities of the Company representing 50 percent or more of the combined voting power of the Company's then outstanding securities having the right to vote in an election of the Board ("Voting Securities") (in such case other than as a result of an acquisition of securities directly from the Company); or

(ii) the date a majority of the members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election; or

(iii) the consummation of (A) any consolidation or merger of the Company where the stockholders of the Company, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing in the aggregate more than 50 percent of the voting shares of the Company issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), or (B) any sale or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of the Company and its affiliates on a consolidated basis.

Notwithstanding the foregoing, a "Change in Control" shall not be deemed to have occurred for purposes of the foregoing clause (i) solely as the result of an acquisition of securities by the Company which, by reducing the number of shares of Voting Securities outstanding, increases the proportionate number of Voting Securities beneficially owned by any person to 50 percent or more of the combined voting power of all of the then outstanding Voting Securities; provided, however, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from the Company) and immediately thereafter beneficially owns 50 percent or more of the combined voting power of all of the then outstanding Voting Securities, then a "Change in Control" shall be deemed to have occurred for purposes of the foregoing clause (i).

6. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Employee's separation from service within the meaning of Section 409A of the Code, the Company determines that the Employee is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Employee becomes entitled to under this Agreement on account of the Employee's separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after the Employee's separation from service, or (B) the Employee's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Employee during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Employee's termination of employment, then such payments or benefits shall be payable only upon the Employee's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to the Employee or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

7. Confidential Information, Noncompetition and Cooperation. The terms of the Confidentiality and Proprietary Rights Agreement (the "Restrictive Covenant Agreement"), between the Company or a subsidiary thereof and the Employee, attached hereto as Exhibit A, shall continue to be in full force and effect and are incorporated by reference in this Agreement. The Employee hereby reaffirms the terms of the Restrictive Covenant Agreement as material terms of this Agreement.

(a) Litigation and Regulatory Cooperation. During and after the Employee's employment, the Employee shall reasonably cooperate with the Company in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while the Employee was employed by the Company. The Employee's cooperation in connection with such claims or actions shall include, but not be limited to, being reasonably available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after the Employee's employment, the Employee also shall cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Employee was employed by the Company. The Company shall reimburse the Employee for any reasonable out-of-pocket expenses incurred in connection with the Employee's performance of obligations pursuant to this Section 7(a) upon presentation of receipts. Nothing about the foregoing shall preclude the Employee from testifying truthfully in any forum or from providing truthful information to any regulatory authority or require the Employee to waive any attorney-client privilege or protection or violate any applicable law.

(b) Relief. The Employee agrees that it would be difficult to measure any damages caused to the Company which might result from any breach by the Employee of the promises set forth in this Section 7, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, subject to Section 8 of this Agreement, the Employee agrees that if the Employee breaches, or proposes to breach, any portion of this Agreement, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company. In addition, in the event the Employee breaches this Section 7 during a period when he is receiving severance payments pursuant to Section 4 or Section 5 hereof, the Company shall have the right to suspend or terminate such severance payments. Such suspension or termination shall not limit the Company's other options with respect to relief for such breach and shall not relieve the Employee of his duties under this Agreement.

(c) Protected Disclosures and Other Protected Action. Nothing contained in this Agreement limits the Employee's ability to communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company.

8. Arbitration of Disputes. Any controversy or claim arising out of or relating to this Agreement or the breach thereof or otherwise arising out of the Employee's employment or the termination of that employment (including, without limitation, any claims of unlawful employment discrimination whether based on age or otherwise) shall, to the fullest extent permitted by law, be settled by arbitration in any forum and form agreed upon by the parties or, in the absence of such an agreement, under the auspices of the American Arbitration Association ("AAA") in Stamford, Connecticut, in accordance with the Employment Dispute Resolution Rules of the AAA, including, but not limited to, the rules and procedures applicable to the selection of arbitrators. In the event that any person or entity other than the Employee or the Company may be a party with regard to any such controversy or claim, such controversy or claim shall be submitted to arbitration subject to such other person or entity's agreement. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. This Section 8 shall be specifically enforceable. Notwithstanding the foregoing, this Section 8 shall not preclude either party from pursuing a court action for the sole purpose of obtaining a temporary restraining order or a preliminary injunction in circumstances in which such relief is appropriate; provided that any other relief shall be pursued through an arbitration proceeding pursuant to this Section 8.

9. Consent to Jurisdiction. To the extent that any court action is permitted consistent with or to enforce Section 8 of this Agreement, the parties hereby consent to the jurisdiction of the courts of the State of Connecticut and the United States District Court for the District of Connecticut. Accordingly, with respect to any such court action, the Employee (a) submits to the personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

10. Integration. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements between the parties concerning such subject matter, including the Prior Agreement.

11. Withholding. All payments made by the Company to the Employee under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law.

12. Successor to the Employee. This Agreement shall inure to the benefit of and be enforceable by the Employee's personal representatives, executors, administrators, heirs, distributees, devisees and legatees. In the event of the Employee's death after his termination of employment but prior to the completion by the Company of all payments due to him under this Agreement, the Company shall continue such payments to the Employee's beneficiary designated in writing to the Company prior to his death (or to his estate, if the Employee fails to make such designation).

13. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

14. Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of the Employee's employment to the extent necessary to effectuate the terms contained herein.

15. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

16. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Employee at the last address the Employee has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

17. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Employee and by a duly authorized representative of the Company.

18. Governing Law. This is a Connecticut contract and shall be construed under and be governed in all respects by the laws of the State of Connecticut without giving effect to the conflict of laws principles thereof.

19. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

20. Successor to Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company expressly to assume and agree to perform this Agreement to the same extent that the Company would be required to perform it if no succession had taken place. Failure of the Company to obtain an assumption of this Agreement at or prior to the effectiveness of any succession shall be a material breach of this Agreement.

21. Gender Neutral. Wherever used herein, a pronoun in the masculine gender shall be considered as including the feminine gender unless the context clearly indicates otherwise.

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the date and year first above written.

SPRINGWORKS THERAPEUTICS, INC.

By: /s/ Saqib Islam
Its: Chief Executive Officer

EMPLOYEE

/s/ Badreddin Edris
Badreddin Edris

Exhibit 10.12

SPRINGWORKS THERAPEUTICS, INC.

EMPLOYMENT AGREEMENT

This Employment Agreement ("Agreement") is made as of October 10, 2019, between SpringWorks Therapeutics, Inc., a Delaware corporation (the "Company"), and Lesley Mary Smith (the "Employee") and is effective as of the closing of the Company's first underwritten public offering of its equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Effective Date").

WHEREAS, the Company or a subsidiary of the Company and the Employee are parties to an offer letter, dated as of August 8, 2017, and a Severance Agreement, dated as of September 4, 2018 (collectively, the "Prior Agreements"); and

WHEREAS, the parties intend to replace the Prior Agreements with this Agreement, effective as of the Effective Date.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Employment.

(a) Term. The term of this Agreement shall commence on the Effective Date and continue until terminated in accordance with the provisions hereof (the "Term"). The Employee's employment with the Company will continue to be "at will," meaning that the Employee's employment may be terminated by the Company or the Employee at any time and for any reason subject to the terms of this Agreement.

(b) Position and Duties. During the Term, the Employee shall serve as the Senior Vice President, Clinical Research and Development of the Company, and shall have such duties and authorities as may from time to time be prescribed by the Chief Executive Officer of the Company (the "CEO"). The Employee shall devote her full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, the Employee may serve on other boards of directors, with the approval of the CEO, or engage in religious, charitable or other community activities as long as such services and activities do not materially interfere with the Employee's performance of her duties to the Company as provided in this Agreement.

2. Compensation and Related Matters.

(a) Base Salary. During the Term, the Employee's annual base salary shall be $390,000. The Employee's base salary shall be reviewed annually by the Compensation Committee of the Board (the "Compensation Committee"). The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices.

(b) Incentive Compensation. During the Term, the Employee shall be eligible to receive cash incentive compensation as determined by the Board or the Compensation Committee from time to time. The Employee's initial target annual incentive compensation shall be forty percent (40%) of her Base Salary (the "Target Annual Incentive Compensation"). The actual cash incentive compensation payable to the Employee will be subject to the Board or Compensation Committee's assessment of your performance, as well as business conditions at the Company. Except as otherwise provided herein, to earn incentive compensation, the Employee must be employed by the Company on the day such incentive compensation is paid.

(c) Expenses. The Employee shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by him during the Term in performing services hereunder upon presentation of receipts and otherwise in accordance with the policies and procedures then in effect and established by the Company.

(d) Other Benefits. During the Term, the Employee shall be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, subject to the terms of such plans.

(e) Vacations. During the Term, the Employee shall be entitled to paid vacation in accordance with the Company's policies and procedures. The Employee shall also be entitled to all paid holidays given by the Company in accordance with the policies and procedures then in effect and established by the Company.

3. Termination. During the Term, the Employee's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. The Employee's employment shall terminate upon her death.

(b) Termination by Company for Cause. The Company may terminate the Employee's employment for Cause. For purposes of this Agreement, "Cause" shall mean that the Company has complied with the "Cause Process" (hereinafter defined) following the occurrence of one of the following events: (i) conduct by the Employee constituting a material act of misconduct in connection with the performance of her duties, including, without limitation, misappropriation of funds or property of the Company or any of its subsidiaries or affiliates other than the occasional, customary and de minimis use of Company property for personal purposes; (ii) the commission by the Employee of any felony or a misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) any conduct by the Employee that would result in material economic harm to the Company or any of its subsidiaries if she were retained in her position; (iv); a material breach by the Employee of any provisions of this Agreement, including without limitation continued non-performance by the Employee of her duties under this Agreement (other than by reason of the Employee's physical or mental illness, incapacity or disability) which has continued for more than 30 days following written notice of such non-performance from the Board; (v) a material violation by the Employee of the Company's employment policies provided to the Employee in writing; or (vi) material failure to cooperate with a bona fide internal investigation by the Board or an investigation by regulatory or law enforcement authorities, after being instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation (subject to the limitations in the final sentence of Section 7(a)). If the Employee rebuts or cures the applicable finding of Cause within the applicable cure period, Cause shall be deemed not to have occurred. "Cause Process" shall mean that: (A) the Board reasonably determines in good faith that a "Cause" condition has occurred; and (B) with regard to any termination of the Employee for Cause under items (i), (iii), (iv), (v) or (vi) above, (1) the Company will provide the Employee with written notice of its intention to terminate the Employee's employment hereunder setting forth with reasonable particularity the basis for Cause and will provide the Employee with a thirty (30) day opportunity to rebut or cure such finding of Cause and (2) the Company cooperates in good faith with the Employee's efforts, for a period of not less than 30 days following such notice to remedy the condition.

(c) Termination Without Cause. The Company may terminate the Employee's employment at any time without Cause. Any termination by the Company of the Employee's employment which does not constitute a termination for Cause under Section 3(b) and does not result from the death of the Employee under Section 3(a) shall be deemed a termination without Cause.

(d) Termination by the Employee. The Employee may terminate her employment at any time for any reason, including but not limited to Good Reason. For purposes of this Agreement, "Good Reason" shall mean that the Employee has complied with the "Good Reason Process" (hereinafter defined) following the occurrence of any of the following events: (i) a material diminution in the Employee's title, responsibilities, authority or duties; (ii) a diminution in the Employee's base salary except for across-the-board salary reductions based on the Company's financial performance similarly affecting all senior management employees of the Company; (iii) a greater than fifty (50) mile change in the principal office location at which the Employee provides services to the Company; or (iv) the material breach of any provisions of this Agreement by the Company. "Good Reason Process" shall mean that (i) the Employee reasonably determines in good faith that a "Good Reason" condition has occurred; (ii) the Employee notifies the Company in writing of the occurrence of the Good Reason condition within 60 days of the Employee obtaining knowledge of the occurrence of such condition; (iii) the Employee cooperates in good faith with the Company's efforts, for a period not less than 30 days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) the Employee terminates her employment within 60 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

(e) Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Employee's employment by the Company or any such termination by the Employee shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a written notice which shall indicate the specific termination provision in this Agreement relied upon Employee.

(f) Date of Termination. "Date of Termination" shall mean: (i) if the Employee's employment is terminated by her death, the date of her death; (ii) if the Employee's employment is terminated by the Company under Section 3(c), the date on which a Notice of Termination is given; (iii) if the Employee's employment is terminated by the Employee under Section 3(d) without Good Reason, the date on which a Notice of Termination is given, and (iv) if the Employee's employment is terminated by the Employee under Section 3(d) with Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period.

4. Compensation Upon Termination.

(a) Termination Generally. If the Employee's employment with the Company is terminated for any reason, the Company shall pay or provide to the Employee (or to her authorized representative or estate) (i) any base salary earned through the Date of Termination, unpaid expense reimbursements (subject to, and in accordance with, Section 3(c) of this Agreement) and unused vacation that accrued through the Date of Termination on or before the time required by law but in no event more than 30 days after the Employee's Date of Termination; and (ii) any vested benefits the Employee may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans (collectively, the "Accrued Benefit").

(b) Termination by the Company Without Cause or by the Employee with Good Reason. If the Employee's employment is terminated by the Company without Cause as provided in Section 3(c), or the Employee terminates her employment for Good Reason as provided in Section 3(d), then the Company shall pay the Employee her Accrued Benefit. In addition, subject to the Employee signing a customary separation agreement containing, among other provisions, a general release of claims in favor of the Company, its subsidiaries and affiliates, confidentiality, return of property and non-disparagement, in a form and substance mutually satisfactory to the Company and the Employee (the "Separation Agreement and Release") and the Separation Agreement and Release becoming irrevocable and fully effective, all within 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

(i) the Company shall pay the Employee an amount equal to nine (9) months of the Employee's Base Salary plus a pro-rata payment (based on the number of days of the applicable fiscal year Employee was employed prior to termination) of the Employee's Target Annual Incentive Compensation (the "Severance Amount"). Notwithstanding the foregoing, if the Employee breaches any of the provisions contained in Section 7 of this Agreement, all payments of the Severance Amount shall immediately cease;

(ii) RESERVED;

(iii) if the Employee was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Employee a monthly cash payment for nine (9) months or the Employee's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Employee if the Employee had remained employed by the Company; and

(iv) the amounts payable under Section 4(b)(i) and (iii) shall be paid out in substantially equal installments in accordance with the Company's payroll practice commencing within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

(c) The amounts payable pursuant to Section 4(a) and 4(b) are in addition to the provisions contained within any equity agreement between the Company and the Employee, if applicable.

5. Change in Control Payment. The provisions of this Section 5 set forth certain terms of an agreement reached between the Employee and the Company regarding the Employee's rights and obligations upon the occurrence of a Change in Control of the Company. These provisions are intended to assure and encourage in advance the Employee's continued attention and dedication to her assigned duties and her objectivity during the pendency and after the occurrence of any such event. These provisions shall apply in lieu of, and expressly supersede, the provisions of Section 4(b) regarding severance pay and benefits upon a termination of employment, if such termination of employment occurs within 18 months after the occurrence of the first event constituting a Change in Control. These provisions shall terminate and be of no further force or effect beginning 18 months after the occurrence of a Change in Control.

(a) Change in Control. During the Term, if the Employee's employment is terminated by the Company without Cause as provided in Section 3(c) or the Employee terminates her employment for Good Reason as provided in Section 3(d), within three (3) months prior to a Change in Control or within 18 months after a Change in Control, then, subject to the signing of the Separation Agreement and Release by the Employee and the Separation Agreement and Release becoming irrevocable and fully effective, all within 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

(i) the Company shall pay the Employee a lump sum in cash in an amount equal to the sum of (A) twelve (12) months of the Employee's Base Salary (or the Employee's Base Salary in effect immediately prior to the Change in Control, if higher) plus (B) one (1) times the Employee's Target Annual Incentive Compensation (or the Employee's Target Annual Incentive Compensation in effect immediately prior to the Change in Control, if higher);

(ii) notwithstanding anything to the contrary in any applicable option agreement or stock-based award agreement, all time-based stock options and other time-based stock-based awards held by the Employee shall immediately accelerate and become fully exercisable or nonforfeitable as of the Date of Termination;

(iii) if the Employee was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Employee a monthly cash payment for twelve (12) months or the Employee's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Employee if the Employee had remained employed by the Company; and

(iv) The amounts payable under Section 5(a)(i) and (iii) shall be paid or commence to be paid within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payment shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period.

(b) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Employee, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Internal Revenue Code of 1986, as amended (the "Code") and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Employee becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Employee receiving a higher After Tax Amount (as defined below) than the Employee would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ii) For purposes of this Section 5(b), the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Employee as a result of the Employee's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Employee shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 5(b)(i) shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Employee within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Employee. Any determination by the Accounting Firm shall be binding upon the Company and the Employee.

(c) Definitions. For purposes of this Section 5, the following terms shall have the following meanings:

"Change in Control" shall mean any of the following:

(i) any "person," as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Act") (other than the Company, any of its subsidiaries, or any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of the Company or any of its subsidiaries), together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Act) of such person, shall become the "beneficial owner" (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities of the Company representing 50 percent or more of the combined voting power of the Company's then outstanding securities having the right to vote in an election of the Board ("Voting Securities") (in such case other than as a result of an acquisition of securities directly from the Company); or

(ii) the date a majority of the members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election; or

(iii) the consummation of (A) any consolidation or merger of the Company where the stockholders of the Company, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing in the aggregate more than 50 percent of the voting shares of the Company issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), or (B) any sale or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of the Company and its affiliates on a consolidated basis.

Notwithstanding the foregoing, a "Change in Control" shall not be deemed to have occurred for purposes of the foregoing clause (i) solely as the result of an acquisition of securities by the Company which, by reducing the number of shares of Voting Securities outstanding, increases the proportionate number of Voting Securities beneficially owned by any person to 50 percent or more of the combined voting power of all of the then outstanding Voting Securities; provided, however, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from the Company) and immediately thereafter beneficially owns 50 percent or more of the combined voting power of all of the then outstanding Voting Securities, then a "Change in Control" shall be deemed to have occurred for purposes of the foregoing clause (i).

6. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Employee's separation from service within the meaning of Section 409A of the Code, the Company determines that the Employee is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Employee becomes entitled to under this Agreement on account of the Employee's separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after the Employee's separation from service, or (B) the Employee's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Employee during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Employee's termination of employment, then such payments or benefits shall be payable only upon the Employee's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to the Employee or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

7. Confidential Information, Noncompetition and Cooperation. The terms of the Confidentiality and Proprietary Rights Agreement (the "Restrictive Covenant Agreement"), between the Company or a subsidiary thereof and the Employee, attached hereto as Exhibit A, shall continue to be in full force and effect and are incorporated by reference in this Agreement. The Employee hereby reaffirms the terms of the Restrictive Covenant Agreement as material terms of this Agreement.

(a) Litigation and Regulatory Cooperation. During and after the Employee's employment, the Employee shall reasonably cooperate with the Company in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while the Employee was employed by the Company. The Employee's cooperation in connection with such claims or actions shall include, but not be limited to, being reasonably available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after the Employee's employment, the Employee also shall cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Employee was employed by the Company. The Company shall reimburse the Employee for any reasonable out-of-pocket expenses incurred in connection with the Employee's performance of obligations pursuant to this Section 7(a) upon presentation of receipts. Nothing about the foregoing shall preclude the Employee from testifying truthfully in any forum or from providing truthful information to any regulatory authority or require the Employee to waive any attorney-client privilege or protection or violate any applicable law.

(b) Relief. The Employee agrees that it would be difficult to measure any damages caused to the Company which might result from any breach by the Employee of the promises set forth in this Section 7, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, subject to Section 8 of this Agreement, the Employee agrees that if the Employee breaches, or proposes to breach, any portion of this Agreement, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company. In addition, in the event the Employee breaches this Section 7 during a period when she is receiving severance payments pursuant to Section 4 or Section 5 hereof, the Company shall have the right to suspend or terminate such severance payments. Such suspension or termination shall not limit the Company's other options with respect to relief for such breach and shall not relieve the Employee of her duties under this Agreement.

(c) Protected Disclosures and Other Protected Action. Nothing contained in this Agreement limits the Employee's ability to communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company.

8. Arbitration of Disputes. Any controversy or claim arising out of or relating to this Agreement or the breach thereof or otherwise arising out of the Employee's employment or the termination of that employment (including, without limitation, any claims of unlawful employment discrimination whether based on age or otherwise) shall, to the fullest extent permitted by law, be settled by arbitration in any forum and form agreed upon by the parties or, in the absence of such an agreement, under the auspices of the American Arbitration Association ("AAA") in Stamford, Connecticut, in accordance with the Employment Dispute Resolution Rules of the AAA, including, but not limited to, the rules and procedures applicable to the selection of arbitrators. In the event that any person or entity other than the Employee or the Company may be a party with regard to any such controversy or claim, such controversy or claim shall be submitted to arbitration subject to such other person or entity's agreement. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. This Section 8 shall be specifically enforceable. Notwithstanding the foregoing, this Section 8 shall not preclude either party from pursuing a court action for the sole purpose of obtaining a temporary restraining order or a preliminary injunction in circumstances in which such relief is appropriate; provided that any other relief shall be pursued through an arbitration proceeding pursuant to this Section 8.

9. Consent to Jurisdiction. To the extent that any court action is permitted consistent with or to enforce Section 8 of this Agreement, the parties hereby consent to the jurisdiction of the courts of the State of Connecticut and the United States District Court for the District of Connecticut. Accordingly, with respect to any such court action, the Employee (a) submits to the personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

10. Integration. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements between the parties concerning such subject matter, including the Prior Agreement.

11. Withholding. All payments made by the Company to the Employee under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law.

12. Successor to the Employee. This Agreement shall inure to the benefit of and be enforceable by the Employee's personal representatives, executors, administrators, heirs, distributees, devisees and legatees. In the event of the Employee's death after her termination of employment but prior to the completion by the Company of all payments due to him under this Agreement, the Company shall continue such payments to the Employee's beneficiary designated in writing to the Company prior to her death (or to her estate, if the Employee fails to make such designation).

13. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

14. Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of the Employee's employment to the extent necessary to effectuate the terms contained herein.

15. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

16. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Employee at the last address the Employee has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

17. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Employee and by a duly authorized representative of the Company.

18. Governing Law. This is a Connecticut contract and shall be construed under and be governed in all respects by the laws of the State of Connecticut without giving effect to the conflict of laws principles thereof.

19. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

20. Successor to Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company expressly to assume and agree to perform this Agreement to the same extent that the Company would be required to perform it if no succession had taken place. Failure of the Company to obtain an assumption of this Agreement at or prior to the effectiveness of any succession shall be a material breach of this Agreement.

21. Gender Neutral. Wherever used herein, a pronoun in the masculine gender shall be considered as including the feminine gender unless the context clearly indicates otherwise.

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the date and year first above written.

SPRINGWORKS THERAPEUTICS, INC.

By: /s/ Saqib Islam
Its: Chief Executive Officer

EMPLOYEE

/s/ L. Mary Smith
L. Mary Smith

Exhibit 31.1

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

CERTIFICATIONS

I, Saqib Islam, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of SpringWorks Therapeutics, 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 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)):

(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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

(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 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 12, 2019

By: /s/ Saqib Islam
Saqib Islam
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

CERTIFICATIONS

I, Francis I. Perier, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of SpringWorks Therapeutics, 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 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)):

(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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

(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 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 12, 2019

By: /s/ Francis I. Perier, Jr.
Francis I. Perier, Jr.
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of SpringWorks Therapeutics, Inc. (the "Company") for the period ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Saqib Islam, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his 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 12, 2019

By: /s/ Saqib Islam
Saqib Islam
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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 SpringWorks Therapeutics, Inc. (the "Company") for the period ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Francis I. Perier, Jr., Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his 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 12, 2019

By: /s/ Francis I. Perier, Jr.
Francis I. Perier, Jr.
Chief Financial Officer
(Principal Financial Officer)