

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 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, 2020

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: 001-39503

Athira Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

45-3368487
(I.R.S. Employer
Identification No.)

4000 Mason Road, Suite 300
Seattle, Washington 98195
(Address of principal executive offices)
(206) 221-8112

(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, \$0.0001 par value per share	ATHA	The Nasdaq Stock Market LLC (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 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised 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

As of November 9, 2020 there were 32,485,184 shares of registrant's common stock, \$0.0001 par value per share, outstanding.

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SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those highlighted in the section of this report captioned “Risk Factors.” The following is a summary of the principal risks we face:

- We are a late clinical-stage biopharmaceutical company with a limited operating history.
- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives.
- Our development of ATH-1017 may never lead to a marketable product.
- Our approach to targeting brain growth factors through the use of small molecules is based on a novel therapeutic approach, which exposes us to unforeseen risks. We have limited data from our Phase 1a and 1b clinical trials, including only 11 patients with mild to moderate Alzheimer’s disease, and we cannot be certain that future trials will yield similar data. In addition, our use of electroencephalogram methods to gather data requires placement of electrodes on a subject’s scalp and, if not properly placed, we may be unable to obtain the data sought or data obtained may be unreliable.
- We have concentrated our research and development efforts on the treatment of central nervous system and peripheral degenerative disorders, a field that has seen very limited success in product development.
- Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of early, smaller-scale studies and clinical trials with a single or few clinical trial sites may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials across multiple clinical trial sites. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all.
- If we experience delays or difficulties in the enrollment and/or retention of patients in clinical trials, our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented.
- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer, or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.
- The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our nonclinical studies and clinical trials.
- We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.
- We will require substantial additional funding to finance our operations, complete the development and commercialization of ATH-1017, and evaluate other and future product candidates. If we are unable to raise this funding when needed, we may be forced to delay, reduce, or eliminate our product development programs or other operations.
- The regulatory approval processes of the U.S. Food and Drug Administration and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.
- We plan to rely on third parties to conduct our nonclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.
- Even if approved, our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.
- We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.
- If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.
- The market price of our common stock may be volatile, which could result in substantial losses for investors.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

Athira Pharma, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 165,725	\$ 2,056
Short-term investments	60,547	—
Prepaid expenses and other current assets	5,994	97
Current portion of unsecured related party note receivable	—	7
Total current assets	232,266	2,160
Property and equipment, net	1,003	—
Operating lease right-of-use asset	959	—
Long-term investments	33,656	—
Other long-term assets	55	—
Unsecured related party note receivable	—	29
Total assets	<u>\$ 267,939</u>	<u>\$ 2,189</u>
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 3,872	\$ 421
Accrued liabilities	2,125	852
Current operating lease liability	57	—
Grant liability	1,500	—
Total current liabilities	7,554	1,273
Operating lease liability, less current portion	915	—
Grant liability	—	1,036
Derivative liability	—	999
Convertible notes, net	—	1,553
Total liabilities	8,469	4,861
Commitments and contingencies (Note 8)		
Convertible preferred stock, \$0.0001 par value; 0 and 2,797,464 shares authorized at September 30, 2020 and December 31, 2019, respectively; 0 and 2,617,386 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	17,051
Stockholders' equity (deficit):		
Common stock, \$0.0001 par value; 900,000,000 and 10,088,017 shares authorized at September 30, 2020 and December 31, 2019, respectively; 31,087,395 and 3,641,449 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	3	—
Additional paid-in capital	292,800	1,364
Accumulated other comprehensive income	7	—
Accumulated deficit	(33,340)	(21,087)
Total stockholders' equity (deficit)	259,470	(19,723)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 267,939</u>	<u>\$ 2,189</u>

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

Athira Pharma, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 5,830	\$ 1,026	\$ 8,099	\$ 3,135
General and administrative	1,567	509	2,817	1,197
Total operating expenses	<u>7,397</u>	<u>1,535</u>	<u>10,916</u>	<u>4,332</u>
Loss from operations	(7,397)	(1,535)	(10,916)	(4,332)
Other income (expense), net	(1,059)	5	(1,337)	145
Net loss	<u>\$ (8,456)</u>	<u>\$ (1,530)</u>	<u>\$ (12,253)</u>	<u>\$ (4,187)</u>
Unrealized (loss)/gain on available-for-sale securities	7	—	7	—
Comprehensive loss attributable to common shareholders	<u>\$ (8,449)</u>	<u>\$ (1,530)</u>	<u>\$ (12,246)</u>	<u>\$ (4,187)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (1.12)</u>	<u>\$ (0.43)</u>	<u>\$ (2.38)</u>	<u>\$ (1.18)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>7,564,538</u>	<u>3,554,345</u>	<u>5,155,338</u>	<u>3,551,586</u>

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

Athira Pharma, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2020	2019
Operating activities		
Net loss	\$ (12,253)	\$ (4,187)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	218	189
Change in fair value of derivative liability	132	84
Change in fair value of convertible preferred stock warrant liability	641	—
Change in fair value of grant liability	464	51
Accretion of discounts on convertible notes	289	175
Non-cash interest expense	76	61
Gain on extinguishment of convertible notes	(199)	—
Amortization of available-for-sale securities	86	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(5,919)	16
Accounts payable and accrued expenses	3,004	927
Operating lease liability	13	—
Net cash (used in) operating activities	<u>(13,448)</u>	<u>(2,684)</u>
Investing activities		
Purchases of available-for-sale securities	(94,281)	(995)
Maturities of available-for-sale securities	—	1,745
Purchases of property and equipment	(65)	—
Principal payments received on stockholder note receivable	36	5
Net cash (used in) provided by investing activities	<u>(94,310)</u>	<u>755</u>
Financing activities		
Proceeds from exercise of common stock options and common stock warrants	613	13
Proceeds from initial public offering, net of issuance costs	187,224	—
Proceeds from sales of convertible preferred stock and stock warrants, net of issuance costs	81,926	—
Proceeds from issuance of convertible notes, including derivative	1,666	884
Issuance costs of convertible notes	(2)	(5)
Proceeds from Paycheck Protection Program loan	215	—
Repayment of Paycheck Protection Program loan	(215)	—
Net cash provided by financing activities	<u>271,427</u>	<u>892</u>
Net increase (decrease) in cash and cash equivalents	163,669	(1,037)
Cash and cash equivalents, beginning of period	2,056	3,317
Cash and cash equivalents, end of period	<u>\$ 165,725</u>	<u>\$ 2,280</u>
Supplemental disclosures of cash flow information:		
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 940	\$ —
Deferred offering costs included in accounts payable and accrued liabilities	\$ 779	\$ —
Issuance of common stock warrants in connection with Series B convertible preferred stock financing	\$ 10,591	\$ —
Issuance of Series B preferred stock upon conversion of promissory notes	\$ 4,515	\$ —
Recognition of warrant liability in connection with Series B convertible preferred stock financing	\$ 364	\$ —
Derivative liability recorded upon issuance of convertible notes	\$ 774	\$ 390
Conversion of convertible preferred stock upon closing of initial public offering	\$ 92,537	\$ —
Right-of-use asset obtained in exchange for new operating lease liability	\$ 975	\$ —

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

Athira Pharma, Inc.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' (Deficit) Equity
For the Three Months Ended September 30, 2020 and 2019
(in thousands, except share amounts)
(Unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount				
Balance as of June 30, 2020	12,503,009	\$ 92,537	4,607,565	\$ —	\$ 12,355	\$ —	\$ (24,884)	\$ (12,529)
Issuance of common stock upon exercise of common stock options	—	—	262,285	—	304	—	—	304
Proceeds from initial public offering, net of underwriters' discounts and commissions and issuance costs of \$3.3 million	—	—	12,000,000	1	186,445	—	—	186,446
Conversion of convertible preferred stock	(12,503,009)	(92,537)	12,503,009	2	92,535	—	—	92,537
Exercise of common stock warrants	—	—	1,714,536	—	1,050	—	—	1,050
Stock-based compensation	—	—	—	—	111	—	—	111
Other comprehensive income	—	—	—	—	—	7	—	7
Net loss	—	—	—	—	—	—	(8,456)	(8,456)
Balance as of September 30, 2020	<u>—</u>	<u>\$ —</u>	<u>31,087,395</u>	<u>\$ 3</u>	<u>\$ 292,800</u>	<u>\$ 7</u>	<u>\$ (33,340)</u>	<u>\$ 259,470</u>

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount				
Balance as of June 30, 2019	2,617,386	\$ 17,051	3,565,789	\$ —	\$ 1,166	\$ —	\$ (18,583)	\$ (17,417)
Issuance of common stock upon exercise of common stock options	—	—	6,305	—	6	—	—	6
Stock-based compensation	—	—	—	—	69	—	—	69
Net loss	—	—	—	—	—	—	(1,530)	(1,530)
Balance as of September 30, 2019	<u>2,617,386</u>	<u>\$ 17,051</u>	<u>3,572,094</u>	<u>\$ —</u>	<u>\$ 1,241</u>	<u>\$ —</u>	<u>\$ (20,113)</u>	<u>\$ (18,872)</u>

Athira Pharma, Inc.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' (Deficit) Equity
For the Nine Months Ended September 30, 2020 and 2019
(in thousands, except share amounts)
(Unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2019	2,617,386	\$ 17,051	3,641,449	\$ —	\$ 1,364	\$ —	\$ (21,087)	\$ (19,723)
Issuance of common stock upon exercise of common stock options	—	—	540,334	—	542	—	—	542
Issuance of Series B convertible preferred stock and common stock warrants, net of issuance costs of \$3.5 million	9,372,765	70,971	—	—	10,591	—	—	10,591
Issuance of the Series B-1 convertible preferred stock upon conversion of convertible notes	512,858	4,515	—	—	—	—	—	—
Proceeds from initial public offering, net of underwriters' discounts and commissions and issuance costs of \$3.3 million	—	—	12,000,000	1	186,445	—	—	186,446
Conversion of convertible preferred stock	(12,503,009)	(92,537)	12,503,009	2	92,535	—	—	92,537
Exercise of common stock warrants	—	—	2,402,603	—	1,105	—	—	1,105
Stock-based compensation	—	—	—	—	218	—	—	218
Other comprehensive income	—	—	—	—	—	7	—	7
Net loss	—	—	—	—	—	—	(12,253)	(12,253)
Balance as of September 30, 2020	<u>—</u>	<u>\$ —</u>	<u>31,087,395</u>	<u>\$ 3</u>	<u>\$ 292,800</u>	<u>\$ 7</u>	<u>\$ (33,340)</u>	<u>\$ 259,470</u>

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2018	2,617,386	\$ 17,051	3,559,484	\$ —	\$ 1,039	\$ —	\$ (15,926)	\$ (14,887)
Issuance of common stock upon exercise of common stock options	—	—	12,610	—	13	—	—	13
Stock-based compensation	—	—	—	—	189	—	—	189
Net loss	—	—	—	—	—	—	(4,187)	(4,187)
Balance as of September 30, 2019	<u>2,617,386</u>	<u>\$ 17,051</u>	<u>3,572,094</u>	<u>\$ —</u>	<u>\$ 1,241</u>	<u>\$ —</u>	<u>\$ (20,113)</u>	<u>\$ (18,872)</u>

ATHIRA PHARMA, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

1. Description of Business

Organization

Athira Pharma, Inc. (the “Company”) was incorporated as M3 Biotechnology, Inc. in the state of Washington on March 31, 2011 and reincorporated in the state of Delaware on October 27, 2015. In April 2019, the Company changed its name to Athira Pharma, Inc. The Company currently has office and laboratory space in Seattle and Bothell Washington. The Company is a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and stop neurodegeneration.

Reverse Stock Split

On September 11, 2020, the Company effected a one-for-7.9302 reverse split of its issued and outstanding common stock, convertible preferred stock, warrants, and stock options. The par value of the common stock and convertible preferred stock was not adjusted as a result of the reverse stock split. All share and per share amounts in the accompanying unaudited condensed financial statements and notes to the unaudited condensed financial statements have been retroactively adjusted for all periods presented to reflect the reverse stock split.

Initial Public Offering

On September 17, 2020, the Company’s registration statement on Form S-1 (File No. 333-248428) for its initial public offering of common stock (“IPO”) was declared effective by the Securities and Exchange Commission (“SEC”). On September 22, 2020, the Company issued and sold 12,000,000 shares of common stock in the IPO at a public offering price of \$17.00 per share, resulting in net proceeds of \$186.4 million after deducting underwriting discounts and commissions and offering expenses paid by the Company.

In connection with the closing of the IPO, all of the Company’s outstanding shares of convertible preferred stock were automatically converted into 12,503,009 shares of common stock. Immediately prior to the Company’s IPO, all outstanding common stock warrants were exercised into 1,085,334 shares of common stock. Additionally, all outstanding Series B convertible preferred stock warrants were remeasured to their fair value. The final remeasurement of the Series B convertible preferred stock warrant liability resulted in a \$0.6 million loss which was recorded to other income (expense), net. Following remeasurement, all Series B convertible preferred stock warrants automatically net exercised into 59,093 shares of common stock and the corresponding liability was reclassified to additional paid in capital. Following the IPO, there are no shares of convertible preferred stock, common stock warrants, or Series B convertible preferred stock warrants outstanding.

Liquidity and Capital Resources

Since the Company’s inception, it has funded its operations primarily with proceeds from the sale and issuance of common stock, convertible preferred stock, common stock warrants, and convertible notes, and to a lesser extent from grant income and stock option exercises. From the Company’s inception through September 30, 2020, it has raised aggregate net cash proceeds of \$288.5 million primarily from the issuance of its common stock, convertible preferred stock, common stock warrants, and convertible notes. As of September 30, 2020, the Company had \$259.9 million in cash, cash equivalents, and investments and had not generated positive cash flows from operations. Since the Company’s inception, it has devoted substantially all of its resources to its research and development efforts such as small molecule compound discovery, nonclinical studies and clinical trials, as well as manufacturing activities, establishing and maintaining the Company’s intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations.

Based upon the Company’s current operating plan, it estimates that its \$259.9 million of cash, cash equivalents, and investments at September 30, 2020 will be sufficient to fund its operating expenses and capital expenditure requirements through at least the 12 months following the date of this Quarterly Report on Form 10-Q.

2. Significant Accounting Policies

Basis of Presentation

The condensed consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles (“U.S. GAAP”). During the third quarter of 2020, the Company incorporated Athira Pharma Australia PTY LTD in Australia and as of September 30, 2020, operations have yet to commence.

Unaudited Interim Condensed Financial Statements

The accompanying unaudited condensed balance sheet as of September 30, 2020, and condensed statements of operations and comprehensive loss, condensed statements of cash flows, and condensed statements of convertible preferred stock and stockholders’ deficit for the three and nine months ended September 30, 2020 and 2019, are unaudited. The balance sheet as of December 31, 2019 was derived from the audited financial statements as of and for the year ended December 31, 2019. The unaudited interim condensed financial statements have been prepared on a basis consistent with the audited annual financial statements as of and for the year ended December 31, 2019, and, in the opinion of management, reflect all adjustments, consisting solely of normal recurring adjustments, necessary for the fair presentation of the Company’s financial position as of September 30, 2020, and the condensed results of its operations and its cash flows for the three and nine months ended September 30, 2020 and 2019. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2020 and 2019 are also unaudited. The condensed results of operations for the three and nine months ended September 30, 2020 are not necessarily indicative of the results to be expected for the full year ending December 31, 2020 or any other period. These interim condensed consolidated financial statements should be read in conjunction with the Company’s audited financial statements as of and for the year ended December 31, 2019 included in its amended registration statement on Form S-1 (File No. 333-248428) filed with the SEC on September 17, 2020.

Fair Value Measurements

The carrying amounts of certain financial instruments, including cash, cash equivalents, investments, accounts payable and accrued expenses approximate their fair values due to the short-term nature of those amounts. The fair values of the grant liability to Washington Life Sciences Discovery Fund (“LSDF”), currently managed by the Washington State Department of Commerce, the derivative liability, and the convertible preferred stock warrant liability were estimated using level 3 unobservable inputs.

Convertible Preferred Stock Warrant Liability

Freestanding warrants to purchase shares of the Company’s convertible preferred stock are accounted for as liabilities at fair value, because the shares underlying the warrants contain contingent redemption features outside the control of the Company. Warrants classified as liabilities are recorded on the Company’s balance sheets at their fair value on the date of issuance and remeasured to fair value on each subsequent reporting period, with the changes in fair value recognized as a component of other income (expense), net in the accompanying statements of operations. The Company adjusted the liability for the final change in the fair value of these warrants immediately preceding their automatic exercise in connection with the Company’s IPO. Subsequently, the corresponding liability was reclassified to additional paid in capital.

Short-term and Long-term Investments

The Company generally invests its excess cash in investment grade short- to intermediate-term fixed income securities. Such investments are included in cash and cash equivalents, short-term investments, and long-term investments on the consolidated balance sheets, classified as available-for-sale, and reported at fair value with unrealized gains and losses included in accumulated other comprehensive loss. Realized gains and losses on the sale of these securities are recognized in net loss.

The Company periodically evaluates whether declines in fair values of its investments below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company’s ability and intent to hold the investment until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any investment before recovery of its amortized cost basis. Factors considered include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, other publicly available information that may affect the value of the investments, duration and severity of the decline in value, and our strategy and intentions for holding the investment.

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 of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Estimates include those used for fair value of assets and liabilities, accrued liabilities, valuation allowance for deferred tax assets, and stock-based compensation. Management evaluates related assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

Research and Development Expenses

Research and development expenses consist primarily of direct and indirect costs incurred for research activities, including development of our pipeline from the Company's proprietary drug discovery platform ("ATH platform"). The Company's drug discovery efforts and the development of its product candidates. Direct costs include laboratory materials and supplies, contracted research and manufacturing, clinical trial costs, consulting fees, and other expenses incurred to sustain the Company's research and development program. Indirect costs include personnel-related expenses, consisting of employee salaries, related benefits, and stock-based compensation expense for employees engaged in research and development activities, and facilities and other expenses consisting of direct and allocated expenses for rent and depreciation and lab consumables.

Research and development costs are expensed as incurred. In-licensing fees and other costs to acquire technologies used in research and development that have not yet received regulatory approval and that are not expected to have an alternative future use are expense when incurred. Non-refundable advance payments for goods and services that will be used over time for research and development are capitalized and recognized as goods are delivered or as the related services are performed. The Company estimates the period over which such services will be performed and the level of effort to be expended in each period. If actual timing of performance or the level of effort varies from the estimate, the Company adjusts the amounts recorded accordingly. The Company has not experienced any material differences between accrued or prepaid costs and actual costs since inception.

Leases

As discussed in *Recently Adopted Accounting Standards* below, the Company adopted Accounting Standards Codification ("ASC") *Topic 842 - Leases*, on July 1, 2020, effective January 1, 2020. The Company determines if an arrangement contains a lease at inception. The Company performed an evaluation of contracts in accordance with ASC 842 and has determined it has an operating lease agreement for the laboratory and office facilities that the Company occupies. Operating lease right-of-use ("ROU") assets and operating lease liabilities are recognized at the date the underlying asset becomes available for the Company's use. Operating lease liabilities are based on the present value of the future minimum lease payments over the lease term. ROU assets are measured at the amount of the lease liability, adjusted for any initial direct costs incurred and any lease payments made at or before the lease commencement date, less lease incentives received. As the Company's lease generally does not provide an implicit interest rate, the present value of the future minimum lease payments is determined using the Company's incremental borrowing rate. This rate is an estimate of the collateralized borrowing rate the Company would incur on its future lease payments over a similar term and is based on the information available to the Company at the lease commencement date, discussed in more detail below.

The Company's lease contains an option to extend the lease; lease terms are adjusted for these options only when it is reasonably certain the Company will exercise these options. The Company's lease agreement does not contain residual value guarantees or covenants.

The Company has made a policy election regarding its real estate leases not to separate nonlease components from lease components, to the extent they are fixed. Nonlease components that are not fixed are expensed as incurred as variable lease expense. The Company's lease includes variable nonlease components, such as common-area maintenance costs. The Company has elected not to record on the balance sheet a lease that has a lease term of 12 months or less and does not contain a purchase option that the Company is reasonably certain to exercise. The Company accounts for leases with initial terms of 12 months or less as operating expenses on a straight-line basis over the lease term.

Lease expense is recognized within operating expenses on a straight-line basis over the terms of the lease. Incentives granted under the Company's facilities lease, including rent holidays, are recognized as adjustments to lease expense on a straight-line basis over the term of the lease.

Stock-based Compensation

The Company measures compensation expense for all stock-based payments to employees, officers and directors based on the estimated fair value of the award at the grant date. For stock options, the Company estimates the grant date fair value of each option award using the Black-Scholes option-pricing model. Compensation expense is recognized over the requisite service period on a straight-line basis. Forfeitures are recognized as they occur.

The Company records compensation expense for stock option grants subject to performance-based milestone vesting using the accelerated attribution 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 relative satisfaction of the performance conditions as of the reporting date.

The Company adopted Accounting Standards Update (“ASU”) 2018-07 as of January 1, 2020. As a result, stock-based payments issued to non-employees prior to January 1, 2020 have been recorded at their fair values as of the transition date and are no longer subject to periodic adjustments as the underlying equity instruments vest. Any remaining compensation expense is recognized over the remaining vesting term on a straight-line basis, which reflects the service period, based on the fair value as of January 1, 2020.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without consideration of potentially dilutive securities. Diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since the effect of potentially dilutive securities is anti-dilutive given the net loss of the Company.

Segments

The Company has determined that it operates and manages one operating segment, which is the business of developing and commercializing therapeutics. The Company’s chief operating decision maker, its chief executive officer, reviews financial information on an aggregate basis for the purpose of allocating resources.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (“JOBS Act”). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it is (a) no longer an emerging growth company or (b) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act, unless early adoption is permitted. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (“FASB”) issued ASU 2016-02, *Leases (Topic 842)*, intended to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheets and disclosing key information about leasing arrangements. The Company adopted the guidance on July 1, 2020, effective January 1, 2020, using the optional transition method described in ASU 2018-11, *Leases (Topic 842) Targeted Improvements*. Prior to adoption, the Company did not have any leases with initial terms longer than 12 months. The Company will continue to account for leases with initial terms of 12 months or less as operating expenses on a straight-line basis over the lease term.

In adopting the new standard, the Company utilized certain practical expedients available. These practical expedients include waiving reassessment of 1) whether any expired or existing contracts are or contain leases; 2) lease classification of expired or existing leases; and 3) initial direct costs for existing leases. The Company also elected to use hindsight in determining the lease term and in assessing impairment of its ROU assets. Furthermore, the Company has made a policy decision regarding its real estate leases not to separate nonlease components from lease components, to the extent they are fixed. The Company has also elected not to record on the balance sheet a lease that has a lease term of 12 months or less and does not contain a purchase option that the Company is reasonably certain to exercise.

The standard had a material impact on the Company's unaudited condensed balance sheets but did not have a material impact on its unaudited condensed statements of operations or unaudited condensed statements of cash flows. The most significant impact was the recognition of \$1.0 million and \$1.0 million of operating lease ROU assets and liabilities, respectively. Refer to Note 8, Leases, for additional information regarding leases.

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 326) Improvements to Nonemployee Share-Based Payment Accounting*. The ASU simplified the accounting for share-based payments to non-employees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The Company adopted the standard on January 1, 2020 and it did not have a material impact on its financial condition, results of operations and cash flows.

In August 2018, the FASB issued ASU 2018-13, *Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. The Company adopted this standard on January 1, 2020 and it did not have a material impact on its financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments: Credit Losses (Topic 326)* as clarified in ASU 2019-04, ASU 2019-05, and ASU 2020-02. The objective of the standard is to provide information about expected credit losses on financial instruments at each reporting date and to change how other-than-temporary impairments on investment securities are recorded. The ASU will become effective beginning January 1, 2023, with early adoption permitted. The Company is currently evaluating the potential impacts of the ASU on its financial condition, results of operations, cash flows and financial statement disclosures.

Although there were several other new accounting pronouncements issued or proposed by the FASB, we do not believe any of these have had or will have material impact on our condensed consolidated financial statements.

3. Fair Value

The Company has certain assets and liabilities that are measured at fair value on a recurring basis according to a fair value hierarchy that prioritizes the inputs, assumptions and valuation techniques used to measure fair value. The three levels of the fair value hierarchy are:

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 in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly.

Level 3—Inputs are generally unobservable and reflect management's estimates of assumptions that market participants would use in pricing the asset or liability. The fair values are determined using model-based techniques, including probability-based simulation methodologies.

The determination of a financial instrument's level within the fair value hierarchy is based on an assessment of the lowest level of any input that is significant to the fair value measurement. The Company considers observable data to be market data, which is readily available, regularly distributed or updated, reliable and verifiable, not proprietary, and provided by independent sources that are actively involved in the relevant market.

The following table reflects the Company's financial asset balances measured on a recurring basis as of September 30, 2020 (in thousands):

	Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:					
Money market fund	1	\$ 66,596	—	—	\$ 66,596
Commercial paper	2	70,392	—	(3)	70,389
U.S. government debt and agency securities	2	835	—	—	835
U.S. treasury bills	2	14,999	—	—	14,999
Total cash equivalents		<u>\$ 152,822</u>	<u>\$ —</u>	<u>\$ (3)</u>	<u>\$ 152,819</u>
Short-term investments:					
Commercial paper	2	30,393	2	(1)	30,394
U.S. government debt and agency securities	2	29,220	7	—	29,227
Corporate bonds	2	926	—	—	926
Total short-term investments		<u>\$ 60,539</u>	<u>\$ 9</u>	<u>\$ (1)</u>	<u>\$ 60,547</u>
Long-term investments:					
U.S. government debt and agency securities	2	32,634	11	(9)	32,636
U. S. treasury bills	2	1,020	—	—	1,020
Total long-term investments		<u>\$ 33,654</u>	<u>\$ 11</u>	<u>\$ (9)</u>	<u>\$ 33,656</u>

The Company evaluated its investments for other-than-temporary impairment and considers the decline in market value for the securities to be primarily attributable to current economic and market conditions. For the investments, it is not more-likely-than-not that the Company will be required to sell the investments, and the Company does not intend to do so prior to the recovery of the amortized cost basis.

Prior to the IPO, the Company's level 3 financial liabilities carried at fair value and remeasured on a recurring basis are the grant liability, derivative liability, and the convertible preferred stock warrant liability. In the third quarter the Company recorded an additional \$464,000 to bring the total grant liability to \$1.5 million as the Company's IPO triggered the repayment obligation (see Note 6), and the derivative was settled upon the Company's conversion of its convertible notes in May 2020 (see Note 7). The losses resulting from the change in fair value of the grant liability, the bifurcated conversion and redemption features related to the derivative liability, and the convertible preferred stock warrant liability are classified as other income (expense), net in the accompanying condensed consolidated statements of operations and comprehensive loss. Changes in any of the assumptions related to the unobservable inputs identified may change the fair value of these instruments. For example, an increase in interest rates would generally correspond to a decrease in the fair value of the liabilities.

The following table presents the activity for the grant liability for the nine months ended September 30, 2020 and year ended December 31, 2019 (in thousands):

	Nine Months Ended September 30, 2020	Year Ended December 31, 2019
Fair value at beginning of period	\$ 1,036	\$ 936
Change in fair value of grant liability	464	100
Fair value at end of period	<u>\$ 1,500</u>	<u>\$ 1,036</u>

The following table presents the activity for the derivative liability for the nine months ended September 30, 2020 and year ended December 31, 2019 (in thousands):

	Nine Months Ended September 30, 2020	Year Ended December 31, 2019
Fair value at beginning of period	\$ 999	\$ 539
Derivative liability recorded upon issuance of convertible notes	774	389
Change in fair value of derivative liability	132	71
Derivative liability settled upon conversion of convertible notes	(1,905)	—
Fair value at end of period	<u>\$ —</u>	<u>\$ 999</u>

The following table presents the activity for the convertible preferred stock warrant liability for the nine months ended September 30, 2020 (in thousands):

	Nine Months Ended September 30, 2020
Fair value at beginning of period	\$ —
Recognition of convertible preferred stock warrant liability	364
Change in fair value	641
Settlement upon IPO	(1,005)
Fair value at end of period	<u>\$ —</u>

Prior to the IPO, the activity for the convertible preferred stock warrant liability presented in the table above was shown in the Company's financial statements as level 3. Following the IPO, the preferred stock warrant liability was revalued based on the IPO price of \$17.00 per share.

4. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	As of September 30, 2020	As of December 31, 2019
Research and development expenses	\$ 1,672	\$ 536
Employee compensation and benefits	229	230
Professional services and other	224	86
Total accrued expenses	<u>\$ 2,125</u>	<u>\$ 852</u>

5. Other Income (Expense), Net

Other income (expense), net consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
<i>Part the Cloud</i> research grant	\$ —	\$ 189	\$ 22	\$ 472
Interest and other income	35	12	45	44
Interest expense	—	(98)	(366)	(236)
Change in fair value of derivative liability	—	(77)	(132)	(84)
Change in fair value of grant liability	(453)	(21)	(464)	(51)
Change in convertible preferred stock warrant liability	(641)	—	(641)	—
Gain on extinguishment of convertible notes	—	—	199	—
Total other income (expense), net	<u>\$ (1,059)</u>	<u>\$ 5</u>	<u>\$ (1,337)</u>	<u>\$ 145</u>

6. Significant Agreements

Washington State University (“WSU”) License Agreement

In December 2011, the Company entered into an exclusive license agreement with sublicensing terms with Washington State University Research Fund (“WSURF”), which, after the dissolution of WSURF in 2013, was superseded by an amended and restated exclusive license agreement with sublicensing terms between the Company and Washington State University (“WSU”) in 2015. Under this agreement, the Company has an exclusive license to make, use, sell, and offer for sale a chemical compound that forms the underlying technology of the drug therapies being developed by the Company.

To keep in good standing, the agreement requires the Company to meet certain development milestones and pay an annual maintenance fee. All contractual requirements have been met as of September 30, 2020.

As of September 30, 2020, the Phase 2 clinical trial milestone had been reached and a \$50,000 liability to WSU was recorded.

The Company may also be obligated to pay the following if the related milestones are reached:

- \$300,000 – At initiation of the first Phase 3 clinical trial in the United States, European Union or Japan for the first licensed product.
- \$600,000 – Marketing approval in the United States, European Union or Japan for the first licensed product.

Under the terms of the agreement, the Company will pay a royalty in the mid-single digits of net sales, with the first \$100,000 of net sales being exempt from royalty payment, and annual minimum royalty payments of \$25,000 beginning after the first commercial sale of a licensed product. As of September 30, 2020, the Company had not incurred a royalty obligation under this agreement.

Additionally, the agreement allows the Company to sublicense the rights conveyed by the agreement, subject to additional payments to WSU for sublicense consideration received. Such amounts are dependent on the terms of the underlying sublicense and range from the mid-single digits to mid-teens of any non-sales based payments received, and low twenties of net sales based sublicense royalties. As of September 30, 2020, the Company has not entered into or incurred any liability from a sublicense agreement.

Grant Liability

In 2014 and 2015, the Company received \$250,000 and \$500,000, respectively, from LSDF under the terms of two matching grant award agreements. In connection with the agreements, LSDF retained the right to receive cash payments of 2.0 times the amounts received, or \$1.5 million, upon the occurrence of specified triggering events, including:

- receipt of license revenue, sales revenue, or consideration related to the underlying IP;
- transfers the underlying IP without receiving consideration;
- relocation of the Company from Washington state;
- completion of an initial public offering;
- a third-party acquisition of a controlling interest in the Company, and;
- termination of the agreements.

To appropriately capture the economics of this arrangement, the grant liability is accounted for under ASC 825-10, *Financial Instruments – Overall*. The estimated fair value of the grant liability is reassessed at each balance sheet date, with changes in fair value reflected in other income (expense), net. To determine the estimated fair value of the grant liability, the Company used a discounted cash flow simulation methodology that assigns probabilities to the timing and likelihood of each triggering event, a discount rate based on market data for securities with similar durations and credit ratings to the Company, and the expected payment amount. The assumptions used to calculate the fair value of the grant liability are subject to significant judgment, and payment may be in an amount different from the liability that the Company estimates. However, total payments under the agreements will not exceed \$1.5 million.

The estimated fair value of the grant liability was \$1.0 million as of December 31, 2019. The consummation of the Company’s IPO in September 2020 was a triggering event under the terms of the grant and the liability was remeasured to the pay-off amount of \$1.5 million as of September 30, 2020. The changes in the fair value of the liability resulted in expense of approximately \$453,000 and \$21,000 for the three months ended September 30, 2020 and 2019, respectively, and \$464,000 and \$51,000 for the nine months ended September 30, 2020 and 2019, respectively, which were included in other income (expense), net in the accompanying condensed consolidated statements of operations and comprehensive loss.

7. Debt

Convertible Notes

The Company issued unsecured convertible notes with an aggregate principal amount of \$1.7 million in 2020. Previously, the Company issued unsecured convertible notes with aggregate principal amounts of \$884,000 and \$1.3 million and in 2019 and 2018, respectively. The notes accrue interest at a rate of 5% per year and mature in December 2021, unless earlier converted. No principal or interest is payable prior to maturity as the convertible notes and any accrued interest will automatically convert upon a qualified financing event at a conversion price equal to 85% of the price per share of the qualified financing. Holders may also elect to convert their notes to shares of common stock upon the maturity of the notes at the then fair value of common stock. If the Company experiences a change in control, holders may either convert the outstanding principal amount plus any accrued interest into shares of common stock at the then fair value of common stock or may require the Company to repurchase the notes in cash at a price equal to 200% of the outstanding principal amount plus any accrued interest.

Certain conversion and redemption features as described above were determined to be an embedded derivative requiring bifurcation and separate accounting in accordance with ASC 815, *Derivatives and Hedging*. The fair value of the embedded derivative was determined using a discounted cash flow simulation methodology that assigns probabilities to the timing and likelihood of each event. The discount rate was determined based on market interest rate data for securities with similar durations and credit ratings to the convertible notes. The fair value of the embedded derivative was recorded as a liability with an offsetting amount recorded as a discount on the convertible notes at each issuance. The discount is being amortized to interest expense using the effective interest method over the contractual term of the notes.

In May 2020, the outstanding principal balance of the convertible notes of \$3.8 million and accrued interest of \$160,000 converted into 512,858 shares of Series B-1 convertible preferred stock.

The excess of the carrying value of the convertible notes and the derivative liability over the fair value of the Series B-1 convertible preferred stock at conversion resulted in a gain upon extinguishment of \$199,000.

Paycheck Protection Program

The Company received a loan of \$215,000 from the U.S. Small Business Administration Paycheck Protection Program (“PPP”) in April 2020. The PPP loans are intended to assist companies impacted by the novel coronavirus disease (“COVID-19”) pandemic to fund certain types of expenditures, including payroll costs, rent and utility payments. PPP loans and any accrued interest may be forgiven to the extent that all employees are retained, proceeds are used within eight weeks of receipt, and if at least 75% of the loan amount utilized was for payroll costs. The loan bears interest at a rate of 1%, and any portion of the loan not forgiven and any accrued interest thereon must be repaid within two years. The loan was fully repaid in June 2020.

8. Leases

Operating Leases

The Company has an operating lease for laboratory and office facilities in Bothell, Washington that expires in August 2027. The initial term of the lease is seven years and the Company has an option to extend the lease for an additional five years that it is not reasonably certain to exercise. As of September 30, 2020, the remaining lease term for the Company’s operating lease was 6.9 years. The Company discounted future operating lease payments using an incremental borrowing rate of 8.2%. Additionally, the Company has a lease agreement for laboratory and office facilities at the University of Washington in Seattle, Washington with an initial term of 12 months for which the Company recognizes expense on a straight-line basis within operating expenses. As of September 30, 2020, the Company was not party to any finance leases.

The following table reconciles the Company's undiscounted operating lease cash flows to its operating lease liability (in thousands):

	As of September 30, 2020
Remaining 2020	\$ —
2021	234
2022	261
2023	269
2024	277
2025 and thereafter	779
Total undiscounted lease payments	1,820
Present value adjustment for minimum lease commitments	(457)
Tenant improvement allowance receivable	(391)
Net lease liability	<u>\$ 972</u>

Operating lease expense was \$34,000 for the three and nine months ended September 30, 2020. The Company did not incur variable lease expense for operating leases during the three and nine months ended September 30, 2020. Rent expense recognized for short term leases was \$18,000 and \$57,000 for the three and nine months ended September 30, 2020, respectively.

Cash paid for amounts included in the measurement of the lease liability for the nine months ended September 30, 2020 was \$21,000.

9. Convertible Preferred Stock

Convertible preferred stock as of December 31, 2019 consisted of the following (in thousands, except share amounts):

Convertible Preferred Stock	Shares Authorized	Issued and Outstanding	Carrying Value	Aggregate Liquidation Preference
Series A	1,714,963	1,534,885	\$ 15,163	\$ 15,215
Series A-1	1,082,501	1,082,501	1,888	1,073
Total	<u>2,797,464</u>	<u>2,617,386</u>	<u>\$ 17,051</u>	<u>\$ 16,288</u>

In May and June 2020, the Company issued an aggregate of 9,372,765 shares of its Series B convertible preferred stock at a purchase price of \$9.12 per share for aggregate proceeds of \$81.6 million, net of offering costs. The Company issued warrants to purchase 2,343,168 shares of its common stock, of which 688,067 were exercised concurrently with the shares of Series B convertible preferred stock issuance, for net proceeds of \$55,000. In addition, the Company issued warrants to purchase 127,481 shares of its Series B convertible preferred stock at a purchase price of \$9.12 per share. The Series B convertible preferred stock financing triggered the automatic conversion of the Company's outstanding convertible promissory notes into 512,858 shares of Series B-1 convertible preferred stock based on a price of \$7.752 per share (85% of the \$9.12 original issuance price of the Series B convertible preferred stock).

In September 2020, upon the consummation of the Company's IPO, all outstanding shares of convertible preferred stock converted into 12,503,009 shares of common stock.

10. Common Stock

Each share of common stock has the right to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and if declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding having priority rights as to dividends. No cash dividends have been declared by the board of directors from inception.

The Company has reserved the following shares of common stock for future issuance, on an as-converted basis, as follows:

	As of September 30, 2020	As of December 31, 2019
Convertible preferred stock	—	2,617,386
Stock options outstanding	1,927,428	1,514,770
Shares available for future grant under the 2020 Equity Incentive Plan	3,790,279	399,737
Shares available for future grant under the Employee Stock Purchase Plan	323,000	—
Common stock warrants	—	3,310
Total	<u>6,040,707</u>	<u>4,535,203</u>

11. Stock-based Compensation

Stock-based compensation expense recognized was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	\$ 43	\$ 13	\$ 62	\$ 42
General and administrative	68	56	156	147
Total stock-based compensation expense	<u>\$ 111</u>	<u>\$ 69</u>	<u>\$ 218</u>	<u>\$ 189</u>

Valuation Assumptions

The fair value of stock options was determined using the Black-Scholes option-pricing model and the assumptions below. Each of these inputs is subjective and generally required significant judgment.

- Fair Value of Common Stock*—The grant date fair market value of the shares of common stock underlying stock options has historically been determined by the Company’s board of directors. Because previously there was no public market for the Company’s common stock, the board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair market value, which include contemporaneous valuations performed by an independent third party, important developments in the Company’s operations, sales of convertible preferred stock, the rights, preferences and privileges of its convertible preferred stock relative to those of its common stock, lack of marketability of its common stock, actual operating results, financial performance, the progress of clinical development, the likelihood of achieving a liquidity event for its security holders, the trends, development and conditions in the life sciences and biotechnology sectors, the economy in general, and the stock price performance and volatility of comparable public companies.
- Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.
- Expected Volatility*—Because the Company was previously privately held and did not have any trading history for its common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded life sciences companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on the similar size, stage in life cycle or area of specialty. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.
- Expected Term*—The expected term represents the period that the stock-based awards are expected to be outstanding and is determined using the simplified method (based on the midpoint between the vesting date and the end of the contractual term) as the Company has limited history of relevant stock option exercise activity.
- Expected Dividend Yield*—The Company has never paid dividends on its common stock and has no plans to pay dividends going forward. Therefore, it used an expected dividend yield of zero.

The fair value of each stock option was estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Nine Months Ended September 30,	
	2020	2019
Risk-free interest rate	0.49%	1.58%
Expected volatility	80.11%	74.59%
Expected term (in years)	6.93	6.59
Expected dividend yield	—	—

The weighted-average grant-date fair value of options granted to employees and directors during the nine months ended September 30, 2020 and 2019 were \$2.1 million and \$259,000 respectively. The weighted-average grant-date fair value of options granted to advisors during the nine months ended September 30, 2020 was \$727,000. The remeasured weighted-average fair value of options granted to advisors during the nine months ended September 30, 2019 was \$46,000.

Stock Option Activity

A summary of option activity for the nine months ended September 30, 2020 was as follows:

	Available for Grant	Shares	Weighted- Average Exercise price per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2019	399,737	1,514,770	\$ 1.03	7.16	\$ 500
Authorized	4,343,534	—			
Granted	(994,293)	994,293	16.20		
Exercised	—	(540,334)	1.00		
Forfeited/expired	41,301	(41,301)	1.35		
Balance at September 30, 2020	<u>3,790,279</u>	<u>1,927,428</u>	\$ 8.85	8.18	\$ 18,521
Expected to vest		<u>1,298,059</u>	\$ 12.71	9.52	\$ 7,460
Options exercisable		<u>629,373</u>	\$ 0.89	5.43	\$ 11,061

The total fair value of options granted to employees, directors, and advisors that vested during the nine months ended September 30, 2020 was \$219,000, which included \$144,000 for options granted to employees and directors and \$75,000 for options granted to advisors. The total fair value of options that vested during the nine months ended September 30, 2019 was \$123,000, which included \$64,000 for options granted to employees and directors and \$59,000 for options granted to advisors.

The aggregate intrinsic value in the table above is calculated as the difference between the exercise price of the underlying options and the estimated fair value of the Company's common stock underlying all options that were in-the-money at September 30, 2020. The aggregate intrinsic value of options exercised was \$9.4 million and \$4,000 during the nine months ended September 30, 2020 and 2019, respectively, determined as of the date of option exercise. As of September 30, 2020, there was \$2.9 million of total unrecognized compensation cost related to unvested stock options. The Company expects to recognize this cost over a remaining weighted-average period of 1.95 years. The Company utilizes newly issued shares to satisfy option exercises.

Stock options outstanding and exercisable consisted of the following at September 30, 2020:

Exercise Price (\$)	Employees and Directors		Non-employees	
	Shares Outstanding	Shares Exercisable	Shares Outstanding	Shares Exercisable
0.16	75,660	75,660	12,611	12,611
0.48	162,353	162,353	—	—
1.00	—	—	37,830	37,830
1.04	70,933	70,933	31,525	31,525
1.19	52,645	38,878	34,677	34,677
1.31	63,050	63,050	—	—
1.35	294,754	27,529	116,642	63,049
1.49	31,525	10,508	—	—
17.00	747,770	770	195,453	—
Total	1,498,690	449,681	428,738	179,692

Restricted Stock Award Activity

In 2018, the Company issued a restricted stock award (“RSA”) to an advisor under the 2014 Plan. The restricted stock award vests over three years and requires continued service to the Company during the vesting period. The vesting provisions of individual awards may vary as approved by the board of directors. If continued service terminates for any reason, the Company has the right to repurchase the unvested shares for no consideration. Shares subject to repurchase as of September 30, 2020 and December 31, 2019 were 4,204 shares and 8,407 shares, respectively, all of which were related to non-employee RSAs.

A summary of RSA activity for the nine months ended September 30, 2020 was as follows:

	Share Equivalent	Weighted-Average Grant Date Fair Value
Non-vested at December 31, 2019	8,407	1.35
Granted	—	—
Vested	(4,203)	1.35
Non-vested at September 30, 2020	4,204	\$ 1.35

12. Net Loss Per Share Attributable to Common Stockholders

The following outstanding shares of potentially dilutive securities were excluded from the computation of the diluted net loss per share attributable to common stockholders for the periods presented because their effect would have been anti-dilutive:

	Nine Months Ended September 30,	
	2020	2019
Convertible preferred stock on an as-converted basis	—	2,617,386
Unvested RSAs	4,204	8,407
Stock options to purchase common stock	1,927,428	1,498,377
Common stock warrants	—	3,310
Total	1,931,632	4,127,480

13. Subsequent Events

Exercise of Underwriters’ Option

On October 16, 2020, the Company sold an additional 1,397,712 shares of common stock to the underwriters of the IPO upon partial exercise of the underwriters’ option to purchase additional shares at the initial public offering price of \$17.00 per share, less underwriting discounts and commissions, resulting in net proceeds to the Company of approximately \$22.1 million.

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

You should read the following management’s discussion and analysis of financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes thereto and Management’s Discussion and Analysis of Financial Condition and Results of Operations included in our final prospectus for our initial public offering, or IPO, filed with the Securities and Exchange Commission, or the SEC, pursuant to Rule 424(b)(4) on September 18, 2020.

Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements that are based on our management’s beliefs and assumptions and on information currently available to our management. This section should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this report. The statements contained in this Quarterly Report on Form 10-Q that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended.

In some cases, you can identify forward- looking statements by the following words: “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other “forward-looking” information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward statements include, but are not limited to, statements about:

- our financial performance;
- the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements;
- our ability to obtain funding for our operations, including funding necessary to develop and commercialize our product candidates;
- the ability of our nonclinical studies and clinical trials to demonstrate safety and efficacy of our product candidates;
- the success, cost and timing of our development activities, nonclinical studies and clinical trials;
- the rate and degree of market acceptance of our product candidates;
- the timing or likelihood of regulatory filings and approvals;
- the timing and focus of our future clinical trials, and the reporting of data from those trials;
- our plans relating to commercializing our product candidates, if approved;
- our plans and ability to establish sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain approval;
- our ability to attract and retain key managerial, scientific and clinical personnel;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our reliance on third parties to conduct clinical trials of our product candidates, and for the manufacture of our product candidates for nonclinical studies and clinical trials;
- the beneficial characteristics, safety and efficacy of our product candidates;
- regulatory developments in the United States and other jurisdictions;
- our ability to obtain and maintain regulatory approval of our product candidates in the United States and other jurisdictions, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- future agreements with third parties in connection with the commercialization of our product candidates;

- our plans relating to the further development and manufacturing of our product candidates, including additional indications for which we may pursue regulatory approval;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- our expectations regarding the impact of the novel coronavirus disease, or COVID-19, pandemic on our business; and
- the potential benefits of any strategic collaboration agreements we may enter into.

These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part II, Item 1A — “Risk Factors,” and elsewhere in this report. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. In this report, “we,” “our,” “us,” “Athira,” and “the Company” refer to Athira Pharma, Inc.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

Overview

We are a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and stop neurodegeneration. With our product candidates, we aim to potentially provide cognitive improvement and alter the course of neurological diseases with our novel mechanism of action. Our approach is designed to augment neuronal growth factor signaling through the hepatocyte growth factor/MET, or HGF/MET, a naturally occurring regenerative system. We believe enhancing HGF/MET signaling has the potential to protect existing neurons from damage, reduce inflammation, promote regeneration, and positively modulate brain activity. We anticipate that all of these characteristics may improve neuronal health and translate into clinical benefits. Our pipeline is built from our proprietary drug discovery platform, or ATH platform, and consists of a series of small molecules that are designed to target either (1) the central nervous system, or CNS, by crossing the blood brain barrier, or BBB, or (2) the peripheral nervous system.

Our lead candidate, ATH-1017, is a subcutaneous administered, BBB-penetrating, small molecule HGF/MET activator. In September 2020, we initiated patient dosing in LIFT-AD, our Phase 2/3 clinical trial for ATH-1017 that may provide pivotal data in support of registration, for the treatment of mild-to-moderate Alzheimer’s disease, or AD, with topline results expected by the end of 2022. By the end of 2020, we plan to initiate dosing in ACT-AD, a P300 Phase 2 clinical trial, in mild-to-moderate AD to better understand the overall effects of ATH-1017 on working memory processing speed and cognitive measures, with topline results expected by early 2022. P300 latency is a functional measure that is highly correlated with cognition; however, we have not yet established a connection between these P300 latency results and improved cognition. Beyond AD, we believe that ATH-1017 can ultimately address the broader dementia patient population. In an effort to begin this expansion, we are planning to conduct a Phase 2 clinical trial for Parkinson’s disease dementia, or PDD, to commence by the end of 2021.

We are also developing ATH compounds for neuropsychiatric conditions including depression. ATH compounds represent a novel mechanism for the treatment of neuropsychiatric conditions with a fast onset of action that may help to reduce disease burden on multiple levels. ATH-1019 is a novel, orally active candidate that is designed to activate the HGF/MET system, and distribute to the CNS, and is neuroactive in animal models. We are advancing ATH-1019 to further development for neuropsychiatric indications including depression and are targeting an investigational new drug, or IND, submission to the U.S. Food and Drug Administration, or FDA, for depression in the first half of 2022.

In addition to ATH-1017 and ATH-1019, we have initiated a discovery program to evaluate ATH compounds for peripheral neuropathy. ATH-1018 is a novel, orally active candidate that has demonstrated ability to significantly promote the activity of the HGF/MET system. We are planning to administer ATH-1018 at doses that are expected to largely relegate its activity to the periphery. ATH-1018 potentially represents a new strategy to address neuropathy by promoting the regenerative power of the HGF/MET system with a small molecule therapy. We are advancing ATH-1018 to further development for neuropathy indications and are targeting an IND submission to the FDA by the end of 2022.

We were incorporated in March 2011 and since our inception, we have devoted substantially all of our resources to our research and development efforts such as small molecule compound discovery, nonclinical studies and clinical trials, as well as manufacturing activities, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. We do not have any products approved for commercial sale, and we have not generated any revenues related to our products since inception. Our ability to generate product revenue sufficient to achieve profitability, if ever, will depend on the successful development of one or more of our product candidates which we expect will take a number of years.

We are focused on the development of small molecule therapeutics which enables us to use well-established and widely available manufacturing processes and infrastructure, formulation compositions and drug administration technologies or devices. We do not currently operate our own facilities for manufacturing, storing, or distributing our product candidates. We utilize third-party contract manufacturing organizations, or CMOs, to manufacture and supply our preclinical and clinical materials during the development of our product candidates. We believe the synthesis of ATH-1017 is reliable and reproducible and the synthetic methods can be further optimized to enable large-scale production that continues to avoid use of toxic materials or specialized equipment or handling during the manufacturing process. We plan to continue to optimize the manufacturing process to support future large-scale and commercial supply. Our goal is to identify and develop small molecule product candidates that are cost-effective to manufacture and easily transferable to third party CMOs. We expect to use similar contract resources for commercialization of our products, at least until our resources and operations are at a scale that justifies investment in internal manufacturing capabilities.

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We intend to build a commercial infrastructure to support sales of our product candidates. We expect to manage sales, marketing and distribution through internal resources and third-party relationships. While we may commit significant financial and management resources to commercial activities, we will also consider collaborating with one or more pharmaceutical companies to enhance our commercial capabilities.

To date, we have funded our operations primarily through proceeds from the sale of equity securities, including proceeds from the sale and issuance of common stock in our IPO, the sale and issuance of convertible preferred stock, common stock warrants, and convertible notes, and to a lesser extent from grant income and stock option exercises. From inception to September 30, 2020, we have raised aggregate net cash proceeds of approximately \$288.5 million primarily from the issuance of our common stock, convertible preferred stock, common stock warrants, and convertible notes. We have incurred significant operating losses to date. Our net losses were \$8.5 million and \$1.5 million for the three months ended September 30, 2020 and 2019, respectively, and \$12.3 million and \$4.2 million for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, we had an accumulated deficit of \$33.3 million and cash, cash equivalents and investments of \$259.9 million.

Recent Developments

In September 2020, we completed an initial public offering of our common stock. As part of the IPO, we issued and sold 12,000,000 shares of our common stock at a public offering price of \$17.00 per share. We received net proceeds of approximately \$186.4 million from the IPO, after deducting underwriting discounts and commissions of \$14.3 million and offering costs of approximately \$3.3 million. In October 2020, the Company sold an additional 1,397,712 shares of common stock to the underwriters of the IPO upon partial exercise of the underwriters' option to purchase additional shares at the initial public offering price of \$17.00 per share, less underwriting discounts and commissions, resulting in net proceeds to the Company of approximately \$22.1 million.

The global COVID-19 pandemic continues to rapidly evolve, and we will continue to monitor the COVID-19 situation closely. The extent of the impact of COVID-19 on our business, supply chain, operations and clinical development timelines and plans remains uncertain, and will depend on certain developments, including the duration and spread of the outbreak and its impact on our clinical trial enrollment, trial sites, contract research organizations, or CROs, third-party manufacturers, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. To the extent possible, we are conducting business as usual, with necessary or advisable modifications to employee travel and most of our employees working remotely. We will continue to actively monitor the rapidly evolving situation related to COVID-19 and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business. At this point, the extent to which the COVID-19 pandemic may affect our business, operations and clinical development timelines and plans, including the resulting impact on our expenditures and capital needs, remains uncertain.

Components of Operating Results

Operating Expenses

Research and Development

Research and development expenses consist primarily of direct and indirect costs incurred for our research activities, including development of the ATH platform, our drug discovery efforts and the development of our product candidates. Direct costs include laboratory materials and supplies, contracted research and manufacturing, clinical trial costs, consulting fees, and other expenses incurred to sustain our research and development program. Indirect costs include personnel-related expenses, consisting of employee salaries, related benefits, and stock-based compensation expense for employees engaged in research and development activities, and facilities, including expenses associated with relocating to and building out our new lab space, and other expenses consisting of direct and allocated expenses for rent and depreciation, and lab consumables.

We expense research and development costs as incurred. Non-refundable advance payments for goods and services that will be used over time for research and development are capitalized and recognized as goods are delivered or as the related services are performed. In-licensing fees and other costs to acquire technologies used in research and development that have not yet received regulatory approval and that are not expected to have an alternative future use are expensed when incurred. We track direct costs by stage of program, clinical or preclinical. However, we do not track indirect costs on a program specific basis because these costs are deployed across multiple programs and, as such, are not separately classified.

As of the date of this report, we cannot reasonably determine the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. Product candidates in later stages of development generally have higher development costs than those in earlier stages. We expect that our research and development expenses will increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, as our product candidates advance into later stages of development, as we begin to conduct larger clinical trials, as we seek regulatory approvals for any product candidates that successfully complete clinical trials, as we expand our product pipeline, as we maintain, expand, protect and enforce our intellectual property portfolio, and as we incur expenses associated with hiring additional personnel to support our research and development efforts. In particular, we expect our research and development expenses will increase substantially as we initiate and conduct planned Phase 2 and Phase 2/3 clinical trials for ATH-1017.

The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. Our research and development expenses may vary significantly based on factors such as:

- the number and scope of preclinical and IND-enabling studies;
- the phases of development of our product candidates;
- the progress and results of our research and development activities;
- per subject trial costs;
- the number of trials required for regulatory approval, in particular with respect to ATH-1017 for the treatment of mild-to-moderate AD;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible subjects and initiate clinical trials;
- the number of subjects that participate in the trials;
- the drop-out and discontinuation rate of subjects;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the cost and timing of manufacturing of our product candidates;
- the receipt of regulatory approvals from applicable regulatory authorities;

- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- the hiring and retention of research and development personnel;
- the degree to which we obtain, maintain, defend and enforce our intellectual property rights;
- the impact of COVID-19 on timelines and clinical operations, which may lead to increased costs; and
- the extent to which we establish collaboration, licensing or similar arrangements and the performance of any related third parties.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

General and Administrative

General and administrative expenses consist primarily of personnel-related costs, consisting of employee salaries, related benefits, and stock-based compensation expense for our employees in the executive, legal, finance and accounting, human resources, and other administrative functions. General and administrative expenses also include third-party costs such as legal costs, insurance costs, accounting, auditing and tax related fees, consulting fees and facilities and other expenses not otherwise included as research and development expenses. We expense general and administrative costs as incurred.

We expect that our general and administrative expenses will increase substantially for the foreseeable future as we increase our headcount to support our continued research activities and development of our programs. We also anticipate that we will incur substantially increased expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, and those of any national securities exchange on which our securities are traded, legal, auditing, additional insurance expenses, investor relations activities, and other administrative and professional services. We also expect to increase the size of our administrative function to support the growth of our business.

Other Income (Expense), Net

Other income (expense), net consists of interest earned on our cash, cash equivalents, and investments, grant income, periodic mark to market gains and losses on the derivative, grant, and convertible preferred stock warrant liabilities carried at fair value, and interest expense on our convertible notes.

Results of Operations

Comparison of the Three Months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the periods presented:

	Three Months Ended September 30,			
	2020	2019	Dollar Change	% Change
	(in thousands)			
Operating expenses:				
Research and development	\$ 5,830	\$ 1,026	\$ 4,804	*%
General and administrative	1,567	509	1,058	*
Total operating expenses	7,397	1,535	5,862	*
Loss from operations	(7,397)	(1,535)	(5,862)	*
Other income (expense), net	(1,059)	5	(1,064)	*
Net loss and comprehensive loss	\$ (8,456)	\$ (1,530)	\$ (6,926)	*

* Not meaningful

Research and Development Expenses

The following table shows the primary components of our research and development expenses for the periods presented:

	Three Months Ended September 30,			
	2020	2019	Dollar Change	% Change
	(in thousands)			
Direct costs:				
ATH-1017	\$ 5,104	\$ 781	\$ 4,323	*0%
Preclinical programs	170	21	149	*
Total direct costs	5,274	802	4,472	*
Indirect costs:				
Personnel-related costs, including stock-based compensation	150	44	106	*
Facilities and other costs	406	180	226	126
Total research and development expenses	\$ 5,830	\$ 1,026	\$ 4,804	*

Research and development expenses increased by \$4.8 million, from \$1.0 million for the three months ended September 30, 2019 to \$5.8 million for the three months ended September 30, 2020. The increase was driven primarily by an increase in expenses for ATH-1017 of \$4.3 million related to start-up activities by our clinical research organization and clinical drug supply manufacturers for Phase 2 clinical trials, and to a lesser extent, by increases in personnel-related costs, facilities, and other costs supporting our general growth.

General and Administrative Expenses

General and administrative expenses increased by \$1.1 million, from \$0.5 million for the three months ended September 30, 2019 to \$1.6 million for the three months ended September 30, 2020. The increase was primarily due to an increase in corporate legal, accounting, technical and consulting services of \$0.6 million, an increase in personnel-related costs of \$0.2 million to support our continued growth, and to a lesser extent, by increases in insurance and marketing costs.

Other Income (Expense), Net

Other income (expense), net, changed from income of less than \$0.1 million for the three months ended September 30, 2019 to expense of \$1.1 million for the three months ended September 30, 2020. The change was primarily due to a decrease in grant income due to a *Part the Cloud* research grant of \$0.2 million received in 2019 with no corresponding grant received in 2020, and an increase of \$1.1 million from increases in liabilities recorded at fair value.

Comparison of the Nine Months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the periods presented:

	Nine Months Ended September 30,			
	2020	2019	Dollar Change	% Change
	(in thousands)			
Operating expenses:				
Research and development	\$ 8,099	\$ 3,135	\$ 4,964	158%
General and administrative	2,817	1,197	1,620	135
Total operating expenses	10,916	4,332	6,584	152
Loss from operations	(10,916)	(4,332)	(6,584)	152
Other income (expense), net	(1,337)	145	(1,482)	*
Net loss and comprehensive loss	\$ (12,253)	\$ (4,187)	\$ (8,066)	193

* Not meaningful

Research and Development Expenses

The following table shows the primary components of our research and development expenses for the periods presented:

	Nine Months Ended September 30,			% Change
	2020	2019	Dollar Change	
	(in thousands)			
Direct costs:				
ATH-1017	\$ 6,834	\$ 2,290	\$ 4,544	198%
Preclinical programs	188	156	32	21
Total direct costs	<u>7,022</u>	<u>2,446</u>	<u>4,576</u>	187
Indirect costs:				
Personnel-related costs, including stock-based compensation	252	112	140	125
Facilities and other costs	825	577	248	43
Total research and development expenses	<u>\$ 8,099</u>	<u>\$ 3,135</u>	<u>\$ 4,964</u>	158

Research and development expenses increased by \$5.0 million, from \$3.1 million for the nine months ended September 30, 2019 to \$8.1 million for the nine months ended September 30, 2020. The increase was driven primarily by an increase in expenses for ATH-1017 of \$4.5 million related to start-up activities by our clinical research organization and clinical drug supply manufacturers for Phase 2 clinical trials, and to a lesser extent, by increases in personnel-related costs and facilities and other costs supporting our general growth.

General and Administrative Expenses

General and administrative expenses increased by \$1.6 million, from \$1.2 million for the nine months ended September 30, 2019 to \$2.8 million for the nine months ended September 30, 2020. The increase was primarily due to an increase in corporate legal, accounting, technical and consulting services of \$1.1 million, an increase in personnel-related costs of \$0.3 million to support our continued growth, and to a lesser extent, by increases in insurance and marketing costs.

Other Income (Expense), Net

Other income (expense), net, changed from income of \$0.1 million for the nine months ended September 30, 2019 to expense of \$1.3 million for the nine months ended September 30, 2020. The change was primarily due to a decrease in grant income due to a *Part the Cloud* research grant of \$0.5 million received in 2019 with no corresponding grant received in 2020, an increase of \$0.1 million in interest expense and accretion of discounts related to the convertible notes, and an increase of \$1.1 million from increases in liabilities recorded at fair value. This was offset by a gain of \$0.2 million on the extinguishment of convertible notes in connection with our Series B convertible preferred stock financing in the second quarter of 2020.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have funded our operations primarily with proceeds from the sale and issuance of convertible preferred stock, common stock warrants, and convertible notes, and to a lesser extent from grant income and stock option exercises. From our inception through September 30, 2020, we have raised aggregate net cash proceeds of \$288.5 million primarily from the issuance of our common stock, convertible preferred stock, common stock warrants, and convertible notes. We issued 12,000,000 shares of our common stock in our IPO at a public offering price of \$17.00 per share for net proceeds of \$186.4 million, after deducting underwriting discounts and commissions and offering costs. As of September 30, 2020, we had \$259.9 million in cash, cash equivalents and investments and have not generated positive cash flows from operations. In October, 2020, we sold an additional 1,397,712 shares of common stock to the underwriters of the IPO upon partial exercise of the underwriters' option to purchase additional shares at the initial public offering price of \$17.00 per share, less underwriting discounts and commissions, resulting in net proceeds to us of approximately \$22.1 million. Since our inception, we have devoted substantially all of our resources to our research and development efforts such as small molecule compound discovery, nonclinical studies and clinical trials, as well as manufacturing activities, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations.

Future Funding Requirements

Based upon our current operating plan, we estimate that our \$259.9 million of cash, cash equivalents, and investments at September 30, 2020 will be sufficient to fund our operating expenses and capital expenditure requirements through at least the 12 months following the date of this Quarterly Report on Form 10-Q. We will need to raise substantial additional capital to fund the development of our product candidates. Until such time as we can generate significant revenue from product sales, we expect to finance our operations through the sale of equity securities, debt financings, or other capital, which could include income from collaboration, licensing or similar arrangements with third parties, or receiving research contributions, or grants. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. 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 capital expenditures or declaring dividends. If we raise funds through collaborations, licenses and other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. Adequate funding may not be available when needed or on terms acceptable to us, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic and otherwise. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. We cannot assure you that we will ever be profitable or generate positive cash flows from operating activities.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of biotechnology products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, timing, progress and results of our ongoing preclinical studies and clinical trials of our product candidates;
- the number of trials required for regulatory approval, in particular with respect to ATH-1017 for the treatment of mild-to-moderate AD;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of other product candidates that we may pursue;
- our ability to establish and maintain collaboration, licensing or other similar arrangements, and the financial terms of any such arrangements, including the timing and amount of any future milestone, royalty or other payments due thereunder;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- any expenses needed to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- the costs associated with relocating to our new facility and building out lab space; and
- the extent to which we acquire or in-license other companies' product candidates and technologies.

A change in the outcome of any of these or other factors with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plan may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plan.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Nine Months Ended September 30,	
	2020	2019
	(unaudited)	
Net cash used provided by (used in):		
Operating activities	\$ (13,448)	\$ (2,684)
Investing activities	(94,310)	755
Financing activities	271,427	892
Net increase (decrease) in cash and cash equivalents	<u>\$ 163,669</u>	<u>\$ (1,037)</u>

Operating Activities

During the nine months ended September 30, 2020, net cash used in operating activities was \$13.4 million. This consisted primarily of a net loss of \$12.3 million, partially offset by non-cash charges of \$1.7 million and an increase in our net operating assets of \$2.9 million. The non-cash charges primarily consisted of stock-based compensation expense, non-cash interest expense and accretion of discounts on our convertible notes, changes in the carrying value of liabilities stated at fair value, and the gain on extinguishment of our convertible notes. The increase in our net operating assets was due to an increase in prepaid expenses and other current assets, partially offset by a decrease in accounts payable and accrued expenses.

During the nine months ended September 30, 2019, net cash used in operating activities was \$2.7 million. This consisted primarily of a net loss of \$4.2 million, partially offset by non-cash charges of \$0.6 million and an increase in our net operating assets of \$0.9 million. The non-cash charges primarily consisted of stock-based compensation expense, non-cash interest expense and accretion of discounts on our convertible notes, and changes in the carrying value of liabilities stated at fair value. The increase in our net operating assets was due to an increase in accounts payable and accrued expenses.

Investing Activities

During the nine months ended September 30, 2020, net cash used in investing was \$94.3 million. This consisted of purchases of available-for-sale securities.

During the nine months ended September 30, 2019, net cash provided by investing activities was \$0.8 million. This consisted primarily of \$1.7 million in proceeds received from short-term investments which matured during the period, partially offset by purchases of short-term investments of \$1.0 million.

Financing Activities

During the nine months ended September 30, 2020, net cash provided by financing activities was \$271.4 million. This consisted primarily of net proceeds received from our IPO of \$187.2 million, net proceeds of \$81.9 million from the issuance of our Series B convertible preferred stock and common stock warrants, \$1.7 million from the issuance of our convertible notes, and to a lesser extent from exercises of stock options and common stock warrants.

During the nine months ended September 30, 2019, net cash provided by financing activities was \$0.9 million. This consisted primarily of proceeds of \$0.9 million from the issuance of our convertible notes and to a lesser extent from exercises of stock options.

Contractual Obligations and Commitments

During the nine months ended September 30, 2020, there have been no material changes, except to the lease commitment discussed in Note 8 to our condensed consolidated financial statements included in "Part I, Item 1—Financial Statements (Unaudited)" of this Quarterly Report on Form 10-Q, outside the ordinary course of business to our contractual obligations from those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our final prospectus dated September 17, 2020 and filed with the SEC on September 18, 2020.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these 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 financial statements, as well as the reported revenue and 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.

Critical accounting policies and significant judgments and estimates are those that we consider the most important to the portrayal of our financial condition and results of operations because they require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

During the nine months ended September 30, 2020, there were no material changes to our critical accounting policies. Our critical accounting policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies, Significant Judgments and Use of Estimates” in our final prospectus filed with the SEC on September 18, 2020 and Note 2 to our unaudited condensed consolidated financial statements included in “Part I, Item 1—Financial Statements (Unaudited)” of this Quarterly Report on Form 10-Q. Note that as a result of the impact of the IPO, for periods subsequent to the third quarter of 2020, certain critical accounting policies, such as those relating to convertible notes, convertible preferred stock warrant liability and grant liability, will cease to be critical accounting policies. We believe that of our critical accounting policies, the following accounting policies involve the most judgment and complexity:

- Research and Development Costs;
- Stock-based Compensation;
- Income Taxes.

Recent Accounting Pronouncements

See Note 2 to our unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information.

Emerging Growth Company Status

We are an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (1) are no longer an emerging growth company or (2) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

We had cash, cash equivalents and investments of \$259.9 million as of September 30, 2020. Our exposure to interest rate risk is not significant and a hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

Foreign Currency

Our functional currency is the U.S. dollar. We are exposed to foreign currency rate risk related to various third-party service contracts denominated in foreign currencies. Transaction gains and losses are included in other income (expense), net on our statements of operations and comprehensive loss and were not material for any of the periods presented. A hypothetical 10% change in exchange rates during any of the periods presented would not have had a material impact on our financial statements. However, we established an Australian subsidiary to facilitate the P300 Phase 2 clinical trial. As a result, our exposure to the foreign currencies, particularly the Australian dollar, will increase.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We believe that inflation has not had a material effect on our financial statements.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms and (2) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our principal executive officer and principal financial and accounting officer, evaluated the effectiveness of our disclosure controls and procedures at the end of the period covered by this Quarterly Report. Based upon such evaluation, our principal executive officer and principal financial and accounting officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2020, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 1. Legal Proceedings.

From time to time, we may be subject to legal proceedings. We are not currently a party to or aware of any proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 1A. Risk Factors.

You should carefully consider the *following risk factors, in addition to the other information contained in this Quarterly Report on Form 10-Q, or Quarterly Report, including the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section and our unaudited condensed consolidated financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed. This Quarterly Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Quarterly Report.*

Risks Relating to Our Business and the Development of Our Product Candidates***We are a late clinical-stage biopharmaceutical company with a limited operating history.***

We are a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and stop neurodegeneration. Our limited operating history may make it difficult to evaluate the success of our business. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have initiated clinical trials for our lead product candidate, ATH-1017, and have not initiated clinical trials for any of our other product candidates. To date, we have not initiated or completed a pivotal clinical trial, obtained marketing approval for any product candidate, manufactured a commercial scale product candidate, arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product candidate commercialization. Our history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by clinical-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to overcome such risks and difficulties successfully. If we do not address these risks and difficulties successfully, our business will suffer.

We may fail to or be unable to design and execute clinical trials to support marketing approval of ATH-1017 or any of our other product candidates. We cannot be certain that our current or planned clinical trials or any other future clinical trials will be completed on time or be successful. We cannot guarantee that the U.S. Food and Drug Administration, or FDA, or foreign regulatory authorities will interpret clinical trial results as we do, and more clinical trials could be required before we are able to submit applications seeking approval of our product candidates. To the extent that the results of the clinical trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential.

Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives.

Our business depends entirely on the successful discovery, development and commercialization of our product candidates. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales for the next several years, if ever. Our ability to generate product revenue will depend heavily on the successful clinical development and eventual commercialization of ATH-1017 and one or more of our other future product candidates. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives, including:

- successful and timely completion of nonclinical and clinical development of our product candidates and any future product candidates, as well as the associated costs, including any unforeseen costs we may incur as a result of nonclinical study or clinical trial delays due to the novel coronavirus disease, or COVID-19, pandemic or other causes;
- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development, both in the United States and internationally, of our product candidates and any future product candidates;

- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- making any required post-marketing approval commitments to applicable regulatory authorities;
- developing an efficient and scalable manufacturing process for our product candidates, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for product candidates that we develop, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether inhouse or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval of our product candidates;
- commercial acceptance of our product candidates by patients, the medical community and third-party payors;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining coverage and adequate reimbursement by hospitals, government and third-party payors for product candidates that we develop;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, 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 may decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations.

We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all. Changes in the manufacturing process or facilities will require further comparability analysis and approval by the FDA before implementation, which could delay our clinical trials and product candidate development, and could require additional clinical trials, including bridging studies, to demonstrate consistent and continued safety and efficacy.

We have not previously submitted a new drug application, or NDA, to the FDA or similar approval filings to a comparable foreign regulatory authority, for any product candidate. An NDA or other relevant regulatory filing must include extensive nonclinical and clinical data and supporting information to establish that the product candidate is safe and effective for each desired indication. The NDA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. We cannot be certain that our current or future product candidates will be successful in clinical trials or receive regulatory approval. Further, even if they are successful in clinical trials, our product candidates or any future product candidates may not receive regulatory approval. If we do not receive regulatory approvals for current or future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a product candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights, as well as the availability of competitive products, whether there is sufficient third-party reimbursement and adoption by physicians.

Our development of ATH-1017 may never lead to a marketable product.

We are developing ATH-1017 as a small molecule aimed at restoring neuronal health. We have not received regulatory approval for ATH-1017 and cannot be certain that our approach will lead to the development of an approvable or marketable product, alone or in combination with other therapies. We may not succeed in demonstrating safety and efficacy of ATH-1017 in our LIFT-AD trial or in other clinical trials.

Advancing ATH-1017 as a small molecule aimed at restoring neuronal health creates significant challenges for us, including:

- obtaining marketing approval;
- if ATH-1017 is approved, educating medical personnel regarding the potential efficacy and safety benefits, as well as the challenges, of incorporating ATH-1017 into existing treatment regimens, including in combination with other treatments for AD; and
- establishing the sales and marketing capabilities upon obtaining any marketing approvals to gain market acceptance.

Our approach to targeting brain growth factors through the use of small molecules is based on a novel therapeutic approach, which exposes us to unforeseen risks. We have limited data from our Phase 1a and 1b clinical trials, including only 11 patients with mild to moderate AD, and we cannot be certain that future trials will yield similar data. In addition, our use of EEG methods to gather data requires placement of electrodes on a subject's scalp and, if not properly placed, we may be unable to obtain the data sought or data obtained may be unreliable.

We have discovered and are developing a platform of small molecule product candidates from which we have selected our lead product candidate, ATH-1017, which is under development to treat Alzheimer's disease, or AD, and other central nervous system, or CNS, disorders. Our product candidates target a brain growth factor which is expected to increase synaptic density, recovery in the network and information transmission in the brain, which we believe could ultimately result in improvement in cognition and clinical symptoms. The therapeutic promise of brain growth factors in neurodegenerative disorders had been hampered in earlier therapies by the lack of efficient and non-invasive delivery to the brain. Our small molecule product candidates are designed to penetrate the blood brain barrier and enhance the activity of a brain growth factor, but we cannot be certain that our clinical trials will provide sufficient evidence that our design approach results in the intended therapeutic effect.

Based on the results of our nonclinical and clinical studies to date, we believe ATH-1017 has the potential to rapidly improve cognition and durably restore the lives of patients suffering from AD. However, these ideas and this approach are novel, and we currently have limited data based on our Phase 1a and 1b clinical trials, which enrolled 88 subjects, including only 11 patients with mild to moderate AD, of whom seven patients were treated with ATH-1017 and the other four patients were randomized to the control. Data from our Phase 1a and 1b clinical trials, while promising, were obtained from a relatively small number of subjects and a single clinical site and we cannot be certain that future trials involving a larger number of subjects and clinical sites will yield similar data. Additionally, in our Phase 1a and 1b clinical trials, we used electroencephalogram, or EEG, methods to gather data that we believe provide valuable insight into cognitive processing of the subjects evaluated. These EEG methods require the placement of electrodes on a subject's scalp and, if these electrodes are not properly placed, we may be unable to obtain the data sought or the data obtained may be compromised and unreliable. In our Phase 1a and 1b clinical trials, data from certain subjects were not obtained due to problems encountered with the placement of the EEG electrodes and other technical issues, such as subject movement. While we believe the lack of data from these subjects did not impact the reliability or interpretation of the remaining data from these trials, we may in the future face similar issues with EEG methods, which could compromise future clinical trial results. We may ultimately discover that ATH-1017, or any of our other small molecules, do not possess certain properties required for therapeutic effectiveness. We have no long-term evidence regarding the efficacy, safety and tolerability of ATH-1017 or other small molecules in our product platform. We may spend substantial funds attempting to develop these product candidates and never succeed in doing so.

We have concentrated our research and development efforts on the treatment of CNS and peripheral degenerative disorders, a field that has seen very limited success in product development.

We have focused our research and development efforts on addressing CNS and peripheral degenerative disorders. Collectively, efforts by pharmaceutical companies in the field of CNS and peripheral degenerative disorders have seen very limited successes in product development. The development of CNS therapies presents unique challenges, including an imperfect understanding of the biology, the presence of the blood brain barrier, or BBB, that can restrict the flow of drugs to the brain, a frequent lack of translatability of preclinical study results in subsequent clinical trials and dose selection, and the product candidate having an effect that may be too small to be detected using the outcome measures selected in clinical trials or if the outcomes measured do not reach statistical significance. There are few effective therapeutic options available for patients with AD and other CNS or peripheral disorders. Our future success is highly dependent on the successful development of our technology and our product candidates for treating CNS and peripheral disorders. Developing and, if approved, commercializing our product candidates for treatment of CNS and peripheral disorders subjects us to a number of challenges, including ensuring that we have selected the optimal doses, executing an appropriate clinical trial to test for efficacy and obtaining regulatory approval from the FDA and other regulatory authorities.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of early, smaller-scale studies and clinical trials with a single or few clinical trial sites may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials across multiple clinical trial sites. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all.

Our lead product candidate, ATH-1017, is in clinical development for the potential treatment of AD and Parkinson's disease dementia, or PDD. Our remaining product candidates, including ATH-1018 and ATH-1019, are in nonclinical development. It is impossible to predict when or if any of our product candidates will prove to be effective and safe in humans or will receive regulatory approval.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive nonclinical studies and clinical trials that our product candidates are both safe and effective for each target indication. Nonclinical and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the nonclinical study and clinical trial processes, and, because our product candidates are in an early stage of development, there is a high risk of failure and we may never succeed in developing marketable products. The results of nonclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Although product candidates may demonstrate promising results in nonclinical studies and early clinical trials, they may not prove to be safe or effective in subsequent clinical trials. For example, testing on animals occurs under different conditions than testing in humans and therefore, the results of animal studies may not accurately predict safety and effectiveness in humans. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through nonclinical studies and clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. Likewise, early, smaller-scale studies and clinical trials with a single or few clinical trial sites may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials across multiple clinical trial sites. Even if data from a pivotal clinical trial are positive, regulators may not agree that such data are sufficient for approval and may require that we conduct additional clinical trials, which could materially delay our anticipated development timelines, require additional funding for such additional clinical trials, and adversely impact our business. For example, LIFT-AD is a trial that we initiated in September 2020, which may provide pivotal data in support of registration. By the end of 2020, we plan to initiate ACT-AD, a P300 Phase 2 clinical trial, to better understand the overall effects of ATH-1017 on working memory processing speed and cognitive measures, with topline results expected by early 2022. These data will help support strategic decisions around any additional pivotal trials that we may initiate in parallel to the LIFT-AD trial if the results from the ACT-AD P300 Phase 2 clinical trial do not meet our expectations. However, even if we receive positive data in our ACT-AD P300 Phase 2 clinical trial and LIFT-AD, we cannot be certain that the FDA or other regulators will find such data sufficient for approval of ATH-1017. Our ability to achieve regulatory approval for ATH-1017 is further complicated by the nature of AD, which historically has been a challenging indication for drug development. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence nonclinical studies and clinical trials are never approved as products.

In some instances, there can be significant variability in safety or efficacy results between different nonclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, some of the clinical trials we conduct in the future may be open-label in study design and may be conducted at a limited number of clinical sites on a limited number of patients. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological 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.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards, or IRBs, of the institutions in which such clinical trials are being conducted, by a data safety monitoring board for such clinical trial or by the FDA or comparable foreign regulatory authorities. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities disagreeing with our ATH platform development strategy;
- changes in governmental regulations or administrative actions;
- delays in our ability to commence a clinical trial;
- 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 IRB approval at each clinical trial site;
- recruiting an adequate number of suitable patients to participate in a clinical trial;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate;
- having subjects complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from clinical trial protocol or dropping out of a clinical trial;
- failure to demonstrate a benefit from using a product candidate;
- addressing subject safety concerns that arise during the course of a clinical trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient product supply of product candidate for use in nonclinical studies or clinical trials from third-party suppliers.

Further, conducting clinical trials in foreign countries, as we intend to do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

If the results of our future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may:

- incur unplanned costs;
- be delayed in or prevented from obtaining marketing approval for our product candidates;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings including boxed warnings;

- be subject to changes in the way the product is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Any “topline”, interim, initial, or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our nonclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our nonclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Additionally, we rely on data received from clinical trials, whether preliminary or final, to inform decisions on future clinical trials, including trial design, trial size, and whether or not to initiate additional clinical trials. For example, by the end of 2020, we plan to initiate ACT-AD, a P300 Phase 2 clinical trial, to better understand the overall effects of ATH-1017 on working memory processing speed and cognitive measures, with topline results expected by early 2022. These data will help support strategic decisions around any additional pivotal trials that we may initiate in parallel to the LIFT-AD trial if the results from the ACT-AD P300 Phase 2 clinical trial do not meet our expectations. The topline results of this ACT-AD P300 Phase 2 clinical trial will be based on a preliminary analysis of then-available data, and a more comprehensive and full review of the data may result in different conclusions, which could have a negative impact on our decisions regarding any additional trials for ATH-1017.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

If we experience delays or difficulties in the enrollment and/or retention of patients in clinical trials, our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to recruit and enroll a sufficient number of eligible patients to participate in these clinical trials through completion of such trials as required by the FDA or other comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. Patient enrollment may also be affected if our competitors have ongoing clinical trials for programs that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors’ programs. If we are unable to locate a sufficient number of such patients, our clinical trial and development plans could be delayed.

For example, we intend to enroll approximately 240 to 300 AD subjects with mild-to-moderate AD in LIFT-AD and 60 to 75 AD subjects with mild-to-moderate AD in our ACT-AD P300 Phase 2 clinical trial. If we are delayed or unsuccessful in enrolling the desired number of subjects in these trials, whether as a result of competing clinical trials, overly stringent eligibility requirements, or the ongoing impact of COVID-19 on both clinical trial sites and potential AD subjects, our clinical trial results could be delayed, the costs of our clinical trials could materially increase, and the overall development timeline for ATH-1017 could be negatively impacted. Even if we are successful in enrolling the targeted number of subjects in these trials, the FDA and other regulators may request additional clinical trials with larger numbers of subjects as a condition to any regulatory approval.

Enrollment of patients in our clinical trials may be delayed or limited as our clinical trial sites limit their onsite staff or temporarily close as a result of the COVID-19 pandemic. In addition, patients may not be able to visit clinical trial sites for data collection purposes due to limitations on travel and physical distancing imposed or recommended by federal or state governments or patients' reluctance to visit the clinical trial sites during the pandemic. The drop-out rates in our clinical trials may be increased during the pandemic. Clinical trial patients who become infected with the COVID-19 virus may complicate the clinical trial data, procedures, and analysis. These factors resulting from the COVID-19 pandemic could delay the anticipated readouts from our clinical trials and our regulatory submissions, and increase the costs associated of the clinical trials.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods.

We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer, or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.

The biotechnology and pharmaceutical industries utilize rapidly advancing technologies and are characterized by intense competition. While we believe that our scientific knowledge, platform technology and development expertise provide us with competitive advantages, we face competitive pressures from both large and small pharmaceutical companies, emerging biotechnology companies, as well as academic, government and private research institutions. Many of our competitors have access to greater financial resources, market presence, expertise in development, preclinical and clinical testing, manufacturing, commercialization, regulatory approval process, and/or marketing and sales than we do. Our competitors may compete with us in patient recruitment, clinical research organization, and operational resources. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

Product candidates that we may successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. Our competitors may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. For additional information regarding our competition, see the section of the final prospectus related to our initial public offering, or IPO, titled "Business—Competition."

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs, therapeutic platforms and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

We may develop product candidates in combination with other therapies, which exposes us to additional risks.

We may develop product candidates in combination with one or more other approved or unapproved therapies. 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 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 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 product candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate we develop in combination with an unapproved therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved 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 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.

Our long-term prospects depend in part upon discovering, developing and commercializing additional product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.

Our future operating results are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates beyond those we currently have in clinical and nonclinical development. A product candidate can unexpectedly fail at any stage of nonclinical and clinical development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from nonclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate.

The success of other future product candidates we may develop will depend on many factors, including the following:

- generating sufficient data to support the initiation or continuation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of the product candidate for use in clinical trials; and
- adverse events in the clinical trials.

Even if we successfully advance any other future product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this “Risk Factors” section. Accordingly, we cannot assure you that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from our other future product candidates.

We conduct certain research and development operations through our Australian wholly owned subsidiary. If we lose our ability to operate in Australia, or if our subsidiary is unable to receive the research and development tax credit allowed by Australian regulations, our business and results of operations could suffer.

In July 2020, we formed a wholly owned Australian subsidiary to conduct various preclinical and clinical activities for our product and development candidates in Australia. Due to the geographical distance and lack of employees currently in Australia, as well as our lack of experience operating in Australia, we may not be able to efficiently or successfully monitor, develop and commercialize our lead products in Australia, including conducting clinical trials. Furthermore, we have no assurance that the results of any clinical trials that we conduct for our product candidates in Australia will be accepted by the FDA or foreign regulatory authorities for development and commercialization approvals.

In addition, current Australian tax regulations provide for a refundable research and development tax credit equal to 43.5% of qualified expenditures. If we lose our ability to operate our subsidiary in Australia, or if we are ineligible or unable to receive the research and development tax credit, or the Australian government significantly reduces or eliminates the tax credit, our business and results of operation may be adversely affected.

Risks Relating to COVID-19 and Other Health Epidemics

The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our nonclinical studies and clinical trials.

The world is in the midst of a pandemic. A novel strain of the coronavirus disease, COVID-19, has spread to a number of countries, including the United States. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we have closed our executive offices with our administrative employees continuing their work outside of our offices and limited the number of staff in any given research and development laboratory. While the extent of the impact of the COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition and operating results.

As a result of the COVID-19 pandemic, we may experience disruptions that could severely impact our business, nonclinical studies and clinical trials, including:

- delays or difficulties in enrolling and retaining patients in our clinical trials, particularly elderly subjects, who are at a higher risk of severe illness or death from COVID-19, which can be further complicated by the presence of comorbidities that are often present in AD subjects;
- difficulties interpreting data from our clinical trials due to the possible effects of COVID-19 on cognition of the subjects enrolled in our clinical trials that contract COVID-19;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in nonclinical studies due to restricted or limited operations at our laboratory facility;
- limitations on employee resources that would otherwise be focused on the conduct of our nonclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption or delays to our sourced discovery and clinical activities; and
- changes in clinical site procedures and requirements as well as regulatory requirements for conducting clinical trials during the pandemic.

We may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus. For example, in March 2020, the FDA issued a guidance, which the FDA subsequently updated, on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical trial report contingency measures implemented to manage the clinical trial, and any disruption of the clinical trial as a result of the COVID-19 pandemic; a list of all subjects affected by the COVID-19-pandemic related study disruption by unique subject identifier and by investigational site and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the clinical trial. In June 2020, FDA also issued a guidance on good manufacturing practice considerations for responding to COVID-19 infection in employees in drug products manufacturing, including recommendations for manufacturing controls to prevent contamination of drugs.

The COVID-19 pandemic continues to develop rapidly, with the status of operations and government restrictions evolving weekly. The extent to which the outbreak impacts our business, nonclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

The trading prices for shares of other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic and the trading prices for shares of our common stock could also experience high volatility. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the COVID-19 pandemic on our business operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted, including the duration of the pandemic, the ultimate geographic spread of the disease, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19 and the actions taken to contain COVID-19 or address its impact in the short and long term, among others. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy. We will continue to monitor the situation closely.

In addition, our business could be significantly adversely affected by other business disruptions to us or our third-party providers that could seriously harm our potential future revenue and financial condition and increase our costs and expenses. Our operations, and those of our CROs, commercial manufacturing organizations, or CMOs, and other contractors, consultants, and third parties could be subject to other global pandemics, earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Risks Relating to Our Financial Position and Capital Needs

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

We have not generated any revenue from product sales and our product candidates will require substantial additional investment before they may provide us with any revenue. We had net losses of \$12.3 million and \$5.2 million for the nine months ended September 30, 2020 and the year ended December 31, 2019, respectively, and an accumulated deficit of \$33.3 million as of September 30, 2020.

We have devoted most of our financial resources to research and development, including our clinical and nonclinical development activities. To date, we have financed our operations primarily with proceeds from the sale and issuance of common stock, convertible preferred stock and convertible notes, and to a lesser extent from grant income and stock option exercises.

We expect to incur significant expenses and increasing operating losses for the foreseeable future as we:

- continue our research and nonclinical and clinical development of our product candidates;
- expand the scope of our clinical studies for our current and prospective product candidates;
- initiate additional nonclinical, clinical or other studies for our product candidates, including any pivotal trials with respect to ATH-1017 for the treatment of mild-to-moderate AD in addition to LIFT-AD;
- change or add additional manufacturers or suppliers and manufacture drug supply and drug product for clinical trials and commercialization;
- seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical trials;
- attract, hire and retain additional personnel;
- operate as a public company;
- relocate to our new facility and build out lab space;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments under our in-license or other agreements;
- maintain, protect and expand our intellectual property portfolio;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- create additional infrastructure to support our operations and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above.

Our expenses could increase beyond expectations for a variety of reasons, including if we are required by the FDA, the European Medicines Agency, or EMA, or other regulatory agencies, domestic or foreign, to perform clinical and other studies in addition to those that we currently anticipate. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity.

We will require substantial additional funding to finance our operations, complete the development and commercialization of ATH-1017, and evaluate other and future product candidates. If we are unable to raise this funding when needed, we may be forced to delay, reduce, or eliminate our product development programs or other operations.

Since our inception, we have used substantial amounts of cash to fund our operations, and we expect our expenses to increase substantially in the foreseeable future in connection with our ongoing activities, particularly as we continue the research and development of, initiate clinical trials of, and seek marketing approval for, ATH-1017. Developing ATH-1017 and conducting clinical trials for the treatment of AD, PDD, and any other indications that we may pursue in the future will require substantial amounts of capital. In addition, if we obtain marketing approval for ATH-1017 or any future product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing, and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company.

Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. As of September 30, 2020, we had cash, cash equivalents, and investments of \$259.9 million. Based upon our current operating plan, we estimate that our existing cash and cash equivalents, including the net proceeds from our IPO, will be sufficient to fund our operating expenses and capital expenditure requirements at least through 2022. However, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may need to raise additional funds sooner than we anticipate if we choose to expand more rapidly than we presently anticipate.

The amount and timing of our future funding requirements depends on many factors, some of which are outside of our control, including but not limited to:

- the progress, costs, clinical trial design, results of and timing of our LIFT-AD trial and other clinical trials of ATH-1017, including for potential additional indications that we are pursuing beyond AD, such as PDD;
- the willingness of the FDA and EMA to accept our LIFT-AD trial, as well as data from our completed and planned clinical and nonclinical studies and other work, as the basis for review and approval of ATH-1017 for AD;
- the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;
- the number and characteristics of product candidates that we pursue;
- our ability to manufacture sufficient quantities of our product candidates;
- our need to expand our research and development activities;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- the costs of acquiring, licensing or investing in businesses, product candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to retain management and hire scientific, clinical and other personnel;
- the effect of competing drugs and product candidates and other market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of any collaboration, licensing or other arrangements into which we may enter in the future.

Additional funding may not be available to us on acceptable terms or at all. Any such funding may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may affect our business. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2019, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of approximately \$9.4 million and federal tax credit carryforwards of approximately \$1.0 million. The federal NOLs generated during and after fiscal 2018 totaling \$9.2 million are carried forward indefinitely, while all others, if not utilized, will expire in various years beginning in 2025. A lack of future taxable income would adversely affect our ability to utilize these NOLs. In addition, under Section 382 of the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We may have already experienced one or more ownership changes. Depending on the timing of any future utilization of our NOLs and tax credit carryforwards, we may be limited as to the amount that can be utilized each year as a result of such previous ownership changes. However, we do not believe such limitations will cause our NOL and tax credit carryforwards to expire unutilized. In addition, future changes in our stock ownership as well as other changes that may be outside of our control, could result in additional ownership changes under Section 382 of the Code. Our NOLs may also be impaired under similar provisions of state law or limited pursuant to provisions of the Tax Cuts and Jobs Act amendments to the Code. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Risks Relating to Regulatory Approval and Other Legal Compliance Matters

The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. Before we can commercialize any of our product candidates, we must obtain marketing approval.

Obtaining approval by the FDA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Further, securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval for our product candidates, the FDA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested or may impose other prescribing limitations or warnings that limit the product's commercial potential. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our product candidates will ever obtain regulatory approval. Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA or other comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- we may be unable to demonstrate to the FDA or other comparable foreign regulatory authorities that our product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we obtain approval of our product candidates, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a risk evaluation and mitigation strategy, or REMS. Regulatory authorities may not approve the price we intend to charge for products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could seriously harm our business.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or comparable foreign regulatory approval processes and are commercialized. The lengthy approval processes as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

Our current or future product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with our product candidates' use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in nonclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the clinical trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

Patients in our clinical trials may in the future suffer significant adverse events or other side effects not observed in our nonclinical studies or previous clinical trials. Some of our product candidates may be used as chronic therapies or be used in populations for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, if our product candidates are used in combination with other therapies, our product candidates may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing separate treatments which can cause side effects or adverse events that are unrelated to our product candidate, but may still impact the success of our clinical trials. The inclusion of elderly patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using. If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our clinical trials, or we may be required to abandon the clinical trials or our development efforts of that product candidate altogether. We, the FDA or other comparable 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 clinical 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 clinical 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, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates and not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on nonclinical studies or early-stage clinical trials.

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. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical 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 establishing and maintaining 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 or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential product candidates will be harmed.

Even if we receive regulatory approval of our 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.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for 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 or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice, or cGMP regulations, good laboratory practice, or GLP, regulations and good clinical practice, or GCP regulations, for any clinical trials that we conduct post-approval. 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, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- 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 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's and other regulatory authorities' policies 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.

Moreover, the FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current U.S. administration may impact our business and industry. Namely, the current U.S. administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders, will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Disruptions at the FDA, the Securities and Exchange Commission and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, 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, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the Securities and Exchange Commission, or 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, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products through April 2020. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. In May 2020, FDA announced that it will continue to postpone domestic and foreign routine surveillance inspections due to COVID-19. While the FDA indicated that it will consider alternative methods for inspections and could exercise discretion on a case-by-case basis to approve products based on a desk review, if a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, 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, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional nonclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous postmarketing requirements, the FDA may seek to withdraw accelerated approval.

We may in the future seek an accelerated approval for our one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We may face difficulties from changes to current regulations and future legislation. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example:

- changes to our manufacturing arrangements;
- additions or modifications to product labeling;
- the recall or discontinuation of our products; or
- 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA contained provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the U.S. Department of Health and Human Services Secretary, or HHS Secretary, as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extending the rebate program to individuals enrolled in Medicaid managed care organizations. The ACA also 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% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) 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.

Members of the U.S. Congress and the Trump administration have expressed an intent to pass legislation or adopt executive orders to fundamentally change or repeal parts of the ACA. While Congress has not passed repeal legislation to date, the Tax Cuts and Jobs Act, or TCJA, 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." On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the 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 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allocated one hour for oral arguments, which are expected to occur in the fall. It is unclear how such litigation and other efforts to repeal and replace the ACA will be affected by the results of the U.S. general election in November 2020 and how such efforts will impact the ACA and our business. 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. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the Affordable Care Act. 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. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay to third-party payors more than \$12 billion in ACA risk corridor payments that they argued were owed to them. This was appealed to the U.S. Supreme Court, who reversed the Federal Circuit's decision on April 27, 2020, and ruled that the government must make risk corridor payments.

Moreover, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices; however on December 20, 2019, President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future. The Bipartisan Budget Act of 2018 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." 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. In addition, CMS has published a final rule to 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 American Taxpayer Relief Act of 2012, or ATRA, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Other legislative changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which was signed into law on March 27, 2020, designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. 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 2021 includes allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Additionally, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained 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. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. It is unclear to what extent the results of the U.S. general election in November 2020 will affect these policies and what the effects will be on our business.

Further, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

At the state level, individual states are increasingly aggressive in 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. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will 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 our product candidates or additional pricing pressures.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the ACA. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Further, it is possible that additional governmental action is taken to address the COVID-19 pandemic. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure to what extent the trajectory of these legislative and regulatory proposals will be affected by the results of the U.S. general election in November 2020, whether additional legislative changes will be enacted, whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval.

The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from 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 does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that 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 False Claims Act, or FCA. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection.
- federal civil and criminal false claims laws, including the FCA, which can be enforced through civil “qui tam” or “whistleblower” actions, and civil monetary penalty laws, impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. 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 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. When an entity is determined to have violated the federal civil FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs.
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new 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 requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. 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 ACA and its implementing regulations, which require 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 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. Effective January 1, 2022, these reporting obligations will extend to include payments and transfers of value made and ownership interests held during the previous year to certain non-physician providers such as physician assistants and nurse practitioners.
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state 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 that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring 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 may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities, including our advisory board arrangements with physicians, some of whom receive stock or stock options as compensation for services provided, and any sales and marketing activities after a product candidate has been approved for marketing in the United States, could be subject to legal challenge and enforcement actions. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to significant civil, criminal, and administrative penalties, including, without limitation, damages, fines, imprisonment, 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, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring 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 have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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 commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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.

Risks Relating to Our Reliance on Third Parties

We plan to rely on third parties to conduct our nonclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We plan to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs, and strategic partners to conduct and support our nonclinical studies and clinical trials under agreements with us.

We expect to have to negotiate budgets and contracts with CROs, clinical trial sites and CMOs and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our nonclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these nonclinical studies and clinical trials and the management of data developed through nonclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with 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 GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with pharmaceutical product produced under cGMP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated 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 our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing, clinical and non-clinical product candidates. 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 drug 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 clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials 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.

Switching or adding third parties to conduct our nonclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We contract with third parties for the manufacture of our product candidates for nonclinical studies and our clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for nonclinical studies and clinical trials under the guidance of members of our organization. We do not have long-term supply agreements. Furthermore, the raw materials for our product candidates are sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. For example, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our products and product candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects. We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations. Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals.

In order to commercially produce our products either at our own facility or at a third party's facility, we will need to comply with the FDA's cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our precision medicines as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our precision medicines for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

If our third-party manufacturers use hazardous materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

We may use strategic collaborations, licensing arrangements or partnerships to accelerate the development and maximize the commercial potential of our programs, and we may not realize the benefits of such collaborations, arrangements or partnerships.

We own worldwide rights to ATH-1017 as well as our pipeline of small molecule candidates. Where appropriate, we may use strategic collaborations, licensing arrangements or partnerships to accelerate the development and maximize the commercial potential of our programs. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy and obtain marketing approval.

If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, 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 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 capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Even if we are successful in entering into collaborations involving our product candidates, these relationships are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, 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 product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into additional strategic collaborations, licensing arrangements or partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic collaboration, licensing arrangement or partnership, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic collaborations, licensing arrangements or partnerships related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and

- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense

Risks Relating to Our Ability to Commercialize our Product

Even if approved, our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- restrictions on the use of our product candidates, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- pricing and the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- the availability of the approved product candidate for use as a combination therapy;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our products or product candidates or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications.

If any of our product candidates is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized a product candidate. We may license certain rights with respect to our product candidates to collaborators, and, if so, we will rely on the assistance and guidance of those collaborators. For product candidates for which we retain commercialization rights and marketing approval, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates, if approved, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, developing adequate educational and marketing programs to increase public acceptance of our approved product candidates, ensuring regulatory compliance of our company, employees and third parties under applicable healthcare laws, and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates upon approval. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.

If the market opportunity for any product candidate that we develop is smaller than we believe, our revenue may be adversely affected and our business may suffer.

We intend to initially focus our product candidate development on treatments for various CNS and peripheral disorder indications. The addressable patient populations that may benefit from treatment with our product candidates, if approved, are based on our estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these CNS and peripheral disorders. Any regulatory approval of our product candidates would be limited to the therapeutic indications examined in our clinical trials and as determined by the FDA, which would not permit us to market our products for any other therapeutic indications not expressly approved by the FDA. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Even if we receive regulatory approval for any of our product candidates, such approval could be conditioned upon label restrictions that materially limit the addressable patient population. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business.

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 the planned clinical testing of our product candidates 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 testing, 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:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants
- 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;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Failure to obtain or retain 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 corporate collaborators. Although we have clinical trial insurance, 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 such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Our product candidates may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices, or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

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

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other future product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, 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.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours.

Reimbursement agencies in Europe may be more conservative than CMS. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care 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 and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

A variety of risks associated with marketing our product candidates internationally may materially adversely affect our business.

We plan to eventually seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries, such as the lack of pathways for accelerated drug approval, may result in foreign regulatory approvals taking longer and being more costly than obtaining approval in the United States;
- foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials or our interpretation of data from nonclinical studies or clinical trials;
- approval policies or regulations of foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval;
- impact of the COVID-19 pandemic on our ability to produce our product candidates and conduct clinical trials in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with legal requirements applicable to privacy, data protection, information security and other matters;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes and government payors in foreign countries;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;

- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

Risks Relating to Our Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. We may also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or the patent applications of any future licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. Thus, the degree of future protection for our and any future licensors' proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

We own or in-license nine U.S. issued patents, own or in-license one U.S. pending patent application, own or in-license 12 patents issued in jurisdictions outside of the United States, and own or in-license nine pending patent applications in jurisdictions outside of the United States. However, we cannot be certain that the claims in our U.S. pending patent applications, corresponding international patent applications, or those of any future licensors, will be considered patentable by the United States Patent and Trademark Office, or USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our owned or in-licensed patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive and time-consuming, and we and any future licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we or any future licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of any future licensors may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or in-license currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents or the patents of any future licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents or the patents of any future licensors may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review, or PGR, and *inter partes* review, or IPR, or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, our patents or the patents of any future licensors may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our claim of priority of invention or other features of patentability with respect to our patents and patent applications and those of any future licensors. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of any future licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- we or any future licensors or collaborators might not have been the first to make the inventions covered by the issued patents or patent application that we own or license;
- we or any future licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we own or license will not lead to issued patents;
- issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, it could significantly harm our business, results of operations and prospects.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;

- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of the date of this report, others may hold proprietary rights that could prevent our product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our products, treatment indications, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market 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. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or a future strategic partner were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates, our treatment indications, or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because our development programs may in the future 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 third-party proprietary rights. 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 for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be involved in lawsuits to protect or enforce our patents or any future licensors' patents, which could be expensive, time consuming and unsuccessful. Further, our issued patents or any future licensors' patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable, and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent or the patent of any future licensors is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, PGR, IPR, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents or any future licensors' patents in such a way that they no longer cover our technology or platform, or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

The outcome following legal assertions of invalidity and/or unenforceability is unpredictable, and prior art could render our patent or any future licensors' patent invalid. There is no assurance that all potentially relevant prior art relating to our patent and patent applications or the patent and patent applications of any future licensors has been found. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patent and patent applications or the patent and patent applications of any future licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patent and patent applications of any future licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights 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. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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

In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of any future licensors. An unfavorable outcome 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. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of any future licensors and the enforcement or defense of our issued patents or those of any future licensors.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a “first inventor to file” system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we may not be certain that we or any future licensors are the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in the patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of any future licensors and the enforcement or defense of our issued patents or those of any future licensors, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

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 a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our 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 U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, 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 patent and the patents we might obtain or license in the future.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

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 may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our U.S. patents or those of any future licensors may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the 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 and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we may not be granted an extension because of, for example, 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 restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and nonclinical data and launch their product earlier than might otherwise be the case.

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

We own or in-license nine U.S. issued patents and own one U.S. pending patent application, as well as 12 in-licensed patents issued in jurisdictions outside of the United States, two in-licensed pending patent applications in jurisdictions outside of the United States, and seven owned patent applications pending in jurisdictions outside of the United States. However, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may 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 will 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 enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents, the patents of any future licensors, 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 many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or any future licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of any future licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of any future licensors at risk of not issuing and could provoke third parties to assert claims against us. 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.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications and those of any future licensors. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, 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. If such an event were to occur, it could have a material adverse effect on our business.

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.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. 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, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

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

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, lessees of shared multi-company property and other third parties. We may become subject to litigation where a third party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. 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. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition and prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biopharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biopharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. 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, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of licenses granted to us by others.

We have entered into license agreements with third parties and we may enter into additional license agreements in the future with others to advance our research or allow commercialization of product candidates. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If any of our future licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected.

Our licensors and any future licensors may have relied on third party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. 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 redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

Disputes may arise between us and our current or future 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 patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

The patent protection and patent prosecution for some of our product candidates may be dependent on third parties.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents relating to our product candidates are controlled by licensors or collaboration partners. If a licensor or collaboration partner fails to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Intellectual property discovered through government funded programs may be subject to federal regulations such as “march-in” rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

We may develop, acquire, or license intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as “march-in rights”). Such “march-in” rights would apply to new subject matter arising from the use of such government funding or grants and would not extend to pre-existing subject matter or subject matter arising from funds unrelated to the government funding or grants. If the U.S. government exercised its march-in rights in our future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

Risks Relating to Cybersecurity

We are dependent on networks, infrastructure and data, which exposes us to data security risks, including security failures or breaches of our systems or those used by our CROs or other contractors or consultants. We are dependent upon our own or third-party information technology systems, infrastructure and data, including mobile technologies, to operate our business. The multitude and complexity of our computer systems may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants may be vulnerable to damage from computer viruses and unauthorized access. Likewise, data privacy or security incidents or breaches by employees or others may pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients, customers or other business partners may be exposed to unauthorized persons or to the public or may otherwise be misused. Cyberattacks are increasing in their frequency, sophistication and intensity. Cyberattacks could include the deployment of harmful malware, denial-of-service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Changes in how our employees work and access our systems during the current COVID-19 pandemic could lead to additional opportunities for bad actors to launch cyberattacks or for employees to cause inadvertent security risks or incidents. Our business partners face similar risks, and any security breach of their systems or that they otherwise suffer could adversely affect our security posture. A security breach or privacy violation that leads to loss of or unauthorized use, disclosure or modification of, or access to personal, sensitive or proprietary information, including personally identifiable information, protected health information, or other patient information, or that prevents access to patient information, as well as the perception that any of the foregoing has occurred, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, cause us to provide other notification or take other steps in response to such breach or violation, require us to verify the correctness of database contents and otherwise subject us to litigation, claims, investigations, penalties or other liability under laws and regulations that protect personal data, any of which could disrupt our business and/or result in increased costs or loss of revenue. The effects of a security breach or privacy violation could be further amplified during the current COVID-19 pandemic. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property.

Despite significant efforts to create security barriers to the above described threats, it is impossible for us to entirely mitigate these risks. We may be unable to anticipate or prevent techniques used to obtain unauthorized access or to compromise our systems because they change frequently and are generally not detected until after an incident has occurred. If a compromise or other security incident 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 clinical trial data from completed, ongoing or future clinical trials 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 systems, or inappropriate use, disclosure or modification of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts will prevent service interruptions, or prevent or identify vulnerabilities or breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information. Any such interruptions or breaches, or the perception any have occurred, could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related privacy and security breaches or incidents.

Data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

If we decide to conduct clinical trials or continue to enroll patients in our future clinical trials, we may be subject to additional restrictions relating to privacy, data protection and data security. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, or EU, including personal health data, is subject to the EU General Data Protection Regulation, or GDPR. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. Certain aspects of cross-border data transfers under the GDPR are uncertain as the result of legal proceedings in the EU, including a recent

decision by the Court of Justice for the European Union that invalidated the EU-U.S. Privacy Shield. This may increase the complexity of transferring personal data across borders. The GDPR increased our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

Further, the vote in the United Kingdom, or UK, in favor of exiting the EU, referred to as Brexit, has created uncertainty with regard to data protection regulation in the UK. Specifically, while the Data Protection Act of 2018, that “implements” and complements the GDPR achieved Royal Assent on May 23, 2018 and is now effective in the UK, aspects of data protection in the UK, such as the transfer of data from the EEA to the UK, remain uncertain. During the period of “transition” (i.e., until December 31, 2020), EU law will continue to apply in the UK, including the GDPR, after which the GDPR will be converted into UK law. Beginning in 2021, the UK will be a “third country” under the GDPR. We may, however, incur liabilities, expenses, costs, and other operational losses under GDPR and applicable EU Member States and the United Kingdom privacy laws in connection with any measures we take to comply with them.

In addition, California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies’ data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA went into effect on January 1, 2020, and the California Attorney General commenced enforcement actions for violations on July 1, 2020. Moreover, a new privacy law, the California Privacy Rights Act, or CPRA, was recently certified by the California Secretary of State to appear on the ballot for the November 3, 2020 election. If this initiative is approved by California voters, the CPRA would significantly modify the CCPA, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. The CCPA and, if it goes into effect, the CPRA, may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Any actual or alleged failure to comply with U.S. or international laws and regulations relating to privacy, data protection, and data security could result in governmental investigations, proceedings and enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity, harm to our reputation, and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information or impose other obligations or restrictions in connection with our use, retention and other processing of information, and we may otherwise face contractual restrictions applicable to our use, retention, and other processing of information. Claims that we have violated individuals’ privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

Risks Relating to Ownership of Our Common Stock

We do not know whether an active market will develop for our common stock or will be sustained, and, as a result, it may be difficult for you to sell your shares of our common stock.

If an active market for our common stock does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at an attractive price or at all. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations and progression of our product pipeline may not meet the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall.

The market price of our common stock may be volatile, which could result in substantial losses for investors.

The market price of our common stock may be volatile. As a result, you may not be able to sell your common stock at or above the price that you paid for such shares. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of nonclinical studies and clinical trials and, in particular, our LIFT-AD and ACT-AD P300 clinical trials;
- the impact of the ongoing COVID-19 pandemic on our business;

- the success of existing or new competitive products or technologies;
- the timing and results of clinical trials for our current product candidates and any future product candidates that we may develop;
- commencement or termination of collaborations for our product candidates;
- failure or discontinuation of any of our product candidates;
- results of nonclinical studies, clinical trials or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- investor reactions to other companies' drug development results, including product failures or negative responses from regulatory authorities;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the commencement of litigation;
- the level of expenses related to any of our research programs, product candidates that we may develop;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other stockholders;
- expiration of market standoff or lock-up agreements;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions; and
- the other factors described in this "Part II, Item 1A—Risk Factors" section.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, upon the expiration of the market standoff and lock-up agreements, the early release of these agreements or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. The 13,397,712 shares we sold in connection with our IPO and partial exercise of the underwriters' over-allotment option may be resold in the public market immediately, except for any shares purchased by our directors, executive officers and employees in our directed share program. The remaining 19,087,472 shares, or 58.8% of our outstanding shares after our IPO as of November 9, 2020, are currently prohibited or otherwise restricted under securities laws, market standoff agreements entered into by our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters; however, subject to applicable securities law restrictions and

excluding shares of restricted stock that will remain unvested, these shares will be able to be sold in the public market beginning 180 days after the date of the final prospectus related to our IPO. The representatives may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements at any time and for any reason. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available-for-sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market standoff and lock-up agreements, and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act.

Moreover, the holders of approximately 18,104,343 shares of our common stock are eligible to exercise certain rights, subject to various conditions and limitations, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also register shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements described in the section of our final prospectus related to our IPO titled “Underwriting.” If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Our directors, executive officers and 5% stockholders own a significant percentage of our common stock, which could limit your ability to affect the outcome of key transactions, including a change of control.

Our directors, executive officers, holders of more than 5% of our outstanding common stock and their respective affiliates beneficially own shares representing approximately 34.7% of our outstanding common stock as of November 9, 2020. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

We are an “emerging growth company,” and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of SOX Section 404, not being required to comply 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, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the regulations of the Nasdaq Global Select Market, the rules and regulations of the Securities and Exchange Commission, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. Commencing with our fiscal year ending December 31, 2021, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. We have never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We anticipate that the process of building our accounting and financial functions and infrastructure will require significant additional professional fees, internal costs and management efforts. We expect that we will need to implement a new internal system to combine and streamline the management of our financial, accounting, human resources and other functions. However, such a system would likely require us to complete many processes and procedures for the effective use of the system or to run our business using the system, which may result in substantial costs. Any disruptions or difficulties in implementing or using such a system could adversely affect our controls and harm our business. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention. In addition, we may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

We have broad discretion in the use of the net proceeds from our initial public offering and may not use them effectively.

We have broad discretion in the application of the net proceeds received from our IPO. We may spend a portion or all of the net proceeds from our IPO in ways that our stockholders may not desire or that may not yield a favorable return. Any failure by us to apply these funds effectively could harm our business, financial condition, results of operations and prospects. Pending their use, we may invest the net proceeds from our IPO in a manner that does not produce income or that loses value.

Anti-takeover provisions in our charter documents and under Delaware or Washington law could make an acquisition of us difficult, limit attempts by our stockholders to replace or remove our current management and limit our stock price.

Provisions of our certificate of incorporation and bylaws that became effective immediately prior to the closing of our IPO may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, the certificate of incorporation and bylaws:

- permit the board of directors to issue up to 100,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that all vacancies, including newly-created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide the board of directors into three classes;
- provide that a director may only be removed from the board of directors by the stockholders for cause;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and meet specific requirements as to the form and content of a stockholder's notice;
- prevent cumulative voting rights (therefore allowing the holders of a plurality of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);

- provide that special meetings of our stockholders may be called only by the chairman of the board, our chief executive officer or by the board of directors; and
- provide that stockholders are permitted to amend the bylaws only upon receiving at least two-thirds of the total votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any “interested” stockholder for a period of three years following the date on which the stockholder became an “interested” stockholder. Likewise, because our principal executive offices are located in Washington, the anti-takeover provisions of the Washington Business Corporation Act may apply to us under certain circumstances now or in the future. These provisions prohibit a “target corporation” from engaging in any of a broad range of business combinations with any stockholder constituting an “acquiring person” for a period of five years following the date on which the stockholder became an “acquiring person.”

Our bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising under the Delaware General Corporation Law, our certificate of incorporation or our bylaws; any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our bylaws further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The enforceability of similar exclusive federal forum provisions in other companies’ organizational documents has been challenged in legal proceedings, and while the Delaware Supreme Court has ruled that this type of exclusive federal forum provision is facially valid under Delaware law, there is uncertainty as to whether other courts would enforce such provisions and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

These exclusive forum provisions may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find either exclusive forum provision in our bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could have a material adverse effect on our business, financial condition, and results of operations.

General Risk Factors

Our advisors and consultants are classified as independent contractors, and we can face consequences if it is determined that they are misclassified as such.

There is often uncertainty in the application of worker classification laws, and consequently there is risk to us that our independent contractors could be deemed to be misclassified under applicable law. The tests governing whether a service provider is an independent contractor or an employee are typically highly fact sensitive and can vary by governing law. Laws and regulations that govern the status and misclassification of independent contractors are also subject to divergent interpretations by various authorities, which can create uncertainty and unpredictability. A misclassification determination or allegation creates potential exposure for us, including but not limited to monetary exposure arising from or relating to failure to withhold and remit taxes, unpaid wages, and wage and hour laws and requirements (such as those pertaining to minimum wage and overtime); claims for employee benefits, social security, workers’ compensation and unemployment; claims of discrimination, harassment, and retaliation under civil rights laws; claims under laws pertaining to unionizing, collective bargaining, and other concerted activity; and other claims, charges, or other proceedings under laws and regulations applicable to employers and employees, including risks relating to allegations of joint employer liability. Such claims could result in monetary damages (including but not limited to wage-based damages or restitution, compensatory damages, liquidated damages, and punitive damages), interest, fines, penalties, costs, fees (including but not limited to attorneys’ fees), criminal and other liability, assessment, or settlement. Such an allegation, claim, adverse determination, including but not limited to with respect to advisors and consultants that provide services to us could also harm our brand and reputation, which could adversely impact our business.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. If no or few analysts commence coverage of us, the trading price of our stock could decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

We will continue to incur 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 and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance, and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We are currently evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

If we are unable to maintain effective internal controls, our business, financial position and results of operations could be adversely affected.

As a public company, we are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act, including the requirements of SOX Section 404, which require annual management assessments of the effectiveness of our internal control over financial reporting.

The rules governing the standards that must be met for management to determine that our internal control over financial reporting is effective are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act of 2002. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. Any failure to maintain effective internal controls could have an adverse effect on our business, financial position and results of operations.

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

Recent Sales of Unregistered Equity Securities

On September 22, 2020, upon the closing of the IPO, all convertible preferred shares then outstanding automatically converted into 12,503,009 shares of common stock. In addition, warrants to purchase 127,481 shares of convertible preferred stock automatically converted into warrants to purchase 127,481 shares of our common stock. Such warrants were then automatically net exercised into 59,093 shares of common stock. In addition, warrants to purchase 1,095,159 shares of our common stock were cash exercised or automatically net exercised into an aggregate of 1,085,334 shares of our common stock. The issuance of such common stock upon conversion of the convertible preferred stock, the issuance of such common stock warrants upon conversion of the convertible preferred

stock warrants and the issuance of such common stock on the net exercise of common stock warrants were exempt from the registration requirements of the Securities Act, pursuant to Section 3(a)(9) thereof, 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. The issuance of the common stock upon the cash exercise of common stock warrants was exempt from registration under the Securities Act pursuant to Section 4(a)(2) thereof as a transaction by an issuer not involving a public offering. No underwriters were involved in the issuance of the shares of common stock or common stock warrants.

During the period between July 1, 2020 and September 11, 2020, we issued 570,186 shares of our common stock pursuant to the cash exercise of outstanding warrants to purchase shares of our common stock at an exercise price of \$0.08 per share. During the period between July 1, 2020 and September 17, 2020, we issued to certain of our employees, consultants and directors, options to purchase an aggregate of 943,223 shares of our common stock at an exercise price of \$17.00 per share pursuant to our 2020 Equity Incentive Plan. During this period we also issued and sold an aggregate of 262,285 shares of our common stock to our employees, directors and consultants at a weighted-average exercise price of \$1.17 per share pursuant to exercises of options granted under our 2014 Equity Incentive Plan. We deemed the issuances of common stock on the exercise of common stock warrants to be exempt from registration under the Securities Act pursuant to Section 4(a)(2), as transactions by an issuer not involving a public offering. The issuances of options to purchase shares of our common stock and the issuances of common stock on the exercise of options were exempt from registration under the Securities Act either in reliance on Rule 701 of the Securities Act as sales and offers under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701, or in reliance on Section 4(a)(2), as transactions by an issuer not involving a public offering. 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 September 18, 2020 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 2014 Equity Incentive Plan, 2020 Equity Incentive Plan and 2020 Employee Stock Purchase Plan.

Use of Proceeds from Initial Public Offering

On September 22, 2020, we closed our IPO, in which we sold and issued 12,000,000 shares of our common stock at a price to the public of \$17.00 per share. On October 16, 2020, we sold and issued an additional 1,397,712 shares of common stock at \$17.00 per share, less underwriting discounts and commissions, to the underwriters of our IPO following the partial exercise of their option to purchase additional shares of 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 (File No. 333-248428), which was declared effective by the SEC on September 17, 2020. Following the sale of the above shares, the offering terminated. Goldman Sachs & Co. LLC, Jefferies LLC and Stifel, Nicolaus & Company, Incorporated acted as joint book-running managers and JMP Securities acted as co-manager.

We received aggregate gross proceeds from our IPO of \$227.8 million, or aggregate net proceeds of \$208.5 million, inclusive of the partial exercise of the underwriters' option to purchase additional shares, after deducting underwriting discounts and commissions of \$15.9 million and offering costs payable by us, which are estimated to be \$3.3 million. None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to (i) our directors or officers or their associates, (ii) persons owning 10% or more of our common stock or (iii) any of our affiliates.

There has been no material change in our planned use of the net proceeds from our IPO as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on September 18, 2020.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Company				
3.2	Amended and Restated Bylaws of the Company				
4.1	Warrant to Purchase Common Stock of the Registrant, dated August 26, 2020	S-1/A	333-248428	4.6	September 9, 2020
10.1**	Form of Director and Executive Officer Indemnification Agreement	S-1	333-248428	10.1	August 26, 2020
10.2**	2014 Equity Incentive Plan, as amended	S-1/A	333-248428	10.2	September 9, 2020
10.3**	2020 Equity Incentive Plan	S-1/A	333-248428	10.5	September 9, 2020
10.4**	Form of Stock Option Agreement under the 2020 Equity Incentive Plan	S-1/A	333-248428	10.6	September 9, 2020
10.5**	Form of Restricted Stock Award Agreement under the 2020 Equity Incentive Plan	S-1/A	333-248428	10.7	September 9, 2020
10.6**	Form of RSU Agreement under the 2020 Equity Incentive Plan	S-1/A	333-248428	10.8	September 9, 2020
10.7†	Amended and Restated Standard Exclusive Licensing Agreement with Sublicensing Terms, dated October 28, 2015, by and between the Registrant and Washington State University, and amendments thereto	S-1	333-248428	10.9	August 26, 2020
10.8**	2020 Employee Stock Purchase Plan and Form of Subscription Agreement Thereunder	S-1/A	333-248428	10.10	September 9, 2020
10.9	Lease agreement, dated July 20, 2020, by and between the Registrant and North Creek Parkway Center Investors, LP	S-1/A	333-248428	10.11	September 9, 2020
10.10**	Outside Director Compensation Policy	S-1/A	333-248428	10.12	September 9, 2020
10.11**	Executive Incentive Compensation Plan	S-1/A	333-248428	10.13	September 9, 2020
10.12**	Confirmatory Employment Letter between the Registrant and Leen Kawas, Ph.D.	S-1/A	333-248428	10.14	September 9, 2020
10.13**	Confirmatory Employment Letter between the Registrant and Mark Litton, Ph.D.	S-1/A	333-248428	10.15	September 9, 2020
10.14**	Confirmatory Employment Letter between the Registrant and Kevin Church, Ph.D.	S-1/A	333-248428	10.16	September 9, 2020
10.15**	Confirmatory Employment Letter between the Registrant and Glenna Mileson	S-1/A	333-248428	10.17	September 9, 2020
10.16**	Change in Control and Severance Agreement between the Registrant and Leen Kawas, Ph.D.	S-1/A	333-248428	10.18	September 9, 2020

10.17**	Change in Control and Severance Agreement between the Registrant and Mark Litton, Ph.D.	S-1/A	333-248428	10.19	September 9, 2020
10.18**	Change in Control and Severance Agreement between the Registrant and Glenna Mileson	S-1/A	333-248428	10.20	September 9, 2020
10.19**	Employment Offer Letter between the Registrant and Hans Moebius, Ph.D.	S-1/A	333-248428	10.21	September 14, 2020
10.20**	Change in Control and Severance Agreement between the Registrant and Hans Moebius, Ph.D.	S-1/A	333-248428	10.22	September 14, 2020
31.1	Certification of Principal Executive Officer 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.				
31.2	Certification of Principal Accounting and Financial Officer 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.				
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 Accounting and 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 Extension 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				

* The certifications filed as Exhibits 32.1 and 32.2 are not deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the Company under the Securities Exchange Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof irrespective of any general incorporation by reference language contained in any such filing, except to the extent that the registrant specifically incorporates it by reference.

** Indicates a management contract or compensatory plan.

† Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted by means of marking such portions with asterisks because the Registrant has determined that the information is not material and would likely cause competitive harm to the Registrant if publicly disclosed.

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.

Athira Pharma, Inc.

Date: November 12, 2020

By: /s/ Leen Kawas
Leen Kawas
President and Chief Executive Officer (*Principal Executive Officer*)

Date: November 12, 2020

By: /s/ Glenna Mileson
Glenna Mileson
Chief Financial Officer (*Principal Financial and Accounting Officer*)

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF

ATHIRA PHARMA, INC.

a Delaware corporation

Athira Pharma, Inc., a corporation organized and existing under the laws of the State of Delaware (the “**Company**”), does hereby certify as follows:

A. The Company was originally incorporated under the name of M3 Biotechnology, Inc., and the original Certificate of Incorporation of the Company was filed with the Secretary of State of the State of Delaware on October 27, 2015.

B. This Amended and Restated Certificate of Incorporation was duly adopted in accordance with Sections 242 and 245 of the General Corporation Law of the State of Delaware (the “**DGCL**”) by the Board of Directors of the Company (the “**Board of Directors**”) and has been duly approved by the written consent of the stockholders of the Company in accordance with Section 228 of the DGCL.

C. The text of the Amended and Restated Certificate of Incorporation is hereby amended and restated in its entirety to read as follows:

ARTICLE I

The name of the Company is Athira Pharma, Inc.

ARTICLE II

The address of the Company’s registered office in the State of Delaware is 251 Little Falls Drive, Wilmington, County of New Castle, Delaware 19808. The name of its registered agent at such address is Corporation Service Company.

ARTICLE III

The nature of the business or purposes to be conducted or promoted by the Company is to engage in any lawful act or activity for which corporations may be organized under the DGCL.

ARTICLE IV

Section 1. This Company is authorized to issue two classes of stock, to be designated, respectively, Common Stock and Preferred Stock. The total number of shares of stock that the Company shall have authority to issue is 1,000,000,000 shares, of which 900,000,000 shares are Common Stock, \$0.0001 par value per share, and 100,000,000 shares are Preferred Stock, \$0.0001 par value per share.

Section 2. Each share of Common Stock outstanding as of the applicable record date shall entitle the holder thereof to one (1) vote on any matter submitted to a vote at a meeting of stockholders.

Section 3. The Preferred Stock may be issued from time to time in one or more series pursuant to a resolution or resolutions providing for such issue duly adopted by the Board of Directors (authority to do so being hereby expressly vested in the Board of Directors). The Board of Directors is further authorized, subject to limitations prescribed by law, to fix by resolution or resolutions the designations, powers, preferences and rights, and the qualifications, limitations or restrictions thereof, of any series of Preferred Stock, including, without limitation, authority to fix by resolution or resolutions the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), redemption price or prices, and liquidation preferences of any such series, and the number of shares constituting any such series and the designation thereof, or any of the foregoing. The Board of Directors is further authorized to increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares of any such series then outstanding) the number of shares of any series, subject to the powers, preferences and rights, and the qualifications, limitations and restrictions thereof stated in this Amended and Restated Certificate of Incorporation or the resolution of the Board of Directors originally fixing the number of shares of such series. Except as may be otherwise specified by the terms of any series of Preferred Stock, if the number of shares of any series of Preferred Stock is so decreased, then the Company shall take all such steps as are necessary to cause the shares constituting such decrease to resume the status which they had prior to the adoption of the resolution originally fixing the number of shares of such series.

Section 4. Except as otherwise required by law or provided in this Amended and Restated Certificate of Incorporation, holders of Common Stock shall not be entitled to vote on any amendment to this Amended and Restated Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon by law or pursuant to this Amended and Restated Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock).

Section 5. The number of authorized shares of Preferred Stock or Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of all the then-outstanding shares of capital stock of the Company entitled to vote thereon, without a separate vote of the holders of the class or classes the number of authorized shares of which are being increased or decreased, unless a vote of any holders of one or more series of Preferred Stock is required pursuant to the terms of any certificate of designation relating to any series of Preferred Stock, irrespective of the provisions of Section 242(b)(2) of the DGCL.

ARTICLE V

Section 1. Subject to the rights of holders of Preferred Stock, the number of directors that constitutes the entire Board of Directors of the Company shall be fixed only by resolution of the Board of Directors acting pursuant to a resolution adopted by a majority of the Whole Board. For the purposes of this Amended and Restated Certificate of Incorporation, the term “**Whole Board**” shall mean the total number of authorized directorships whether or not there exist any vacancies or other unfilled seats in previously authorized directorships. At each annual meeting of stockholders, directors of the Company shall be elected to hold office until the expiration of the term for which they are elected and until their successors have been duly elected and qualified or until their earlier resignation or removal; except that if any such meeting shall not be so held, such election shall take place at a stockholders’ meeting called and held in accordance with the DGCL.

Section 2. From and after the effectiveness of this Amended and Restated Certificate of Incorporation, the directors of the Company (other than any who may be elected by holders of Preferred Stock under specified circumstances) shall be divided into three classes as nearly equal in size as is practicable, hereby designated Class I, Class II and Class III. Directors already in office shall be assigned to each class at the time such classification becomes effective in accordance with a resolution or resolutions adopted by the Board of Directors. At the first annual meeting of stockholders following the date hereof, the term of office of the Class I directors shall expire and Class I directors shall be elected for a full term of three years. At the second annual meeting of stockholders following the date hereof, the term of office of the Class II directors shall expire and Class II directors shall be elected for a full term of three years. At the third annual meeting of stockholders following the date hereof, the term of office of the Class III directors shall expire and Class III directors shall be elected for a full term of three years. At each succeeding annual meeting of stockholders, directors shall be elected for a full term of three years to succeed the directors of the class whose terms expire at such annual meeting. If the number of directors is changed, any newly created directorships or decrease in directorships shall be so apportioned hereafter among the classes as to make all classes as nearly equal in number as is practicable, *provided that* no decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

ARTICLE VI

Section 1. From and after the effectiveness of this Amended and Restated Certificate of Incorporation, only for so long as the Board of Directors is classified and subject to the rights of holders of Preferred Stock, any director or the entire Board of Directors may be removed from office at any time, but only for cause, and only by the affirmative vote of the holders of at least 66 2/3% of the voting power of the issued and outstanding capital stock of the Company entitled to vote in the election of directors.

Section 2. Except as otherwise provided for or fixed by or pursuant to the provisions of ARTICLE IV hereof in relation to the rights of the holders of Preferred Stock to elect directors under specified circumstances or except as otherwise provided by resolution of a majority of the Whole Board, newly created directorships resulting from any increase in the number of directors, created in accordance with the Bylaws of the Company, and any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other cause shall be filled only by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum of the Board of Directors, or by a sole remaining director, and not by the stockholders. A person so elected by the Board of Directors to fill a vacancy or newly created directorship shall hold office until the next election of the class for which such director shall have been chosen until his or her successor shall have been duly elected and qualified, or until such director's earlier death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

ARTICLE VII

Section 1. The Company is to have perpetual existence.

Section 2. The business and affairs of the Company shall be managed by or under the direction of the Board of Directors. In addition to the powers and authority expressly conferred upon them by statute or by this Amended and Restated Certificate of Incorporation or the Bylaws of the Company, the directors are hereby empowered to exercise all such powers and do all such acts and things as may be exercised or done by the Company.

Section 3. In furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to adopt, alter, amend or repeal the Bylaws of the Company. The affirmative vote of at least a majority of the Whole Board shall be required in order for the Board of Directors to adopt, amend, alter or repeal the Company's Bylaws. The Company's Bylaws may also be adopted, amended, altered or repealed by the stockholders of the Company; provided that the affirmative vote of the holders of at least 66 2/3% of the total voting power of outstanding voting securities, voting together as a single class, shall be required for the stockholders of the Company to alter, amend or repeal, or adopt any bylaw inconsistent with, Article II, Sections 3.1, 3.2, 3.4 and 3.11 of Article III, Article VIII, Section 9.5 of Article IX or Article X of the Bylaws (including, without limitation, any such Article or Section as renumbered as a result of any amendment, alteration, change, repeal, or adoption of any other Bylaw). No Bylaw hereafter legally adopted, amended, altered or repealed shall invalidate any prior act of the directors or officers of the Company that would have been valid if such Bylaw had not been adopted, amended, altered or repealed.

Section 4. The election of directors need not be by written ballot unless the Bylaws of the Company shall so provide.

Section 5. No stockholder will be permitted to cumulate votes at any election of directors.

ARTICLE VIII

Section 1. From and after the closing of a firm commitment underwritten initial public offering of securities of the Company pursuant to an effective registration statement filed under the Securities Act of 1933, as amended, and subject to the rights of holders of Preferred Stock, any action required or permitted to be taken by the stockholders of the Company must be effected at a duly called annual or special meeting of stockholders of the Company and may not be effected by any consent in writing by such stockholders.

Section 2. Subject to the terms of any series of Preferred Stock, special meetings of stockholders of the Company may be called only by the Chairperson of the Board of Directors, the Chief Executive Officer, the President or the Board of Directors acting pursuant to a resolution adopted by a majority of the Whole Board, but a special meeting may not be called by any other person or persons and any power of stockholders to call a special meeting of stockholders is specifically denied. Only such business shall be considered at a special meeting of stockholders as shall have been stated in the notice for such meeting.

Section 3. Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the Company shall be given in the manner and to the extent provided in the Bylaws of the Company.

ARTICLE IX

Section 1. To the fullest extent permitted by the DGCL as the same exists or as may hereafter be amended from time to time, a director of the Company shall not be personally liable to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director. If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Company shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

Section 2. Subject to any provisions in the Bylaws of the Company related to indemnification of directors of the Company, the Company shall indemnify, to the fullest extent permitted by applicable law, any director of the Company who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (a "**Proceeding**") by reason of the fact that he or she is or was a director of the Company or is or was serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with any such Proceeding. The Company shall be required to indemnify a person in connection with a Proceeding (or part thereof) initiated by such person only if the Proceeding (or part thereof) was authorized by the Board of Directors.

Section 3. The Company shall have the power to indemnify, to the extent permitted by applicable law, any officer, employee or agent of the Company who was or is a party or is threatened to be made a party to any Proceeding by reason of the fact that he or she is or was a director, officer, employee or agent of the Company or is or was serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with any such Proceeding.

Section 4. Neither any amendment nor repeal of any Section of this ARTICLE IX, nor the adoption of any provision of this Amended and Restated Certificate of Incorporation or the Bylaws of the Company inconsistent with this ARTICLE IX, shall eliminate or reduce the effect of this ARTICLE IX in respect of any matter occurring, or any Proceeding accruing or arising or that, but for this ARTICLE IX, would accrue or arise, prior to such amendment, repeal or adoption of an inconsistent provision.

ARTICLE X

Meetings of stockholders may be held within or outside of the State of Delaware, as the Bylaws may provide. The books of the Company may be kept (subject to any provision of applicable law) outside of the State of Delaware at such place or places or in such manner or manners as may be designated from time to time by the Board of Directors or in the Bylaws of the Company.

ARTICLE XI

The Company reserves the right to amend or repeal any provision contained in this Amended and Restated Certificate of Incorporation in the manner prescribed by the laws of the State of Delaware and all rights conferred upon stockholders are granted subject to this reservation; *provided, however*, that notwithstanding any other provision of this Amended and Restated Certificate of Incorporation or any provision of law that might otherwise permit a lesser vote, the Board of Directors acting pursuant to a resolution adopted by a majority of the Whole Board and the affirmative vote of 66 2/3% of the voting power of the then outstanding voting securities of the Company, voting together as a single class, shall be required for the amendment, repeal or modification of the provisions of Section 3 of ARTICLE IV, Section 2 of ARTICLE V, Section 1 of ARTICLE VI, Section 2 of ARTICLE VI, Section 5 of ARTICLE VII, Section 1 of ARTICLE VIII, Section 2 of ARTICLE VIII, Section 3 of ARTICLE VIII or this ARTICLE XI of this Amended and Restated Certificate of Incorporation.

IN WITNESS WHEREOF, Athira Pharma, Inc. has caused this Amended and Restated Certificate of Incorporation to be signed by the President and Chief Executive Officer of the Company on this 22nd day of September 2020.

By: /s/ Leen Kawas _____

Leen Kawas

President and Chief Executive Officer

AMENDED AND RESTATED BYLAWS OF

ATHIRA PHARMA, INC.

(initially adopted on October 27, 2015)

(as amended on September 22, 2020)

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ARTICLE I - CORPORATE OFFICES

1.1 REGISTERED OFFICE

The registered office of Athira Pharma, Inc. (the “**Company**”) shall be fixed in the Company’s certificate of incorporation, as the same may be amended from time to time.

1.2 OTHER OFFICES

The Company may at any time establish other offices.

ARTICLE II - MEETINGS OF STOCKHOLDERS

2.1 PLACE OF MEETINGS

Meetings of stockholders shall be held at a place, if any, within or outside the State of Delaware, determined by the board of directors of the Company (the “**Board of Directors**”). The Board of Directors may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211(a)(2) of the Delaware General Corporation Law (the “**DGCL**”). In the absence of any such designation or determination, stockholders’ meetings shall be held at the Company’s principal executive office.

2.2 ANNUAL MEETING

The annual meeting of stockholders shall be held each year. The Board of Directors shall designate the date and time of the annual meeting. At the annual meeting, directors shall be elected and any other proper business, brought in accordance with Section 2.4 of these bylaws, may be transacted. The Board of Directors acting pursuant to a resolution adopted by a majority of the Whole Board may cancel, postpone or reschedule any previously scheduled annual meeting at any time, before or after the notice for such meeting has been sent to the stockholders. For the purposes of these bylaws, the term “**Whole Board**” shall mean the total number of authorized directorships whether or not there exist any vacancies or other unfilled seats in previously authorized directorships.

2.3 SPECIAL MEETING

(a) A special meeting of the stockholders, other than as required by statute, may be called at any time by (i) the Board of Directors acting pursuant to a resolution adopted by a majority of the Whole Board, (ii) the chairperson of the Board of Directors, (iii) the chief executive officer or (iv) the president, but a special meeting may not be called by any other person or persons and any power of stockholders to call a special meeting of stockholders is specifically denied. The Board of Directors acting pursuant to a resolution adopted by a majority of the Whole Board may cancel, postpone or reschedule any previously scheduled special meeting at any time, before or after the notice for such meeting has been sent to the stockholders.

(b) The notice of a special meeting shall include the purpose for which the meeting is called. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting by or at the direction of a majority of the Whole Board, the chairperson of the Board of Directors, the chief executive officer or the president. Nothing contained in this Section 2.3(b) shall be construed as limiting, fixing or affecting the time when a meeting of stockholders called by action of the Board of Directors may be held.

2.4 ADVANCE NOTICE PROCEDURES

(a) *Annual Meetings of Stockholders.*

(i) Nominations of persons for election to the Board of Directors or the proposal of other business to be transacted by the stockholders at an annual meeting of stockholders may be made only (1) pursuant to the Company's notice of meeting (or any supplement thereto); (2) by or at the direction of the Board of Directors; (3) as may be provided in the certificate of designations for any class or series of preferred stock; or (4) by any stockholder of the Company who (A) is a stockholder of record at the time of giving of the notice contemplated by Section 2.4(a)(ii); (B) is a stockholder of record on the record date for the determination of stockholders entitled to notice of the annual meeting; (C) is a stockholder of record on the record date for the determination of stockholders entitled to vote at the annual meeting; (D) is a stockholder of record at the time of the annual meeting; and (E) complies with the procedures set forth in this Section 2.4(a).

(ii) For nominations or other business to be properly brought before an annual meeting of stockholders by a stockholder pursuant to clause (4) of Section 2.4(a)(i), the stockholder must have given timely notice in writing to the secretary and any such nomination or proposed business must constitute a proper matter for stockholder action. To be timely, a stockholder's notice must be received by the secretary at the principal executive offices of the Company no earlier than 8:00 a.m., local time, on the 120th day and no later than 5:00 p.m., local time, on the 90th day prior to the day of the first anniversary of the preceding year's annual meeting of stockholders. However, if no annual meeting of stockholders was held in the preceding year, or if the date of the applicable annual meeting has been changed by more than 25 days from the first anniversary of the preceding year's annual meeting, then to be timely such notice must be received by the secretary at the principal executive offices of the Company no earlier than 8:00 a.m., local time, on the 120th day prior to the day of the annual meeting and no later than 5:00 p.m., local time, on the 10th day following the day on which public announcement of the date of the annual meeting was first made by the Company. In no event will the adjournment, rescheduling or postponement of any annual meeting, or any announcement thereof, commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above. If the number of directors to be elected to the Board of Directors is increased and there is no public announcement naming all of the nominees for director or specifying the size of the increased Board of Directors at least 10 days before the last day that a stockholder may deliver a notice of nomination pursuant to the foregoing provisions, then a stockholder's notice required by this Section 2.4(a)(ii) will also be considered timely, but only with respect to nominees for any new positions created by such increase, if it is received by the secretary at the principal executive offices of the Company no later than 5:00 p.m., local time, on the 10th day following the day on which such public announcement is first made. "**Public announcement**" means disclosure in a press release reported by a national news service or in a document publicly filed by the Company with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Securities Exchange Act of 1934 (as amended and inclusive of rules and regulations thereunder, the "**1934 Act**").

(iii) A stockholder's notice to the secretary must set forth:

(1) as to each person whom the stockholder proposes to nominate for election as a director:

(A) such person's name, age, business address, residence address and principal occupation or employment; the class and number of shares of the Company that are held of record or are beneficially owned by such person and a description of any Derivative Instruments (defined below) held or beneficially owned thereby or of any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares), the effect or intent of which is to mitigate loss to, or to manage the risk or benefit of share price changes for, or to increase or decrease the voting power of such person; and all information relating to such person that is required to be disclosed in solicitations of proxies for the contested election of directors, or is otherwise required, in each case pursuant to the Section 14 of the 1934 Act;

(B) such person's written consent to being named in such stockholder's proxy statement as a nominee of such stockholder and to serving as a director of the Company if elected;

(C) a reasonably detailed description of any direct or indirect compensatory, payment, indemnification or other financial agreement, arrangement or understanding that such person has, or has had within the past three years, with any person or entity other than the Company (including the amount of any payment or payments received or receivable thereunder), in each case in connection with candidacy or service as a director of the Company (a "**Third-Party Compensation Arrangement**"); and

(D) a description of any other material relationships between such person and such person's respective affiliates and associates, or others acting in concert with them, on the one hand, and such stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination is made, and their respective affiliates and associates, or others acting in concert with them, on the other hand;

(2) as to any other business that the stockholder proposes to bring before the annual meeting:

(A) a brief description of the business desired to be brought before the annual meeting;

(B) the text of the proposal or business (including the text of any resolutions proposed for consideration and, if applicable, the text of any proposed amendment to these bylaws or the Company's certificate of incorporation);

(C) the reasons for conducting such business at the annual meeting;

(D) any material interest in such business of such stockholder giving the notice and the beneficial owner, if any, on whose behalf the proposal is made, and their respective affiliates and associates, or others acting in concert with them; and

(E) a description of all agreements, arrangements and understandings between such stockholder and the beneficial owner, if any, on whose behalf the proposal is made, and their respective affiliates or associates or others acting in concert with them, and any other person or persons (including their names) in connection with the proposal of such business by such stockholder; and

(3) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made:

(A) the name and address of such stockholder (as they appear on the Company's books), of such beneficial owner and of their respective affiliates or associates or others acting in concert with them;

(B) for each class or series, the number of shares of stock of the Company that are, directly or indirectly, held of record or are beneficially owned by such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them;

(C) a description of any agreement, arrangement or understanding between such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, and any other person or persons (including, in each case, their names) in connection with the proposal of such nomination or other business;

(D) a description of any agreement, arrangement or understanding (including, regardless of the form of settlement, any derivative, long or short positions, profit interests, forwards, futures, swaps, options, warrants, convertible securities, stock appreciation or similar rights, hedging transactions and borrowed or loaned shares) that has been entered into by or on behalf of such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, with respect to the Company's securities (any of the foregoing, a "**Derivative Instrument**"), or any other agreement, arrangement or understanding that has been made the effect or intent of which is to create or mitigate loss to, manage risk or benefit of share price changes for or increase or decrease the voting power of such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, with respect to the Company's securities;

(E) any rights to dividends on the Company's securities owned beneficially by such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, that are separated or separable from the underlying security;

(F) any proportionate interest in the Company's securities or Derivative Instruments held, directly or indirectly, by a general or limited partnership in which such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, is a general partner or, directly or indirectly, beneficially owns an interest in a general partner of such general or limited partnership;

(G) any performance-related fees (other than an asset-based fee) that such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, is entitled to based on any increase or decrease in the value of the Company's securities or Derivative Instruments, including, without limitation, any such interests held by members of the immediate family of such persons sharing the same household;

(H) any significant equity interests or any Derivative Instruments in any principal competitor of the Company that are held by such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them;

(I) any direct or indirect interest of such stockholder, such beneficial owner or their respective affiliates or associates or others acting in concert with them, in any contract with the Company, any affiliate of the Company or any principal competitor of the Company (in each case, including any employment agreement, collective bargaining agreement or consulting agreement);

(J) a representation and undertaking that the stockholder is a holder of record of stock of the Company as of the date of submission of the stockholder's notice and intends to appear in person or by proxy at the meeting to bring such nomination or other business before the meeting;

(K) a representation and undertaking that such stockholder or any such beneficial owner intends, or is part of a group that intends, to (x) deliver a proxy statement or form of proxy to holders of at least the percentage of the voting power of the Company's then-outstanding stock required to approve or adopt the proposal or to elect each such nominee; or (y) otherwise solicit proxies from stockholders in support of such proposal or nomination;

(L) any other information relating to such stockholder, such beneficial owner, or their respective affiliates or associates or others acting in concert with them, or director nominee or proposed business that, in each case, would be required to be disclosed in a proxy statement or other filing required to be made in connection with the solicitation of proxies in support of such nominee (in a contested election of directors) or proposal pursuant to Section 14 of the 1934 Act; and

(M) such other information relating to any proposed item of business as the Company may reasonably require to determine whether such proposed item of business is a proper matter for stockholder action.

(iv) In addition to the requirements of this Section 2.4, to be timely, a stockholder's notice (and any additional information submitted to the Company in connection therewith) must further be updated and supplemented (1) if necessary, so that the information provided or required to be provided in such notice is true and correct as of the record date(s) for determining the stockholders entitled to notice of, and to vote at, the meeting and as of the date that is 10 business days prior to the meeting or any adjournment, rescheduling or postponement thereof and (2) to provide any additional information that the Company may reasonably request. Such update and supplement or additional information, if applicable, must be received by the secretary at the principal executive offices of the Company, in the case of a request for additional information, promptly following a request therefor, which response must be delivered not later than such reasonable time as is specified in any such request from the Company or, in the case of any other update or supplement of any information, not later than five business days after the record date(s) for the meeting (in the case of any update and supplement required to be made as of the record date(s)), and not later than eight business days prior to the date for the meeting or any adjournment, rescheduling or postponement thereof (in the case of the update and supplement required to be made as of 10 business days prior to the meeting or any adjournment, rescheduling or postponement thereof). The failure to timely provide such update, supplement or additional information shall result in the nomination or proposal no longer being eligible for consideration at the meeting.

(b) *Special Meetings of Stockholders.* Except to the extent required by the DGCL, and subject to Section 2.3(a), special meetings of stockholders may be called only in accordance with the Company's certificate of incorporation and these bylaws. Only such business will be conducted at a special meeting of stockholders as has been brought before the special meeting pursuant to the Company's notice of meeting. If the election of directors is included as business to be brought before a special meeting in the Company's notice of meeting, then nominations of persons for election to the Board of Directors at such special meeting may be made by any stockholder who (i) is a stockholder of record at the time of giving of the notice contemplated by this Section 2.4(b); (ii) is a stockholder of record on the record date for the determination of stockholders entitled to notice of the special meeting; (iii) is a stockholder of record on the record date for the determination of stockholders entitled to vote at the special meeting; (iv) is a stockholder of record at the time of the special meeting; and (v) complies with the procedures set forth in this Section 2.4(b). For nominations to be properly brought by a stockholder before a special meeting pursuant to this Section 2.4(b), the stockholder's notice must be received by the secretary at the principal executive offices of the Company no earlier than 8:00 a.m., local time, on the 120th day prior to the day of the special meeting and no later than 5:00 p.m., local time, on the 10th day following the day on which public announcement of the date of the special meeting was first made. In no event will any adjournment, rescheduling or postponement of a special meeting or the announcement thereof commence a new time period (or extend any time period) for the giving of a stockholder's notice. A stockholder's notice to the Secretary must comply with the applicable notice requirements of Section 2.4(a)(iii).

(c) *Other Requirements.*

(i) To be eligible to be a nominee by any stockholder for election as a director of the Company, the proposed nominee must provide to the secretary, in accordance with the applicable time periods prescribed for delivery of notice under Section 2.4(a)(ii) or Section 2.4(b):

(1) a signed and completed written questionnaire (in the form provided by the secretary at the written request of the nominating stockholder, which form will be provided by the secretary within 10 days of receiving such request) containing information regarding such nominee's background and qualifications and such other information as may reasonably be required by the Company to determine the eligibility of such nominee to serve as a director of the Company or to serve as an independent director of the Company;

(2) a written representation and undertaking that, unless previously disclosed to the Company, such nominee is not, and will not become, a party to any voting agreement, arrangement, commitment, assurance or understanding with any person or entity as to how such nominee, if elected as a director, will vote on any issue;

(3) a written representation and undertaking that, unless previously disclosed to the Company, such nominee is not, and will not become, a party to any Third-Party Compensation Arrangement;

(4) a written representation and undertaking that, if elected as a director, such nominee would be in compliance, and will continue to comply, with the Company's corporate governance guidelines as disclosed on the Company's website, as amended from time to time; and

(5) a written representation and undertaking that such nominee, if elected, intends to serve a full term on the Board of Directors.

(ii) At the request of the Board of Directors, any person nominated by the Board of Directors for election as a director must furnish to the secretary the information that is required to be set forth in a stockholder's notice of nomination that pertains to such nominee.

(iii) No person will be eligible to be nominated by a stockholder for election as a director of the Company unless nominated in accordance with the procedures set forth in this Section 2.4. No business proposed by a stockholder will be conducted at a stockholder meeting except in accordance with this Section 2.4.

(iv) The chairperson of the applicable meeting of stockholders will, if the facts warrant, determine and declare to the meeting that a nomination was not made in accordance with the procedures prescribed by these bylaws or that business was not properly brought before the meeting. If the chairperson of the meeting should so determine, then the chairperson of the meeting will so declare to the meeting and the defective nomination will be disregarded or such business will not be transacted, as the case may be.

(v) Notwithstanding anything to the contrary in this Section 2.4, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear in person at the meeting to present a nomination or other proposed business, such nomination will be disregarded or such proposed business will not be transacted, as the case may be, notwithstanding that proxies in respect of such nomination or business may have been received by the Company and counted for purposes of determining a quorum. For purposes of this Section 2.4, to be considered a qualified representative of the stockholder, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting, and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the meeting.

(vi) Without limiting this Section 2.4, a stockholder must also comply with all applicable requirements of the 1934 Act with respect to the matters set forth in this Section 2.4, it being understood that (1) any references in these bylaws to the 1934 Act are not intended to, and will not, limit any requirements applicable to nominations or proposals as to any other business to be considered pursuant to this Section 2.4; and (2) compliance with clause (4) of Section 2.4(a)(i) and with Section 2.4(b) are the exclusive means for a stockholder to make nominations or submit other business (other than as provided in Section 2.4(c)(vii)).

(vii) Notwithstanding anything to the contrary in this Section 2.4, the notice requirements set forth in these bylaws with respect to the proposal of any business pursuant to this Section 2.4 will be deemed to be satisfied by a stockholder if (1) such stockholder has submitted a proposal to the Company in compliance with Rule 14a-8 under the 1934 Act; and (2) such stockholder's proposal has been included in a proxy statement that has been prepared by the Company to solicit proxies for the meeting of stockholders. Subject to Rule 14a-8 and other applicable rules and regulations under the 1934 Act, nothing in these bylaws will be construed to permit any stockholder, or give any stockholder the right, to include or have disseminated or described in the Company's proxy statement any nomination of a director or any other business proposal.

2.5 NOTICE OF STOCKHOLDERS' MEETINGS

Whenever stockholders are required or permitted to take any action at a meeting, a notice of the meeting shall be given which shall state the place, if any, date and hour of the meeting, the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, the record date for determining the stockholders entitled to vote at the meeting, if such date is different from the record date for determining stockholders entitled to notice of the meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called. Except as otherwise provided in the DGCL, the certificate of incorporation or these bylaws, the notice of any meeting of stockholders shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting.

2.6 QUORUM

The holders of a majority of the voting power of the capital stock of the Company issued and outstanding and entitled to vote, present in person or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders. Where a separate vote by a class or series or classes or series is required, a majority of the voting power of the outstanding shares of such class or series or classes or series, present in person or represented by proxy, shall constitute a quorum entitled to take action with respect to that vote on that matter, except as otherwise provided by law, the certificate of incorporation or these bylaws.

If, however, such quorum is not present or represented at any meeting of the stockholders, then either (a) the chairperson of the meeting, or (b) the stockholders entitled to vote at the meeting, present in person or represented by proxy, shall have power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present or represented. At such adjourned meeting at which a quorum is present or represented, any business may be transacted that might have been transacted at the original meeting.

2.7 ADJOURNED MEETING; NOTICE

When a meeting is adjourned to another time or place, unless these bylaws otherwise require, notice need not be given of the adjourned meeting if the time, place, if any, thereof, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the Company may transact any business which might have been transacted at the original meeting. If the adjournment is for more than 30 days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If after the adjournment a new record date for stockholders entitled to vote is fixed for the adjourned meeting, the Board of Directors shall fix a new record date for notice of such adjourned meeting in accordance with Section 213(a) of the DGCL and Section 2.11 of these bylaws, and shall give notice of the adjourned meeting to each stockholder of record entitled to vote at such adjourned meeting as of the record date fixed for notice of such adjourned meeting.

2.8 CONDUCT OF BUSINESS

The chairperson of any meeting of stockholders shall determine the order of business and the procedure at the meeting, including such regulation of the manner of voting and the conduct of business and discussion as seem to the chairperson in order. The chairperson of any meeting of stockholders shall be designated by the Board of Directors; in the absence of such designation, the chairperson of the Board of Directors, if any, or the chief executive officer (in the absence of the chairperson of the Board of Directors) or the president (in the absence of the chairperson of the Board of Directors and the chief executive officer), or in their absence any other executive officer of the Company, shall serve as chairperson of the stockholder meeting. The chairperson of any meeting of stockholders shall have the power to adjourn the meeting to another place, if any, date or time, whether or not a quorum is present.

2.9 VOTING

The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of Section 2.11 of these bylaws, subject to Section 217 (relating to voting rights of fiduciaries, pledgors and joint owners of stock) and Section 218 (relating to voting trusts and other voting agreements) of the DGCL.

Except as may be otherwise provided in the certificate of incorporation or these bylaws, each stockholder shall be entitled to one vote for each share of capital stock held by such stockholder.

Except as otherwise provided by law, the certificate of incorporation, these bylaws or the rules of the stock exchange on which the Company's securities are listed, in all matters other than the election of directors, the affirmative vote of a majority of the voting power of the shares cast, affirmatively or negatively, shall be the act of the stockholders and broker non-votes and abstentions will be considered for purposes of establishing a quorum, but will not be considered as votes cast for or against a proposal. Except as otherwise required by law, the certificate of incorporation or these bylaws, directors shall be elected by a plurality of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. Where a separate vote by a class or series or classes or series is required, in all matters other than the election of directors, the affirmative vote of the majority of the voting power of the shares of such class or series or classes or series cast, affirmatively or negatively, at the meeting and entitled to vote on the subject matter shall be the act of such class or series or classes or series (and broker non-votes and abstentions will not be considered as votes cast for or against a proposal), except as otherwise provided by law, the certificate of incorporation, these bylaws or the rules of the stock exchange on which the securities of the Company are listed.

2.10 STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING

Subject to the rights of holders of preferred stock of the Company, any action required or permitted to be taken by the stockholders of the Company must be effected at a duly called annual or special meeting of stockholders of the Company and may not be effected by any consent in writing by such stockholders.

2.11 RECORD DATES

In order that the Company may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors and which record date shall not be more than 60 nor less than 10 days before the date of such meeting. If the Board of Directors so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board of Directors determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination.

If no record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of and to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided, however*, that the Board of Directors may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance with the provisions of Section 213 of the DGCL and this Section 2.11 at the adjourned meeting.

In order that the Company may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than 60 days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

2.12 PROXIES

Each stockholder entitled to vote at a meeting of stockholders, or such stockholder's authorized officer, director, employee or agent, may authorize another person or persons to act for such stockholder by proxy authorized by a document or by a transmission permitted by law filed in accordance with the procedure established for the meeting, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212 of the DGCL.

2.13 LIST OF STOCKHOLDERS ENTITLED TO VOTE

The Company shall prepare, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting; *provided, however*, if the record date for determining the stockholders entitled to vote is less than 10 days before the meeting date, the list shall reflect the stockholders entitled to vote as of the tenth day before the meeting date, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. The Company shall not be required to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder for any purpose germane to the meeting for a period of at least 10 days prior to the meeting: (a) on a reasonably accessible electronic network, *provided* that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the Company's principal place of business. In the event that the Company determines to make the list available on an electronic network, the Company may take reasonable steps to ensure that such information is available only to stockholders of the Company. If the meeting is to be held at a place, then a list of stockholders entitled to vote at the meeting shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be examined by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then such list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting.

2.14 INSPECTORS OF ELECTION

Before any meeting of stockholders, the Company shall appoint an inspector or inspectors of election to act at the meeting or its adjournment. The Company may designate one or more persons as alternate inspectors to replace any inspector who fails to act.

Such inspectors shall:

- (a) ascertain the number of shares outstanding and the voting power of each;
- (b) determine the shares represented at the meeting and the validity of proxies and ballots;
- (c) count all votes and ballots;
- (d) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspectors; and
- (e) certify their determination of the number of shares represented at the meeting, and their count of all votes and ballots.

The inspectors of election shall perform their duties impartially, in good faith, to the best of their ability and as expeditiously as is practical. If there are multiple inspectors of election, the decision, act or certificate of a majority is effective in all respects as the decision, act or certificate of all. Any report or certificate made by the inspectors of election is *prima facie* evidence of the facts stated therein.

ARTICLE III - DIRECTORS

3.1 POWERS

The business and affairs of the Company shall be managed by or under the direction of the Board of Directors, except as may be otherwise provided in the DGCL or the certificate of incorporation.

3.2 NUMBER OF DIRECTORS

The Board of Directors shall consist of one or more members, each of whom shall be a natural person. Unless the certificate of incorporation fixes the number of directors, the number of directors shall be determined from time to time by resolution of a majority of the Whole Board. No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires.

3.3 ELECTION, QUALIFICATION AND TERM OF OFFICE OF DIRECTORS

Except as provided in Section 3.4 of these bylaws, each director, including a director elected to fill a vacancy, shall hold office until the expiration of the term for which elected and until such director's successor is elected and qualified or until such director's earlier death, resignation or removal. Directors need not be stockholders unless so required by the certificate of incorporation or these bylaws. The certificate of incorporation or these bylaws may prescribe other qualifications for directors.

If so provided in the certificate of incorporation, the directors of the Company shall be divided into three classes.

3.4 RESIGNATION AND VACANCIES

Any director may resign at any time upon notice given in writing or by electronic transmission to the Company. A resignation is effective when the resignation is delivered unless the resignation specifies a later effective date or an effective date determined upon the happening of an event or events. A resignation which is conditioned upon the director failing to receive a specified vote for reelection as a director may provide that it is irrevocable. Unless otherwise provided in the certificate of incorporation or these bylaws, when one or more directors resign from the Board of Directors, effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective.

Unless otherwise provided in the certificate of incorporation or these bylaws or permitted in the specific case by resolution of the Board of Directors, and subject to the rights of holders of Preferred Stock, vacancies and newly created directorships resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class may be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director, and not by stockholders. If the directors are divided into classes, a person so chosen to fill a vacancy or newly created directorship shall hold office until the next election of the class for which such director shall have been chosen and until his or her successor shall have been duly elected and qualified.

3.5 PLACE OF MEETINGS; MEETINGS BY TELEPHONE

The Board of Directors may hold meetings, both regular and special, either within or outside the State of Delaware.

Unless otherwise restricted by the certificate of incorporation or these bylaws, members of the Board of Directors may participate in a meeting of the Board of Directors by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at the meeting.

3.6 REGULAR MEETINGS

Regular meetings of the Board of Directors may be held without notice at such time and at such place as shall from time to time be determined by the Board of Directors.

3.7 SPECIAL MEETINGS; NOTICE

Special meetings of the Board of Directors for any purpose or purposes may be called at any time by the chairperson of the Board of Directors, the chief executive officer, the president, the secretary or a majority of the Whole Board.

Notice of the time and place of special meetings shall be:

- (a) delivered personally by hand, by courier or by telephone;
- (b) sent by United States first-class mail, postage prepaid;
- (c) sent by facsimile;
- (d) sent by electronic mail; or
- (e) otherwise given by electronic transmission (as defined in Section 232 of the DGCL),

directed to each director at that director's address, telephone number, facsimile number, electronic mail address or other contact for notice by electronic transmission, as the case may be, as shown on the Company's records.

If the notice is (i) delivered personally by hand, by courier or by telephone, (ii) sent by facsimile, (iii) sent by electronic mail or (iv) otherwise given by electronic transmission, it shall be delivered, sent or otherwise directed to each director, as applicable, at least 24 hours before the time of the holding of the meeting. If the notice is sent by United States mail, it shall be deposited in the United States mail at least four days before the time of the holding of the meeting. Any oral notice may be communicated to the director. The notice need not specify the place of the meeting (if the meeting is to be held at the Company's principal executive office) nor the purpose of the meeting, unless required by statute.

3.8 QUORUM; VOTING

At all meetings of the Board of Directors, a majority of the Whole Board shall constitute a quorum for the transaction of business. If a quorum is not present at any meeting of the Board of Directors, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present.

The affirmative vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the Board of Directors, except as may be otherwise specifically provided by statute, the certificate of incorporation or these bylaws.

If the certificate of incorporation provides that one or more directors shall have more or less than one vote per director on any matter, except as may otherwise be expressly provided herein or therein and denoted with the phrase “notwithstanding the final paragraph of Section 3.8 of the bylaws” or language to similar effect, every reference in these bylaws to a majority or other proportion of the directors shall refer to a majority or other proportion of the votes of the directors.

3.9 BOARD ACTION BY WRITTEN CONSENT WITHOUT A MEETING

Unless otherwise restricted by the certificate of incorporation or these bylaws, any action required or permitted to be taken at any meeting of the Board of Directors, or of any committee thereof, may be taken without a meeting if all members of the Board of Directors or committee, as the case may be, consent thereto in writing or by electronic transmission. Any person (whether or not then a director) may provide, whether through instruction to an agent or otherwise, that a consent to action will be effective at a future time (including a time determined upon the happening of an event), no later than 60 days after such instruction is given or such provision is made and such consent shall be deemed to have been given for purposes of this Section 3.9 at such effective time so long as such person is then a director and did not revoke the consent prior to such time. Any such consent shall be revocable prior to its becoming effective.

3.10 FEES AND COMPENSATION OF DIRECTORS

Unless otherwise restricted by the certificate of incorporation or these bylaws, the Board of Directors shall have the authority to fix the compensation of directors.

3.11 REMOVAL OF DIRECTORS

Any director or the entire Board of Directors may be removed from office by stockholders of the Company in the manner specified in the certificate of incorporation and applicable law. No reduction of the authorized number of directors shall have the effect of removing any director prior to the expiration of such director's term of office.

ARTICLE IV - COMMITTEES

4.1 COMMITTEES OF DIRECTORS

The Board of Directors may, by resolution passed by a majority of the Whole Board, designate one or more committees, each committee to consist of one or more of the directors of the Company. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board of Directors or in these bylaws, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the Company, and may authorize the seal of the Company to be affixed to all papers that may require it; but no such committee shall have the power or authority to (a) approve or adopt, or recommend to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval, or (b) adopt, amend or repeal any bylaw of the Company.

4.2 COMMITTEE MINUTES

Each committee and subcommittee shall keep regular minutes of its meetings.

4.3 MEETINGS AND ACTION OF COMMITTEES

Meetings and actions of committees and subcommittees shall be governed by, and held and taken in accordance with, the provisions of:

- (a) Section 3.5 (place of meetings and meetings by telephone);
- (b) Section 3.6 (regular meetings);
- (c) Section 3.7 (special meetings and notice);
- (d) Section 3.8 (quorum; voting);
- (e) Section 3.9 (action without a meeting); and
- (f) Section 7.4 (waiver of notice)

with such changes in the context of those bylaws as are necessary to substitute the committee or subcommittee and its members for the Board of Directors and its members. *However*, (i) the time and place of regular meetings of committees or subcommittees may be determined either by resolution of the Board of Directors or by resolution of the committee or subcommittee; (ii) special meetings of committees or subcommittees may also be called by resolution of the Board of Directors or the committee or subcommittee; and (iii) notice of special meetings of committees and subcommittees shall also be given to all alternate members who shall have the right to attend all meetings of the committee or subcommittee. The Board of Directors may adopt rules for the government of any committee not inconsistent with the provisions of these bylaws.

Any provision in the certificate of incorporation providing that one or more directors shall have more or less than one vote per director on any matter shall apply to voting in any committee or subcommittee, unless otherwise provided in the certificate of incorporation or these bylaws.

4.4 SUBCOMMITTEES

Unless otherwise provided in the certificate of incorporation, these bylaws or the resolutions of the Board of Directors designating the committee, a committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and delegate to a subcommittee any or all of the powers and authority of the committee.

ARTICLE V - OFFICERS

5.1 OFFICERS

The officers of the Company shall be a president and a secretary. The Company may also have, at the discretion of the Board of Directors, a chairperson of the Board of Directors, a vice chairperson of the Board of Directors, a chief executive officer, a chief financial officer or treasurer, one or more vice presidents, one or more assistant vice presidents, one or more assistant treasurers, one or more assistant secretaries and any such other officers as may be appointed in accordance with the provisions of these bylaws. Any number of offices may be held by the same person.

5.2 APPOINTMENT OF OFFICERS

The Board of Directors shall appoint the officers of the Company, except such officers as may be appointed in accordance with the provisions of Section 5.3 of these bylaws, subject to the rights, if any, of an officer under any contract of employment.

5.3 SUBORDINATE OFFICERS

The Board of Directors may appoint, or empower the chief executive officer or, in the absence of a chief executive officer, the president, to appoint, such other officers as the business of the Company may require. Each of such officers shall hold office for such period, have such authority, and perform such duties as are provided in these bylaws or as the Board of Directors may from time to time determine.

5.4 REMOVAL AND RESIGNATION OF OFFICERS

Subject to the rights, if any, of an officer under any contract of employment, any officer may be removed, either with or without cause, by the Board of Directors or, for the avoidance of doubt, any duly authorized committee or subcommittee thereof or by any officer who has been conferred such power of removal.

Any officer may resign at any time by giving notice, in writing or by electronic transmission, to the Company. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice. Unless otherwise specified in the notice of resignation, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the Company under any contract to which the officer is a party.

5.5 VACANCIES IN OFFICES

Any vacancy occurring in any office of the Company shall be filled by the Board of Directors or as provided in Section 5.3.

5.6 REPRESENTATION OF SECURITIES OF OTHER ENTITIES

The chairperson of the Board of Directors, the chief executive officer, the president, any vice president, the treasurer, the secretary or assistant secretary of this Company or any other person authorized by the Board of Directors or the chief executive officer, the president or a vice president, is authorized to vote, represent and exercise on behalf of this Company all rights incident to any and all shares or other securities of any other entity or entities, and all rights incident to any management authority conferred on the Company in accordance with the governing documents of any entity or entities, standing in the name of this Company, including the right to act by written consent. The authority granted herein may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

5.7 AUTHORITY AND DUTIES OF OFFICERS

All officers of the Company shall respectively have such authority and perform such duties in the management of the business of the Company as may be designated from time to time by the Board of Directors and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the Board of Directors.

ARTICLE VI - STOCK

6.1 STOCK CERTIFICATES; PARTLY PAID SHARES

The shares of the Company shall be represented by certificates, provided that the Board of Directors may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the Company. Unless otherwise provided by resolution of the Board of Directors, every holder of stock represented by certificates shall be entitled to have a certificate signed by, or in the name of, the Company by any two officers of the Company representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Company with the same effect as if such person were such officer, transfer agent or registrar at the date of issue. The Company shall not have power to issue a certificate in bearer form.

The Company may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly-paid shares, or upon the books and records of the Company in the case of uncertificated partly-paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully-paid shares, the Company shall declare a dividend upon partly-paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

6.2 SPECIAL DESIGNATION ON CERTIFICATES

If the Company is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the Company shall issue to represent such class or series of stock; *provided, however*, that, except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements, there may be set forth on the face or back of the certificate that the Company shall issue to represent such class or series of stock, a statement that the Company will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Within a reasonable time after the issuance or transfer of uncertificated stock, the registered owner thereof shall be given a notice, in writing or by electronic transmission, containing the information required to be set forth or stated on certificates pursuant to this Section 6.2 or Sections 156, 202(a), 218(a) or 364 of the DGCL or with respect to this Section 6.2 a statement that the Company will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Except as otherwise expressly provided by law, the rights and obligations of the holders of uncertificated stock and the rights and obligations of the holders of certificates representing stock of the same class and series shall be identical.

6.3 LOST CERTIFICATES

Except as provided in this Section 6.3, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the Company and cancelled at the same time. The Company may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Company may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to give the Company a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

6.4 DIVIDENDS

The Board of Directors, subject to any restrictions contained in the certificate of incorporation or applicable law, may declare and pay dividends upon the shares of the Company's capital stock. Dividends may be paid in cash, in property, or in shares of the Company's capital stock, subject to the provisions of the certificate of incorporation. The Board of Directors may set apart out of any of the funds of the Company available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve.

6.5 TRANSFER OF STOCK

Transfers of record of shares of stock of the Company shall be made only upon its books by the holders thereof, in person or by an attorney duly authorized, and, if such stock is certificated, upon the surrender of a certificate or certificates for a like number of shares, properly endorsed or accompanied by proper evidence of succession, assignation or authority to transfer.

6.6 STOCK TRANSFER AGREEMENTS

The Company shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the Company to restrict the transfer of shares of stock of the Company of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

6.7 REGISTERED STOCKHOLDERS

The Company:

(a) shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and notices and to vote as such owner; and

(b) shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

ARTICLE VII - MANNER OF GIVING NOTICE AND WAIVER

7.1 NOTICE OF STOCKHOLDERS' MEETINGS

Notice of any meeting of stockholders shall be given in the manner set forth in the DGCL.

7.2 NOTICE TO STOCKHOLDERS SHARING AN ADDRESS

Except as otherwise prohibited under the DGCL, without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the Company under the provisions of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a single written notice to stockholders who share an address if consented to by the stockholders at that address to whom such notice is given. Any such consent shall be revocable by the stockholder by written notice to the Company. Any stockholder who fails to object in writing to the Company, within 60 days of having been given written notice by the Company of its intention to send the single notice, shall be deemed to have consented to receiving such single written notice. This Section 7.2 shall not apply to Sections 164, 296, 311, 312 or 324 of the DGCL.

7.3 NOTICE TO PERSON WITH WHOM COMMUNICATION IS UNLAWFUL

Whenever notice is required to be given, under the DGCL, the certificate of incorporation or these bylaws, to any person with whom communication is unlawful, the giving of such notice to such person shall not be required and there shall be no duty to apply to any governmental authority or agency for a license or permit to give such notice to such person. Any action or meeting which shall be taken or held without notice to any such person with whom communication is unlawful shall have the same force and effect as if such notice had been duly given. In the event that the action taken by the Company is such as to require the filing of a certificate under the DGCL, the certificate shall state, if such is the fact and if notice is required, that notice was given to all persons entitled to receive notice except such persons with whom communication is unlawful.

7.4 WAIVER OF NOTICE

Whenever notice is required to be given under any provision of the DGCL, the certificate of incorporation or these bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time of the event for which notice is to be given, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the certificate of incorporation or these bylaws.

ARTICLE VIII - INDEMNIFICATION

8.1 INDEMNIFICATION OF DIRECTORS AND OFFICERS IN THIRD PARTY PROCEEDINGS

Subject to the other provisions of this Article VIII, the Company shall indemnify, to the fullest extent permitted by the DGCL, as now or hereinafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (a "**Proceeding**") (other than an action by or in the right of the Company) by reason of the fact that such person is or was a director or officer of the Company, or is or was a director or officer of the Company serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such Proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Company, and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person's conduct was unlawful. The termination of any Proceeding by judgment, order, settlement, conviction, or upon a plea of *nolo contendere* or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which such person reasonably believed to be in or not opposed to the best interests of the Company, and, with respect to any criminal action or proceeding, had reasonable cause to believe that such person's conduct was unlawful.

8.2 INDEMNIFICATION OF DIRECTORS AND OFFICERS IN ACTIONS BY OR IN THE RIGHT OF THE COMPANY

Subject to the other provisions of this Article VIII, the Company shall indemnify, to the fullest extent permitted by the DGCL, as now or hereinafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed Proceeding by or in the right of the Company to procure a judgment in its favor against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such Proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Company; except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the Company unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

8.3 SUCCESSFUL DEFENSE

To the extent that a present or former director or officer (for purposes of this Section 8.3 only, as such term is defined in Section 145(c)(1) of the DGCL) of the Company has been successful on the merits or otherwise in defense of any action, suit or proceeding described in Section 8.1 or Section 8.2, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith. The Company may indemnify any other person who is not a present or former director or officer of the Company against expenses (including attorneys' fees) actually and reasonably incurred by such person to the extent he or she has been successful on the merits or otherwise in defense of any suit or proceeding described in Section 8.1 or Section 8.2, or in defense of any claim, issue or matter therein.

8.4 INDEMNIFICATION OF OTHERS

Subject to the other provisions of this Article VIII, the Company shall have power to indemnify its employees and agents, or any other persons, to the extent not prohibited by the DGCL or other applicable law. The Board of Directors shall have the power to delegate to any person or persons identified in subsections (1) through (4) of Section 145(d) of the DGCL the determination of whether employees or agents shall be indemnified.

8.5 ADVANCED PAYMENT OF EXPENSES

Expenses (including attorneys' fees) actually and reasonably incurred by an officer or director of the Company in defending any Proceeding shall be paid by the Company in advance of the final disposition of such Proceeding upon receipt of a written request therefor (together with documentation reasonably evidencing such expenses) and an undertaking by or on behalf of the person to repay such amounts if it shall ultimately be determined that the person is not entitled to be indemnified under this Article VIII or the DGCL. Such expenses (including attorneys' fees) actually and reasonably incurred by former directors and officers or other employees and agents of the Company or by persons serving at the request of the Company as directors, officers, employees or agents of another corporation, partnership, joint venture, trust or other enterprise may be so paid upon such terms and conditions, if any, as the Company deems appropriate. The right to advancement of expenses shall not apply to any Proceeding (or any part of any Proceeding) for which indemnity is excluded pursuant to these bylaws, but shall apply to any Proceeding (or any part of any Proceeding) referenced in Section 8.6(b) or 8.6(c) prior to a determination that the person is not entitled to be indemnified by the Company.

Notwithstanding the foregoing, unless otherwise determined pursuant to Section 8.8, no advance shall be made by the Company to an officer of the Company (except by reason of the fact that such officer is or was a director of the Company, in which event this paragraph shall not apply) in any Proceeding if a determination is reasonably and promptly made (a) by a vote of the directors who are not parties to such Proceeding, even though less than a quorum, or (b) by a committee of such directors designated by the vote of the majority of such directors, even though less than a quorum, or (c) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, that facts known to the decision-making party at the time such determination is made demonstrate clearly and convincingly that such person acted in bad faith or in a manner that such person did not believe to be in or not opposed to the best interests of the Company.

8.6 LIMITATION ON INDEMNIFICATION

Subject to the requirements in Section 8.3 and the DGCL, the Company shall not be obligated to indemnify any person pursuant to this Article VIII in connection with any Proceeding (or any part of any Proceeding):

(a) for which payment has actually been made to or on behalf of such person under any statute, insurance policy, indemnity provision, vote or otherwise, except with respect to any excess beyond the amount paid;

(b) for an accounting or disgorgement of profits pursuant to Section 16(b) of the 1934 Act, or similar provisions of federal, state or local statutory law or common law, if such person is held liable therefor (including pursuant to any settlement arrangements);

(c) for any reimbursement of the Company by such person of any bonus or other incentive-based or equity-based compensation or of any profits realized by such person from the sale of securities of the Company, as required in each case under the 1934 Act (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "**Sarbanes-Oxley Act**"), or the payment to the Company of profits arising from the purchase and sale by such person of securities in violation of Section 306 of the Sarbanes-Oxley Act), if such person is held liable therefor (including pursuant to any settlement arrangements);

(d) initiated by such person, including any Proceeding (or any part of any Proceeding) initiated by such person against the Company or its directors, officers, employees, agents or other indemnitees, unless (i) the Board of Directors authorized the Proceeding (or the relevant part of the Proceeding) prior to its initiation, (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law, (iii) otherwise required to be made under Section 8.7 or (iv) otherwise required by applicable law; or

(e) if prohibited by applicable law.

8.7 DETERMINATION; CLAIM

If a claim for indemnification or advancement of expenses under this Article VIII is not paid in full within 90 days after receipt by the Company of the written request therefor, the claimant shall be entitled to an adjudication by a court of competent jurisdiction of his or her entitlement to such indemnification or advancement of expenses. The Company shall indemnify such person against any and all expenses that are actually and reasonably incurred by such person in connection with any action for indemnification or advancement of expenses from the Company under this Article VIII, to the extent such person is successful in such action, and to the extent not prohibited by law. In any such suit, the Company shall, to the fullest extent not prohibited by law, have the burden of proving that the claimant is not entitled to the requested indemnification or advancement of expenses.

8.8 NON-EXCLUSIVITY OF RIGHTS

The indemnification and advancement of expenses provided by, or granted pursuant to, this Article VIII shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under the certificate of incorporation or any statute, bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office. The Company is specifically authorized to enter into individual contracts with any or all of its directors, officers, employees or agents respecting indemnification and advancement of expenses, to the fullest extent not prohibited by the DGCL or other applicable law.

8.9 INSURANCE

The Company may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Company, or is or was serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the Company would have the power to indemnify such person against such liability under the provisions of the DGCL.

8.10 SURVIVAL

The rights to indemnification and advancement of expenses conferred by this Article VIII shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

8.11 EFFECT OF REPEAL OR MODIFICATION

A right to indemnification or to advancement of expenses arising under a provision of the certificate of incorporation or a bylaw shall not be eliminated or impaired by an amendment to or repeal or elimination of the certificate of incorporation or these bylaws after the occurrence of the act or omission that is the subject of the civil, criminal, administrative or investigative action, suit or proceeding for which indemnification or advancement of expenses is sought, unless the provision in effect at the time of such act or omission explicitly authorizes such elimination or impairment after such action or omission has occurred.

8.12 CERTAIN DEFINITIONS

For purposes of this Article VIII, references to the "**Company**" shall include, in addition to the resulting company, any constituent company (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent company, or is or was serving at the request of such constituent company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this Article VIII with respect to the resulting or surviving company as such person would have with respect to such constituent company if its separate existence had continued. For purposes of this Article VIII, references to "**other enterprises**" shall include employee benefit plans; references to "**finances**" shall include any excise taxes assessed on a person with respect to an employee benefit plan; and references to "**servicing at the request of the Company**" shall include any service as a director, officer, employee or agent of the Company which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "**not opposed to the best interests of the Company**" as referred to in this Article VIII.

ARTICLE IX - GENERAL MATTERS

9.1 EXECUTION OF CORPORATE CONTRACTS AND INSTRUMENTS

Except as otherwise provided by law, the certificate of incorporation or these bylaws, the Board of Directors may authorize any officer or officers, or agent or agents, to enter into any contract or execute any document or instrument in the name of and on behalf of the Company; such authority may be general or confined to specific instances. Unless so authorized or ratified by the Board of Directors or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the Company by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

9.2 FISCAL YEAR

The fiscal year of the Company shall be fixed by resolution of the Board of Directors and may be changed by the Board of Directors.

9.3 SEAL

The Company may adopt a corporate seal, which shall be adopted and which may be altered by the Board of Directors. The Company may use the corporate seal by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

9.4 CONSTRUCTION; DEFINITIONS

Unless the context requires otherwise, the general provisions, rules of construction, and definitions in the DGCL shall govern the construction of these bylaws. Without limiting the generality of this provision, the singular number includes the plural, the plural number includes the singular, and the term “**person**” includes a company (including, but not limited to, a limited liability company), corporation, partnership, joint venture, trust or other enterprise, and a natural person. Any reference in these bylaws to a section of the DGCL shall be deemed to refer to such section as amended from time to time and any successor provisions thereto.

9.5 FORUM SELECTION

Unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of the Company, (b) any action asserting a claim of breach of a fiduciary duty owed by any director, stockholder, officer or other employee of the Company to the Company or the Company’s stockholders, (c) any action arising pursuant to any provision of the DGCL or the certificate of incorporation or these bylaws (as either may be amended from time to time) or (d) any action asserting a claim governed by the internal affairs doctrine, except for, as to each of (a) through (d) above, any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction.

Unless the Company consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended.

Any person or entity purchasing or otherwise acquiring any interest in any security of the Company shall be deemed to have notice of and consented to the provisions of this Section 9.5. For the avoidance of doubt, nothing contained in this Section 9.5 shall apply to any action brought to enforce a duty or liability created by the 1934 Act or any successor thereto.

ARTICLE X - AMENDMENTS

These bylaws may be adopted, amended or repealed by the stockholders entitled to vote; provided, however, that the affirmative vote of the holders of at least 66 2/3% of the total voting power of outstanding voting securities, voting together as a single class, shall be required for the stockholders of the Company to alter, amend or repeal, or adopt any bylaw inconsistent with, the following provisions of these bylaws: Article II, Sections 3.1, 3.2, 3.4 and 3.11 of Article III, Article VIII, Section 9.5 of Article IX or this Article X (including, without limitation, any such Article or Section as renumbered as a result of any amendment, alteration, change, repeal, or adoption of any other Bylaw). The Board of Directors shall also have the power to adopt, amend or repeal bylaws; provided, however, that a bylaw amendment adopted by stockholders which specifies the votes that shall be necessary for the election of directors shall not be further amended or repealed by the Board of Directors.

CERTIFICATIONS

I, Leen Kawas, certify that:

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

Date: November 12, 2020

/s/ Leen Kawas

Leen Kawas

President and Chief Executive Officer

(Principal Executive Officer)

CERTIFICATIONS

I, Glenna Milesen, certify that:

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

Date: November 12, 2020

/s/ Glenna Milesen

Glenna Milesen

Chief Financial Officer

(Principal Financial and Accounting Officer)

**ATHIRA PHARMA, INC.
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 of Athira Pharma, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leen Kawas, President and Chief Executive Officer (*Principal Executive Officer*) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my 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.

/s/ Leen Kawas

Leen Kawas

President and Chief Executive Officer

(Principal Executive Officer)

Date: November 12, 2020

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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

**ATHIRA PHARMA, INC.
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 of Athira Pharma, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Glenna Mileson, Chief Financial Officer (*Principal Financial and Accounting Officer*) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my 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.

/s/ Glenna Mileson

Glenna Mileson

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: November 12, 2020

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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