As confidentially submitted with the Securities and Exchange Commission on July 24, 2020. This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT

Under
The Securities Act of 1933

ATHIRA PHARMA, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**2836**	**45-3368487**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

4000 Mason Road, Suite 300
Seattle, WA 98195
(206) 221-8112
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Leen Kawas, Ph.D.
President and Chief Executive Officer
Athira Pharma, Inc.
4000 Mason Road, Suite 300
Seattle, WA 98195
(206) 221-8112
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Cooley LLP
1700 Seventh Avenue, Suite 1900
Seattle, WA 98101
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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to Be Registered	**Proposed Maximum Aggregate Offering Price(1)(2)**	**Amount of Registration Fee**
Common Stock, $0.0001 par value	$	**$**

(1) The proposed maximum aggregate offering price includes the offering price of additional shares that the underwriters have the option to purchase.

(2) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission acting pursuant to said Section 8(a) may determine.

Subject to Completion, Dated , 2020

Shares

Common Stock

This is the initial public offering of shares of common stock of Athira Pharma, Inc. We are offering shares of common stock.

Prior to this offering, there has been no public market for our common stock. It is currently estimated that the initial public offering price will be between $ and $ per share.

We intend to apply to list our common stock on the Nasdaq Global Market under the symbol "ATHA."

We are an "emerging growth company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements in this prospectus and may elect to do so in future filings.

See the section titled "Risk Factors" beginning on page 17 to read about factors you should consider before deciding to invest in shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds, before expenses, to Athira Pharma, Inc.	$	$

(1) See the section titled "Underwriting" for a description of the compensation payable to the underwriters.

To the extent that the underwriters sell more than shares of common stock, the underwriters have an option to purchase up to an additional shares from us at the initial public offering price, less the underwriting discounts and commissions.

The underwriters expect to deliver the shares against payment in New York, New York on , 2020.

Goldman Sachs & Co. LLC **Jefferies** **Stifel**

JMP Securities

Prospectus dated , 2020

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Through and including , 2020 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

You should rely only on the information contained in this prospectus and any free writing prospectus prepared by or on behalf of us or to which we have referred you. Neither we nor any of the underwriters have authorized anyone to provide you with information that is different. This prospectus is an offer to sell only the securities offered hereby and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the securities offered hereby. Our business, financial condition, results of operations and prospects may have changed since that date.

Neither we nor any of the underwriters have taken any action that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons who have come into possession of this prospectus in a jurisdiction outside the United States are required to inform themselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus. It may not contain all the information that may be important to you. You should read this entire prospectus carefully, including the sections of this prospectus titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our financial statements and related notes included elsewhere in this prospectus, before making an investment decision. In this prospectus, unless the context requires otherwise, all references to "we," "our," "us," "Athira," and the "Company" refer to Athira Pharma, Inc.

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 provide rapid 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 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. All of these characteristics are expected to 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 our Phase 1a and Phase 1b clinical trials, ATH-1017 for the treatment of Alzheimer's disease, or AD, was well tolerated with no serious adverse events. These clinical trials recruited 88 subjects, including 11 subjects with mild-to-moderate AD. Nonclinical studies and Phase 1 clinical trials with ATH-1017 demonstrated improvements in brain network activity indicating positive effects on brain function. In the AD subjects, multiple dosing of ATH-1017 significantly improved brain activity as measured by P300 latency, a functional measure that is highly correlated with cognition. By the end of 2020, we plan to initiate a pivotal Phase 2/3 clinical trial for ATH-1017, or LIFT-AD, for the treatment of mild-to-moderate AD with topline results expected by the end of 2022. By the end of 2020, we also plan to initiate 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.

The primary focus of our Phase 1a and Phase 1b clinical trials of ATH-1017 for the treatment of AD was to establish safety and drug exposure levels. ATH-1017 was well tolerated at all tested doses, produced predictable pharmacokinetics with dose-linear exposures, and did not accumulate over the course of treatment. Pharmacodynamic measures evaluating brain penetration, target engagement, and brain function with electroencephalogram, or EEG, methods produced a strong suite of data, justifying further investigation of ATH-1017 in future clinical trials. Individuals with AD typically experience a general slowing of EEG, including a reduction in higher frequency waves, such as gamma. Gamma power is typically associated with learning, memory, and cognitive function. Administration of ATH-1017 increased high frequency gamma power activity with a single dose in both young healthy volunteers and elderly healthy volunteers. Gamma power also improved in AD subjects. P300 latency, a functional measure of working memory processing speed that highly correlates with cognition, was also substantially improved. After a single dose of ATH-1017, all AD subjects tested had improved P300 latency, and by the end of an 8-day treatment cycle, average latency across the AD treatment group had returned to levels close to those observed in healthy elderly subjects. Taken together, these results suggest that ATH-1017 has the potential to substantially improve synaptic connectivity and brain function in AD subjects.

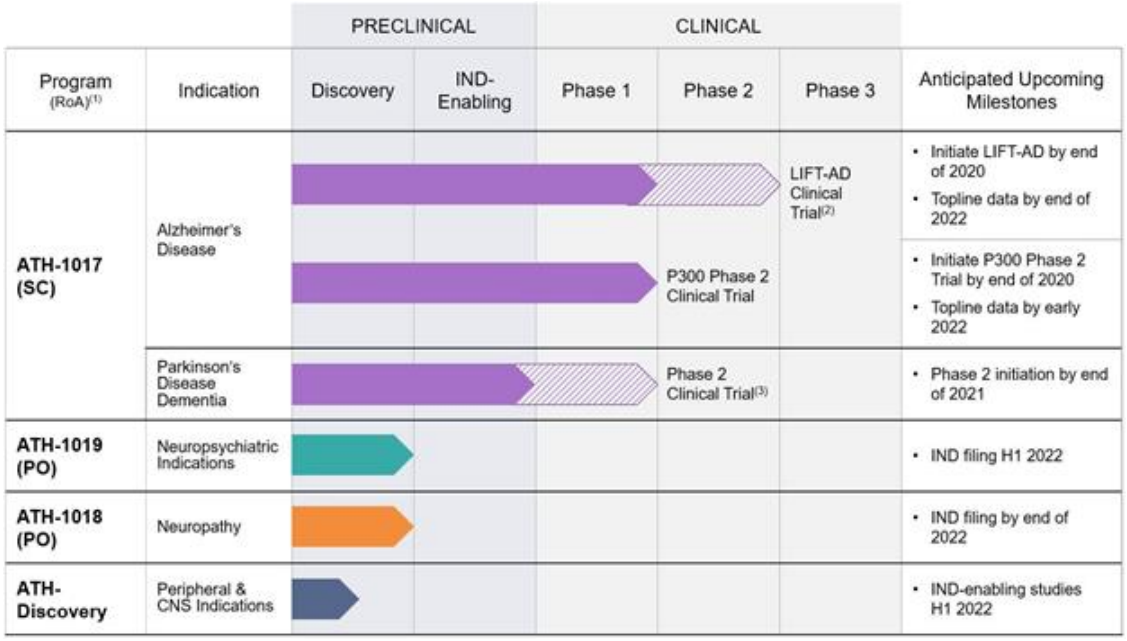
AD is a significant unmet medical need with as many as 35 million cases estimated worldwide and no treatments that can significantly reduce the burden on people impacted by the disease. Failures of approaches targeting specific hypotheses of underlying AD pathology highlight the need for novel strategies to address the disease. Regardless of the underlying pathology, it has been established that the loss of synaptic density and breakdown of the neuronal network leads to cognitive impairment in subjects with AD and other forms of dementia. We believe the activation of the hepatocyte growth factor/MET, or HGF/MET, growth factor in the brain will lead to increased synaptic density, network recovery, and information transmission in the brain, which could ultimately result in cognitive improvement and clinical benefit.

We are pioneering the use of small molecules to promote HGF/MET, a naturally occurring regenerative system, in neurological disorders. While discovered in the liver, HGF is a critical growth factor across multiple organs, including in the brain. HGF/MET has long been known as a promising therapeutic target for CNS disorders however, delivery of large proteins or gene therapy to the CNS to augment HGF/MET is challenging due to the invasive methods needed for them to bypass the BBB and the risk of potential adverse immune response. Our novel BBB-penetrating small molecules are designed to overcome many of these hurdles, allowing us to efficiently tap into the regenerative potential of HGF/MET. For therapeutic applications in CNS disorders, particularly AD, treatments that target neuronal growth factors can potentially accomplish several therapeutic goals, including rapid cognitive improvement and sustained neuroprotective effects.

We believe that our ability to enhance the body's repair mechanism of HGF/MET through our ATH platform has the potential to address a wide range of clinical applications ranging from CNS disorders, such as AD, Parkinson's disease dementia, or PDD, multiple sclerosis, or MS, and amyotrophic lateral sclerosis, or ALS, to more peripheral conditions such as neuropathy. In addition, we believe that HGF/MET biology plays a role in neuropsychiatric disorders such as depression and anxiety. We are planning to initiate a Phase 2 clinical trial for ATH-1017 for the treatment of PDD by the end of 2021. Currently we have two preclinical candidates for non-AD indications: ATH-1018, which is being advanced to address depression, and ATH-1019, which is being advanced to address peripheral neuropathy. Our ATH platform allows us the flexibility to engineer compounds that are BBB-penetrating or that generate specific activity in the periphery and molecules for subcutaneous or oral route of administration.

Our Pipeline and ATH Platform

The following figure illustrates the current development stage of our ATH compounds and discovery research programs. We are expanding our ATH platform to additional indications in the CNS and peripheral nervous system as we aim to improve neuronal health in multiple disorders.



(1) RoA: route of administration; SC: subcutaneous; PO: oral.

(2) ATH-1017 for AD, is moving from Phase 1b to a potentially pivotal Phase 2/3 clinical trial based on discussions with FDA.

(3) Following IND clearance, we plan to initiate a Phase 2 clinical trial in PDD based on results from Phase 1a and 1b clinical trials in AD with ATH-1017.

Our ATH platform utilizes proprietary technology to target and enhance the activity of a vital neuronal growth factor that promotes neuronal health and regeneration. We believe that our ATH platform has multiple advantages compared to previous strategies that have targeted growth factors, including:

- small molecule focus;
- efficient and scalable manufacturing process; and
- avoids alteration of target system regulation.

ATH-1017 for the Potential Treatment of AD

We are developing our lead product candidate, ATH-1017, for the treatment of neurodegenerative disorders, with an initial focus on AD. ATH-1017 is designed to improve neuronal health and promote regeneration, thereby improving symptoms in cognitively impaired subjects. As we continue to develop ATH-1017, we will plan to assess additional functional and behavioral benefits. In our Phase 1a and Phase 1b clinical trials, ATH-1017:

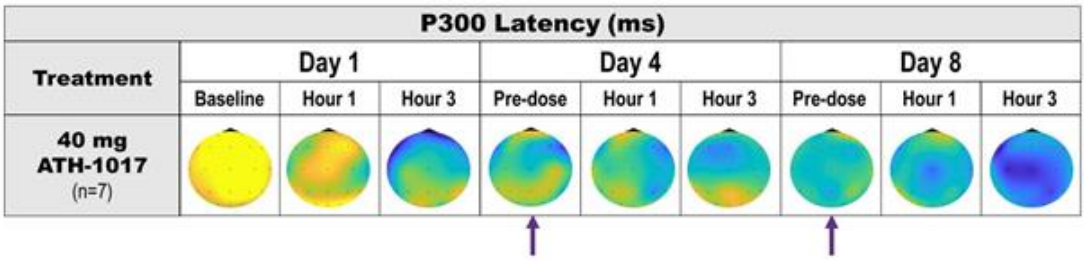
- was well tolerated with no serious adverse events across 88 subjects, including 11 subjects with mild-to-moderate AD;

- led to improvements in brain network activity that indicated positive effects on brain function; and
- demonstrated significantly improved brain activity in the AD subjects with multiple dosing as measured by P300 latency, a functional measure that is highly correlated with cognition.

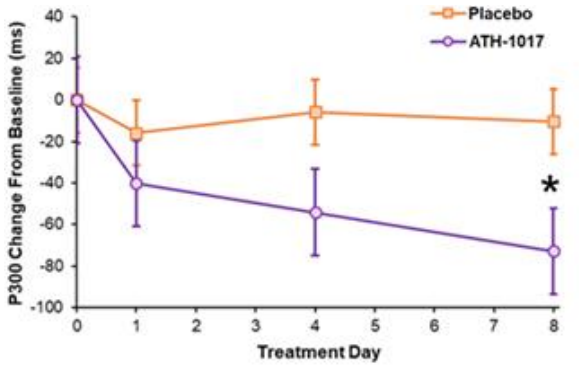
Results from Our Phase 1b Clinical Trial

In our Phase 1b clinical trial, event-related potential, or ERP, P300 recordings were collected from the multiple ascending dose, or MAD, healthy elderly and AD subjects. Analysis of these P300 data demonstrated that one daily dose of ATH-1017 improved P300 latency over an 8-day dosing period, as shown in the figures below. P300 latency, a functional measure of working memory processing speed that highly correlates with cognition, was dramatically improved. All AD subjects tested had improved P300 latency after a single dose of ATH-1017 and average latency across the AD treatment group had returned to levels close to those observed in healthy elderly subjects by the end of an 8-day treatment cycle. The acute effect observed on Day 1 is likely the result of the rapid augmentation of N-methyl-D-aspartate, or NMDA, neurotransmitter receptor. The sustained effects on P300 latency observed in the pre-dose recordings on subsequent testing days (the arrows in the figure below show the average P300 latency value from the ATH-1017 group as a heat map) most likely reflect the long-term regeneration of neuronal connections and the improvement in brain function, since at these time points, which are 24 hours after the last dose, ATH-1017 was measured and shown to be completely cleared from the plasma. These data indicate ATH-1017 treatment has recovered disruptions to brain function and network connectivity, likely through several components of the mechanism, including NMDA receptor modulation, increased connectivity through recovery of synaptic density, and overall improvement in neuronal health and function.

ATH-1017 Treatment Led to Continued and Sustained Improvement in P300 Latency. The arrows highlight the sustained P300 latency benefit due to ATH-1017 treatment.



Quantification of the Change in P300 Latency from Baseline, ATH-1017 Significantly Reduced P300 Latency Compared to the Placebo Group on Day 8 Recordings. Data show the average of P300 latency values of 7 AD subjects treated with ATH-1017 vs. 8 AD subjects on placebo * p≤0.05.



Development Strategy

LIFT-AD Pivotal Trial: A 26-Week Phase 2/3 Clinical Trial in Mild-to-Moderate AD Subjects

Based on the safety and translational Phase 1a and Phase 1b clinical trial results, including AD subjects, we plan to initiate LIFT-AD, a Phase 2/3 randomized, double-blind, placebo-controlled clinical trial. This clinical trial is designed to assess the efficacy, safety, and tolerability of two dose levels of ATH-1017 (low and high) in subjects with mild-to-moderate AD compared to placebo. The clinical trial is intended to enroll approximately 240 to 300 AD subjects. We plan to initiate the LIFT-AD potentially pivotal trial by the end of 2020, with topline results expected by the end of 2022.

P300 Trial: A 26-Week Phase 2 Clinical Trial in Mild-to-Moderate AD Subjects

In addition to LIFT-AD, we are planning a randomized, placebo-controlled clinical trial that will be initiated in parallel. This clinical trial is designed to test the same dose levels of ATH-1017 (low and high) in subjects with mild-to-moderate AD compared to placebo. We intend to enroll approximately 60 to 75 mild-to-moderate AD subjects. By the end of 2020, we plan to initiate this 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.

Our Strategy

We intend to create, develop, and commercialize therapeutics with the potential to transform lives by repairing, restoring, and reversing the damage to nerve cells throughout the body. Key aspects of our business strategy to achieve these goals are to:

- rapidly advance ATH-1017 through clinical development for AD;
- expand the development of ATH-1017 to include additional indications and delivery methods;
- focus on translational and functional endpoints to efficiently develop product candidates;
- continue developing additional pipeline programs and utilize our ATH platform for further drug discovery; and
- optimize the value of ATH-1017 and other candidates in major markets.

Significant Scientific Data Support HGF/MET's Role in Maintaining Neuronal Health and Function

Growing evidence suggests that complex CNS disorders, such as AD, are unlikely to be caused by a single route of pathology. Modulation of a neuronal growth factor has gained considerable attention for the potential treatment of neurodegenerative disorders. Promoting the HGF/MET system has been shown to have multiple beneficial downstream effects that are relevant to AD:

- HGF/MET is a critical neurotrophic factor for normative brain function and it is reduced in AD subjects;
- promotion of the HGF/MET system has shown in several animal models the potential to directly halt neurodegeneration and induce regeneration, improve cerebral blood flow, and reduce inflammation; and
- we expect HGF/MET system activation to improve P300 latency, as observed in AD subjects after ATH-1017 treatment in our Phase 1a and Phase 1b clinical trials.

Multiple third-party studies have documented the regenerative impact of HGF/MET promotion in models of AD, PDD, MS, and ALS. Notably, promotion of the HGF/MET system improved memory in AD and PDD models and improvement in neuronal survival was reported in various disease models including MS and ALS. These studies support the HGF/MET system as a therapeutic target in a diverse array of nervous system disorders.

Challenges with Approved and Traditional Neuronal and AD Therapy Approaches

The development of neuronal therapies presents unique challenges including: an imperfect understanding of the biology, the presence of the BBB that restricts the flow of drugs to the brain, and a lack of translatability of preclinical study results in human trials. Currently approved neuronal therapies have limited efficacy, poor side effect profiles, and minimal impact on quality of life. There remains an urgent need for new and novel approaches to address most neuronal disorders including progressive and severe conditions such as AD, PDD, MS, and others.

Specific to AD, each of the currently approved therapies only works on a single neurotransmitter target with limited and transient effects on cognition and low tolerability, which negatively impacts compliance and minimally reduces the caregiver burden. Other therapies in development that target a slowdown in disease progression have a marginal benefit on clinical decline and are mainly focused on mild cognitive impairment, or MCI, and early-mild AD, and lack any immediate benefit in reducing the burden on people impacted by the disease. These approaches rely on the body's repair mechanisms, which may be damaged, and do not promote additional activation of regenerative pathways, and hence can lead to variability of treatment outcomes and longer clinical development timelines.

Further complicating drug development in AD has been the lack of utilization of biomarkers and measures that are able to detect early signs of efficacy and find promising candidates to take forward into larger trials. These methods have revolutionized clinical research in oncology and other therapeutic areas, but traditionally not in AD. Traditionally, AD testing in clinical trials has relied heavily on imaging techniques to assess changes in amyloid PET scans over several years, creating enormous costs and elongated timelines for the development process while not showing any direct correlation to cognitive functional improvement.

Our Differentiated Approach

We believe our ATH platform of small molecules will promote neuronal health and function through stimulating the HGF/MET system. Our small molecules are BBB-penetrating, can be delivered non-invasively, have very low risk of an immune reaction and are more cost efficient to manufacture and distribute. Boosting the HGF/MET system leads to the following primary downstream effects:

- *Modulation of NMDA neurotransmitter system by enhancing synaptic localization and signaling*, leading to a rapid increase in brain network function. The NMDA receptor plays a key role in memory and learning. Other approaches work directly on the NMDA receptors and lack the specificity to modulate the NMDA receptor to the synaptic cleft, which is required to increase transmission of brain signals.

- *Restoration of traditional neuronal growth factor pathways* that are critical to neuronal survival and activate brain systems that reduce oxidative stress, which is expected to reduce damage and slow down disease progression and improve network activity. Many therapies in development are focused only on slowing disease progression.

- *Improvement in cerebral blood flow, as well as reducing inflammation* by modulating inflammatory cytokine expression from the glia. Many other therapies only have a single mode of activity.

These factors positively impact neuronal health and function, not only by slowing down disease progression, but also by improving brain network activity and function. We believe these effects position Athira, and initially ATH-1017, to address the complex pathology in neurodegenerative diseases.

Our Use of Highly Translatable and Predictive Measures to Guide Clinical Development

We believe EEG and ERP have the potential to revolutionize the paradigm in AD clinical trials. EEG and ERP methods are highly translatable and predictive measures that can guide clinical dose decisions and provide predictable measures of potential clinical benefit. These methods focus on changes in cognition and function, can result in more efficient and cost-effective clinical trials, and potentially provide an accelerated development path compared to traditional AD drug development programs.

Our focused drug development approach aims to understand the potential clinical benefit of a product candidate at early stages of clinical development by utilizing EEG and ERP methods. Commonly used in clinical research and clinical practice, EEG and ERP methods provide valuable insight into cognitive function, but have been largely overlooked in AD clinical trials. At Athira, we are innovatively using these non-invasive methods to gain early insight into potential therapeutic effects. Improvement in the brain network, as well as changes in neurotransmitter activity, can be captured in the electrical activity of the brain. By focusing on these direct measures of brain activity and cognition, we believe we will be able to more efficiently develop ATH-1017 for treatment of AD and broader dementia.

Insights from Approved Therapies and Applications to Our ATH Platform

Companies with approved therapies have demonstrated parallel improvement in P300 latency and cognition as assessed by ADAS-cog, as shown in the table below. While these changes induced by acetylcholinesterase inhibitors are modest and often transient, these previously published results support the correlation of P300 latency and cognition in AD subjects.

Studies Suggest Changes in P300 Latency Have Been Predictive of Changes in Cognition.

Treatment	P300 Latency Effect	Change in P300 Latency	Population	Cognitive Effect	Summary
ATH-1017	**Improved**	**(73) ms**	**AD**	**To be determined**	**Large magnitude improvement in P300 latency, expected to produce a correlated cognitive improvement.**
Donepezil	Improved	(16) ms	AD	Improved	P300 latency and cognition both improved in mild-to-moderate AD, though improvements were modest.
Rivastigmine	Improved	(22) ms	AD	Improved	P300 latency and cognition both improved in mild-to-moderate AD, though improvements were modest.
Memantine	Improved	(15) ms	AD	Improved	P300 latency and cognition both improved in moderate to severe AD, though improvements were modest.
Scopolamine	Worsened	50 ms	Healthy	Worsened	Scopolamine offers a counter example; P300 latency increases while cognitive performance is reduced.

Source: Results for donepezil and rivastigmine adapted from Thomas et al., 2001; results for memantine adapted from Sallach et al., 2011, and results for scopolamine adapted from Potter et al., 2000.

In CNS disorders, fluid or imaging biomarkers have been extensively used in drug development. However, these can be invasive and expensive, and the connection of these biomarkers to cognition is not clear. We sought to develop a translational strategy for ATH that was highly correlated to brain function and cognition which led us to use EEG/ERP for the clinical development of ATH-1017. Positive changes in EEG and ERP P300 latency potentially indicate a positive cognitive effect of ATH treatment, which increases our confidence that these effects may translate to clinical benefit in later-stage clinical trials.

Our Team and Investors

Our leadership team includes experienced neuroscience biotech executives who have both developed and commercialized CNS drugs and founded successful companies. Dr. Leen Kawas, our founder and chief executive officer, has been essential in creating our innovative translational development strategy. Dr. Hans Moebius, our chief medical officer, is a pioneer in the AD space and led the effort in getting Namenda, among other CNS drugs, approved. Dr. Mark Litton, our chief operating officer, is one of the co-founders and builders of Alder BioPharmaceuticals, which was acquired by Lundbeck A/S in October 2019. Dr. Kevin Church, our vice president of discovery, has over 10 years of research and management experience in the biotech space and is an expert in HGF biology.

Our advisory board is a world class team of leaders in the neuroregenerative, drug development and neurophysiology fields, including Dr. Larry Ereshefsky and Dr. Marwan Sabbagh. Dr. Ereshefsky is a pioneer in the application of translational drug development tools, including neurocircuitry/biomarker-based strategies such as quantitative EEG, or qEEG, ERP P300 latency, and cognitive and behavioral paradigms. Dr. Sabbagh, the director of Cleveland Clinic Lou Ruvo Center for Brain Health, is considered to be one of the leading experts in AD and dementia.

Our team is further supported by a group of investors that share our vision, mission, and commitment to develop innovative therapies for neurodegeneration. Our key investors include Perceptive Advisors, RTW Investments, Viking Global Investors, Venrock Healthcare Capital Partners, Franklin Templeton, Rock Springs Capital, LifeSci Venture Partners, Surveyor Capital (a Citadel company), Highside Capital Management, Logos Capital, funds managed by Janus Henderson Investors, Sofinnova Investments, and Avidity Partners.

Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties that you should consider before investing in our company. These risks are described more fully in the section titled “Risk Factors” in this prospectus. These risks include, but are not limited to, the following:

- We have a limited operating history.
- We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.
- Even if this offering is successful, 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.
- 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 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. Further, our product candidates are based on new approaches and novel technology, which makes it difficult to predict the time and cost of product candidate development and the regulatory approval process.
- Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and clinical trials may not be predictive of future clinical trial results. 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.
- The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our nonclinical studies and clinical trials.
- 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.
- 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.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Corporate Information

We were incorporated in Washington as a corporation in March 2011 under the name M3 Biotechnology, Inc. In October 2015, we converted to a Delaware corporation and subsequently changed our name to “Athira Pharma, Inc.” Our principal executive office is located at 4000 Mason Road, Suite 300, Seattle, Washington 98195. Our telephone number is (206) 221-8112. Our website is www.athira.com. Information contained in, or that can be accessed through, our website is not a part of, and is not incorporated into, this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

Trademarks and Service Marks

We use Athira, Athira Pharma, the Athira logo, and other marks as trademarks in the United States and other countries. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Implications of Being an Emerging Growth Company

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As such, we may take advantage of reduced disclosure and other requirements otherwise generally applicable to public companies, including:

- presentation of only two years of audited financial statements and related financial disclosure;
- exemption from requirement to have our registered independent public accounting firm attest to management's assessment of our internal control over financial reporting;
- reduced disclosure about our executive compensation arrangements; and
- exemption from requirement to hold non-binding advisory votes on executive compensation or golden parachute arrangements.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have at least $1.07 billion in annual revenue; (2) the last day of the fiscal year in which we are deemed to be a “large accelerated filer,” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700 million as of the last business day of the second fiscal quarter of such year; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

As a result of this status, we have taken advantage of reduced reporting requirements in this prospectus and may elect to take advantage of other reduced reporting requirements in our future filings with the SEC. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies unless it otherwise irrevocably elects not to avail itself of this exemption. We have 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 are no longer an emerging growth company or 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.

In addition, we are also a “smaller reporting company” because the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700 million as of June 30, 2019 and our annual revenue was less than $100 million during the fiscal year ended December 31, 2019. We may continue to be a smaller reporting company after this offering in any given year if either (1) the market value of our stock held by non-affiliates is less than $250 million as of June 30 in the most recently completed fiscal year or (2) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million as of June 30 in the most recently completed fiscal year. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

The Offering

Common stock offered by us	shares.
Option to purchase additional shares	We have granted the underwriters an option to purchase up to additional shares of common stock from us. The underwriters can exercise this option at any time within 30 days from the date of this prospectus.
Common stock to be outstanding after the offering	shares (or shares if the underwriters exercise in full their option to purchase additional shares).
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $ million, or $ million if the underwriters exercise in full their option to purchase additional shares of common stock, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering for the following purposes: (1) approximately $ million to fund our planned LIFT-AD potentially pivotal trial of ATH-1017 and our planned P300 Phase 2 trial of ATH-1017, each for the treatment of mild-to-moderate Alzheimer's disease; (2) approximately $ million to fund our planned Phase 2 trial of ATH-1017 for the treatment of Parkinson's disease dementia; (3) approximately $ million to fund our IND-enabling studies of ATH-1019 for the treatment of neuropsychiatric indications and ATH-1018 for the treatment of neuropathy; and (4) the remainder for our other research and development activities, as well as for working capital and other general corporate purposes. For a more complete description of our intended use of the proceeds from this offering, see the section of this prospectus titled "Use of Proceeds."

Directed share program	At our request, the underwriters have reserved % of the shares of common stock to be offered by this prospectus for sale, at the initial public offering price, to directors, officers, employees, business associates and other persons related to us. If purchased by these persons, these shares will not be subject to a lock-up restriction, except in the case of shares purchased by any director, executive officer or employee. The number of shares of common stock available for sale to the general public will be reduced to the extent these individuals purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus.
Risk factors	See the section of this prospectus titled “Risk Factors” beginning on page 17 and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.
Proposed Nasdaq Global Market trading symbol	“ATHA”

The number of shares of our common stock outstanding after this offering is based on shares of common stock outstanding as of June 30, 2020 (including our convertible preferred stock on an as-converted basis), and excludes:

- shares of common stock issuable upon the exercise of outstanding options as of June 30, 2020 with a weighted-average exercise price of $ per share;
- shares of common stock reserved for future issuance under our 2014 Equity Incentive Plan as of June 30, 2020;
- shares of common stock reserved for future issuance under our 2020 Equity Incentive Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part; and
- shares of common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part.

Except as otherwise indicated, all information in this prospectus assumes or gives effect to the following:

- the automatic conversion of our outstanding shares of convertible preferred stock as of June 30, 2020 into an aggregate of shares of common stock immediately prior to the closing of this offering;
- no exercise of outstanding options described above;
- the issuance of shares of common stock upon the automatic exercise of an outstanding warrant to purchase shares of our Series B convertible preferred stock immediately prior to the closing of this offering that would otherwise expire at an exercise price of $1.15 per share;

- the issuance of shares of common stock immediately prior to the closing of this offering issuable upon the exercise of an outstanding warrant to purchase our common stock at an exercise price of $1.00 per share;

- the issuance of shares of common stock upon the automatic exercise of warrants to purchase common stock immediately prior to the closing of this offering that would otherwise expire at an exercise price of $0.01 per share;

- the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, which will occur immediately prior to the closing of this offering; and

- no exercise of the underwriters' option to purchase additional shares.

Summary Financial Data

The following tables set forth a summary of our financial data. The summary statements of operations data for the years ended December 31, 2018 and 2019 are derived from our audited financial statements included elsewhere in this prospectus. The summary statements of operations data for the six months ended June 30, 2019 and 2020 and the summary balance sheet data as of June 30, 2020 are derived from our unaudited interim condensed financial statements included elsewhere in this prospectus. Our unaudited interim condensed financial statements have been prepared on a basis consistent with our audited financial statements and, in the opinion of management, reflect all adjustments, consisting solely of normal recurring adjustments, necessary for the fair presentation of the financial information in those statements. You should read this summary data together with our financial statements and related notes included elsewhere in this prospectus and the information in the sections of this prospectus titled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of our future results, and the results of operations for the six months ended June 30, 2020 are not necessarily indicative of the results to be expected for the full year ending December 31, 2020 or any other period. The summary financial data in this section are not intended to replace the financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,		Six Months Ended June 30,	
	2018	2019	2019	2020
			(unaudited)	
	(in thousands, except share and per share data)			
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 3,589	$ 3,793	$	$
General and administrative	1,420	1,656		
Total operating expenses	5,009	5,449		
Loss from operations	(5,009)	(5,449)		
Other income (expense), net	(88)	288		
Net loss and comprehensive loss	$ (5,097)	$ (5,161)	$	$
Net loss per share attributable to common stockholders, basic and diluted[1]	$ (0.19)	$ (0.18)	$	$
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted[1]	27,511,082	28,285,902		
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[1]		$		$
Weighted-average shares outstanding used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[1]				

(1) See Notes 15 and 16 to our audited financial statements and Notes and to our unaudited interim condensed financial statements included elsewhere in this prospectus for the calculation of our basic and diluted net loss per share attributable to common stockholders and our basic and diluted pro forma net loss per share attributable to common stockholders, and the weighted-average number of shares used in computing the per share amounts.

	As of June 30, 2020		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[2]
		(unaudited) (in thousands)	
Balance Sheet Data:			
Cash and cash equivalents	$	$	$
Working capital[3]			
Total assets			
Grant liability			
Total liabilities			
Convertible preferred stock			
Total stockholders' (deficit) equity			

(1) Reflects, on a pro forma basis, (a) the automatic conversion of our convertible preferred stock into an aggregate of shares of common stock as of June 30, 2020; (b) the issuance of an aggregate of shares of our common stock upon the exercise of outstanding warrants immediately prior to the closing of this offering; (c) the repayment of $1.5 million in grant liability; and (d) the filing of our amended and restated certificate of incorporation, each of which will occur immediately prior to the closing of this offering.

(2) Reflects, on a pro forma as adjusted basis, the pro forma adjustments described in footnote (1) above, as well as the sale and issuance by us of shares of common stock in this offering at the assumed initial public offering price of $ per share, which is the midpoint of the range reflected on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Each $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, as applicable, each of our cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase or decrease of 1.0 million in the number of shares offered by us would increase or decrease, as applicable, each of our cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity by $ million, assuming that the assumed initial public offering price remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will adjust based on the actual initial public offering price and other terms of this offering determined at pricing.

(3) Accounting Standards Codification Topic 210, *Balance Sheet*, defines working capital as current assets less current liabilities. See our financial statements and related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and the section of this prospectus titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

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.

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 $5.2 million and $ million for year ended December 31, 2019 and the six months ended June 30, 2020, respectively, and an accumulated deficit of $ million as of June 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 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.

Even if this offering is successful, 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 Alzheimer's disease, or AD, Parkinson's disease dementias, or 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, upon the closing of this offering, we expect 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 June 30, 2020, we had cash and cash equivalents of $ million. Based upon our current operating plan, we estimate that our existing cash and cash equivalents, together with the anticipated net proceeds from this offering, will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next months. 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 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 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 first-in-class 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 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 AD and other 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. Data from our Phase 1a and 1b clinical trials, while promising, were obtained from a relatively small number of subjects and we cannot be certain that future trials involving a larger number of subjects 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 function 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 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 while 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 earlier studies and clinical trials may not be predictive of future clinical trial results. 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 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 clinical trials may not be predictive of eventual safety or effectiveness in large-scale pivotal clinical trials. 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 potentially pivotal trial that we expect to initiate by the end of 2020. In parallel to LIFT-AD, we plan to initiate 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 potentially pivotal LIFT-AD trial if the results from the P300 Phase 2 clinical trial do not meet our expectations. However, even if we receive positive data in our 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 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 REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

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 following this offering 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.

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 after this offering.

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, in parallel to our potentially pivotal LIFT-AD clinical trial, we plan to initiate 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 potentially pivotal LIFT-AD trial if the results from the P300 Phase 2 clinical trial do not meet our expectations. The topline results of this 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.

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 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 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 this prospectus 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.

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.

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.

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 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.

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.

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 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 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.

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.

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 cGMPs, good laboratory practice, or GLP, regulations and GCPs, 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, upon completion of this offering and in our operations as a public company, 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 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 inseverable 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 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.

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 whether additional legislative changes will be enacted, or 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.

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.

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.

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.

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 Cut 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 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 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 prospectus, 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"). 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 This Offering and Ownership of Our Common Stock

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

Before this offering, there was no public trading market for 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 purchasing shares in this offering.

The initial public offering price for our common stock was determined through negotiations with the underwriters. This initial public offering price may differ from the market price of our common stock after the offering. As a result, you may not be able to sell your common stock at or above the initial public offering price. 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 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;
- 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 “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. These fluctuations may be even more pronounced in the trading market for our stock shortly following this offering. 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.

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. We do not currently have and may never obtain research coverage by industry or financial analysts. 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.

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. After this offering and after giving effect to the conversion of all outstanding shares of our convertible preferred stock and the exercise of outstanding warrants into an aggregate of shares of our common stock, shares of our common stock will be outstanding, or shares of common stock if the underwriters exercise their option to purchase additional shares in full, based on our shares outstanding as of June 30, 2020. Of these shares, the shares we are selling in this offering, or shares if the underwriters exercise their option to purchase additional shares in full, may be resold in the public market immediately. The remaining shares, or % of our outstanding shares after this offering, or % of our outstanding shares after this offering if the underwriters exercise their option to purchase additional shares in full, 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 this prospectus. 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. See the section of this prospectus titled "Shares Eligible for Future Sale" for additional information.

Moreover, upon completion of this offering, the holders of approximately shares of our common stock will be 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 plan to register all 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 this prospectus 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.

Insiders will continue to have substantial influence over us after this offering, which could limit your ability to affect the outcome of key transactions, including a change of control.

After this offering, our directors, executive officers, holders of more than 5% of our outstanding common stock and their respective affiliates will beneficially own shares representing approximately % of our outstanding common stock, or % of our common stock if the underwriters exercise their option to purchase additional shares in full. 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. In this prospectus, we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. 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.

We will 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. Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global 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.

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 will 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 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 the year after this offering is completed, 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. Prior to this offering, 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.

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 will be 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.

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

We cannot specify with certainty the particular uses of the net proceeds we will receive from this offering. We will have broad discretion in the application of the net proceeds, including for any of the purposes described in the section of this prospectus titled "Use of Proceeds." We may spend a portion or all of the net proceeds from this offering 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 this offering 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 will become effective immediately prior to the closing of this offering 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 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 certificate of incorporation provides 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 certificate of incorporation that will become effective immediately prior to the closing of this offering provides 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 certificate of incorporation that will become effective immediately prior to the closing of this offering further provides 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 certificate of incorporation 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. Some of the statements in the sections of this prospectus titled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" and elsewhere in this prospectus contain forward-looking statements. 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.

These statements involve risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this prospectus 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;
- the pricing and reimbursement of our product candidates, if approved;
- 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;
- our ability to expand our product candidates into additional indications and patient populations;
- the success of competing therapies that are or may become available;

- 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, 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;
- the size and growth potential of the markets for our product candidates, if approved for commercial use, and our ability to serve those markets;
- the potential benefits of any strategic collaboration agreements we may enter into;
- our anticipated use of the proceeds from this offering;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

You should refer to the section of this prospectus titled “Risk Factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. 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 prospectus, 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 investors are cautioned not to unduly rely upon these statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

MARKET, INDUSTRY AND OTHER DATA

This prospectus contains estimates, projections and other information concerning market, industry and other data. We obtained this data from our own internal estimates and research and from academic and industry research, publications, surveys, and studies conducted by third parties, including governmental agencies. In some cases, we do not expressly refer to the sources from which these data are derived. These data involve a number of assumptions and limitations, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed in the section of this prospectus titled “Risk Factors” and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us. You are therefore cautioned not to give undue weight to such information. We have not independently verified any third-party information. While we believe such information included in this prospectus is generally reliable, it is inherently imprecise.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $ million (or $ million if the underwriters exercise their option to purchase additional shares in full), assuming an initial offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and offering expenses payable by us.

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, as applicable, the net proceeds to us from this offering by $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase or decrease of 1.0 million shares in the number of shares offered by us would increase or decrease, as applicable, the net proceeds to us from this offering by $ million, assuming that the assumed initial public offering price remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the initial public offering price or the number of shares by these amounts would have a material effect on our uses of the proceeds from this offering, although it may accelerate the time when we need to seek additional capital.

The principal purposes of this offering are to increase our capitalization and financial flexibility, establish a public market for our common stock and to facilitate future access to the public equity markets by us, our employees and our stockholders, obtain additional capital to support our operations and increase our visibility in the marketplace. We currently intend to use the net proceeds from this offering together with our existing cash and cash equivalents as follows:

- approximately $ million to fund our planned LIFT-AD potentially pivotal trial of ATH-1017 and our planned P300 Phase 2 trial of ATH-1017, each for the treatment of mild-to-moderate Alzheimer's disease;
- approximately $ million to fund our planned Phase 2 trial of ATH-1017 for the treatment of Parkinson's disease dementia;
- approximately $ million to fund our IND-enabling studies of ATH-1019 for the treatment of neuropsychiatric indications and ATH-1018 for the treatment of neuropathy; and
- the remainder for our other research and development activities, as well as for working capital and other general corporate purposes.

The estimated amounts set forth above do not include any related payments that may be due under our collaboration and grant agreements, including the $1.5 million payable to Washington Life Sciences Discovery Fund upon the completion of this offering. For additional details regarding our collaboration and grant agreements, see the section of this prospectus titled "Business—Our Collaboration and Grant Agreements," as well as our financial statements and related notes included elsewhere in this prospectus.

This expected use of the net proceeds from this offering represents our intentions based on our current plans and business conditions, which could change in the future as our plans and business conditions evolve. Further, due to the uncertainties inherent in the small molecule development process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. We may also use a portion of our net proceeds to acquire or invest in complementary products, technologies, or businesses. However, we currently have no agreements or commitments to do so. As a result, our management will have broad discretion over the use of the net proceeds from this offering, and our investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering. The amounts and timing of our expenditures will depend upon numerous factors including the results of our research and development efforts, the timing, number, scope and success of our nonclinical studies and clinical trials, and the timing and success of any regulatory submissions.

Based upon our current operating plan, we estimate that our existing cash and cash equivalents and the anticipated net proceeds from this offering, will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next months. In particular, we expect that the net proceeds from this offering will fund us through receipt of topline data readouts for our planned LIFT-AD potentially pivotal trial of ATH-1017 and our planned P300 Phase 2 trial of ATH-1017, each for the treatment of mild-to-moderate AD, as well as IND-enabling studies and IND applications for ATH-1019 for the treatment of neuropsychiatric indications including depression and anxiety and ATH-1018 for the treatment of neuropathy. In addition, if the data from our planned LIFT-AD clinical trial, P300 clinical trial, or both lead us to decide to initiate additional trials for ATH-1017 for the treatment of AD, we currently estimate the cost of such additional trial will be approximately $. However, the expected net proceeds from this offering will not be sufficient for us to fund any of our product candidates through regulatory approval and commercialization, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors. For additional information regarding our potential capital requirements, including factors that could cause actual costs to vary from the estimates set forth above, see the section of this prospectus titled “Risk Factors.”

As of the date of this prospectus, we intend to invest the net proceeds in short-term interest-bearing investment-grade securities, certificates of deposit or government securities. The goal with respect to the investment of these net proceeds is capital preservation and liquidity so that such funds are readily available to fund our operations.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. Any future determination to pay dividends will be made at the discretion of our board of directors subject to applicable laws and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements. Our future ability to pay cash dividends on our capital stock may be limited by any future debt instruments or preferred securities.

CAPITALIZATION

The following table summarizes our cash and cash equivalents and capitalization as of June 30, 2020:

- on an actual basis;
- on a pro forma basis to reflect (1) the automatic conversion of our convertible preferred stock into an aggregate of shares of our common stock as of June 30, 2020, (2) the issuance of an aggregate of shares of our common stock upon the exercise of outstanding warrants immediately prior to the closing of this offering; (3) the repayment of $1.5 million in grant liability; and (4) the filing of our amended and restated certificate of incorporation, which will occur immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis to reflect (1) the pro forma adjustments set forth above and (2) the sale and issuance by us of shares of common stock in this offering at the assumed initial public offering price of $ per share, which is the midpoint of the range reflected on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the information in this table together with our financial statements and related notes included elsewhere in this prospectus, as well as the sections of this prospectus titled “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	As of June 30, 2020		
	Actual	Pro Forma	Pro Forma As Adjusted[1]
		(unaudited) (in thousands)	
Cash and cash equivalents	$	$	$
Grant liability	$	$	$
Convertible preferred stock; $0.0001 par value per share; shares authorized; shares issued and outstanding, actual; no shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted			
Stockholders’ (deficit) equity:			
Preferred stock, $0.0001 par value per share; no shares authorized and no shares issued and outstanding, actual; shares authorized and no shares issued and outstanding, pro forma and pro forma as adjusted			
Common stock, $0.0001 par value per share, 80,000,000 shares authorized, shares issued and outstanding, actual; shares authorized, shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted			
Additional paid-in capital			
Accumulated deficit			
Total stockholders’ (deficit) equity			
Total capitalization	$	$	$

(1) Each $1.00 increase or decrease in the assumed initial public offering price of $ per share, the midpoint of the range reflected on the cover page of this prospectus, would increase or decrease, as applicable, each of our cash and cash equivalents, additional paid-in capital, total stockholders’ (deficit) equity and total capitalization by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase or decrease of 1.0 million shares in the number of shares offered by us would increase or decrease, as applicable, each of our cash and cash equivalents, additional paid-in capital, total stockholders’ (deficit) equity and total capitalization by $ million, assuming that the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma and pro forma as adjusted information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing.

The number of shares of our common stock issued and outstanding, pro forma and pro forma as adjusted in the table above is based on shares of common stock outstanding as of June 30, 2020 (including our convertible preferred stock on an as-converted basis), and excludes:

- shares of common stock issuable upon the exercise of outstanding options as of June 30, 2020 with a weighted-average exercise price of $ per share;
- shares of common stock reserved for future issuance under our 2014 Equity Incentive Plan as of June 30, 2020;
- shares of common stock reserved for future issuance under our 2020 Equity Incentive Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part; and
- shares of common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part.

DILUTION

If you invest in our common stock you will experience immediate and substantial dilution in the pro forma net tangible book value of your shares of common stock. Dilution in pro forma net tangible book value represents the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock.

Historical net tangible book value (deficit) represents our total tangible assets (total assets less deferred offering costs) less total liabilities and our convertible preferred stock. As of June 30, 2020, our historical net tangible book deficit was $ million and our historical net tangible book deficit per share was $.

On a pro forma basis, after giving effect to the automatic conversion of all outstanding shares of convertible preferred stock into an aggregate of shares of our common stock in connection with this offering and the issuance of an aggregate of shares of our common stock upon the exercise of outstanding warrants immediately prior to the closing of this offering, and the repayment of $1.5 million in grant liability, our pro forma net tangible book value as of June 30, 2020 would have been $ million, or $ per share.

On a pro forma basis, after giving further effect to the sale and issuance of shares of our common stock in this offering at the assumed initial public offering price of $ per share, which is the midpoint of the range reflected on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2020 would have been $ million, or $ per share. This represents an immediate increase in pro forma net tangible book value of $ per share to existing stockholders and an immediate dilution of the pro forma net tangible book value of $ per share to new investors purchasing common stock in this offering.

The following table illustrates this dilution on a per share basis to new investors:

Assumed initial public offering price per share		$
Historical net tangible book value (deficit) per share as of June 30, 2020		
Pro forma increase in historical net tangible book deficit per share as of June 30, 2020 attributable to the pro forma adjustments identified above		
Pro forma net tangible book value per share as of June 30, 2020		
Increase in pro forma net tangible book value per share attributable to new investors participating in the offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors participating in this offering		$

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, as applicable, our pro forma as adjusted net tangible book value by $ million, or $ per share, and increase or decrease, as applicable, the dilution per share to investors participating in this offering by $ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase of 1.0 million in the number of shares offered by us would increase our pro forma as adjusted net tangible book value by $ million, or $ per share, and the dilution per share to investors participating in this offering would be $ per share, assuming that the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each decrease of 1.0 million shares in the number of shares offered by us would decrease our pro forma as adjusted net tangible book value by $ million, or $ per share, and the dilution per share to investors participating in this offering would be $ per share, assuming that the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing.

If the underwriters exercise their option in full to purchase additional shares of common stock in this offering, the pro forma as adjusted net tangible book value per share after the offering would be $ per share, the increase in the pro forma net tangible book value per share to existing stockholders would be $ per share, and the pro forma as adjusted dilution to new investors purchasing common stock in this offering would be $ per share.

The following table summarizes, on a pro forma basis as adjusted basis as described above as of June 30, 2020, the differences between the number of shares of common stock purchased from us, the total consideration and the weighted-average price per share paid by existing stockholders and by investors participating in this offering at the initial public offering price of $ per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price
	Number	Percent	Amount	Percent	Per Share
Existing stockholders		%	$	%	$
New public investors					
Total		100.0%	$	100.0%	$

Each $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, as applicable, total consideration paid by new investors by $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. An increase or decrease of 1.0 million in the number of shares offered by us would increase or decrease, as applicable, total consideration paid by new investors by $ million, assuming that the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The foregoing tables and calculations (other than the historical net tangible book value calculation) are based on the shares of common stock outstanding as of June 30, 2020 (including our convertible preferred stock on an as-converted basis), which excludes:

- shares of common stock issuable upon the exercise of outstanding options as of June 30, 2020 with a weighted-average exercise price of $ per share;
- shares of common stock reserved for future issuance under our 2014 Equity Incentive Plan as of June 30, 2020;

- shares of common stock reserved for future issuance under our 2020 Equity Incentive Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part; and

- shares of common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part.

To the extent that any outstanding options are exercised, new options or other equity awards are issued under our equity incentive plans, or we issue additional shares in the future, there will be further dilution to new investors participating in this offering.

SELECTED FINANCIAL DATA

The following tables set forth our selected financial data. The selected statements of operations data for the years ended December 31, 2018 and 2019 and the selected balance sheet data as of December 31, 2018 and 2019 are derived from our audited financial statements included elsewhere in this prospectus. The selected statements of operations data for the six months ended June 30, 2019 and 2020 and the selected balance sheet data as of June 30, 2020 are derived from our unaudited interim condensed financial statements included elsewhere in this prospectus. Our unaudited interim condensed financial statements have been prepared on a basis similar to our audited financial statements and, in the opinion of management, reflect all adjustments, consisting solely of normal recurring adjustments, necessary for the fair presentation of the financial information in those statements. You should read this selected data together with our financial statements and related notes appearing elsewhere in this prospectus and the information in the section of this prospectus titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of our future results, and the results of operations for the six months ended June 30, 2020 are not necessarily indicative of the results to be expected for the full year ending December 31, 2020 or any other period. The selected financial data in this section are not intended to replace our financial statements and the related notes included elsewhere in this prospectus.

	Year Ended December 31,		Six Months Ended June 30,	
	2018	2019	2019	2020
			(unaudited)	
	(in thousands, except per share data)			
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 3,589	$ 3,793	$	$
General and administrative	1,420	1,656		
Total operating expenses	5,009	5,449		
Loss from operations	(5,009)	(5,449)		
Other income (expense), net	(88)	288		
Net loss and comprehensive loss	$ (5,097)	$ (5,161)	$	$
Net loss per share attributable to common stockholders, basic and diluted[1]	$ (0.19)	$ (0.18)	$	$
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted[1]	27,511,082	28,285,902		
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[1]		$		$
Weighted-average shares outstanding used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[1]				

	As of December 31,		As of June 30,
	2018	2019	2020
			(unaudited)
	(in thousands)		
Balance Sheet Data:			
Cash, cash equivalents and short-term investments	$ 4,817	$ 2,056	$
Working capital[2]	4,325	887	
Total assets	4,933	2,189	
Total liabilities	2,769	4,861	
Convertible preferred stock	17,051	17,051	
Total stockholders' (deficit) equity	(14,887)	(19,723)	

(1) See Notes 15 and 16 to our audited financial statements and Notes and to our unaudited interim condensed financial statements included elsewhere in this prospectus tor the calculation of our basic and diluted net loss per share attributable to common stockholders and our basic and diluted pro forma net loss per share attributable to common stockholders and the weighted-average number of shares used in computing the per share amounts.

(2) Accounting Standards Codification Topic 210, *Balance Sheet*, defines working capital as current assets less current liabilities. See our financial statements and related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the section of this prospectus titled "Selected Financial Data" and our financial statements and related notes included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives, expectations, forecasts and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under the section of this prospectus titled "Risk Factors" and elsewhere in this prospectus. You should carefully read the "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section of this prospectus titled "Special Note Regarding Forward-Looking 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 provide rapid 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. All of these characteristics are expected to 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 our Phase 1a and Phase 1b clinical trials, ATH-1017 for the treatment of Alzheimer's disease, or AD, was well tolerated with no serious adverse events. These clinical trials recruited 88 subjects, including 11 subjects with mild-to-moderate AD. Nonclinical studies and Phase 1 clinical trials with ATH-1017 demonstrated improvements in brain network activity indicating positive effects on brain function. In the AD subjects, multiple dosing of ATH-1017 significantly improved brain activity as measured by P300 latency, a functional measure that is highly correlated with cognition. By the end of 2020, we plan to initiate a pivotal Phase 2/3 clinical trial for ATH-1017, or LIFT-AD, for the treatment of mild-to-moderate AD with topline results expected by the end of 2022. By the end of 2020, we also plan to initiate 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.

The following illustrates the development stages of our current ATH compounds and discovery research programs:

(1) RoA: route of administration; SC: subcutaneous; PO: oral.
(2) ATH-1017 for AD, is moving from Phase 1b to a potentially pivotal Phase 2/3 clinical trial based on discussions with FDA.
(3) Following IND clearance, we plan to initiate a Phase 2 clinical trial in PDD based on results from Phase 1a and 1b clinical trials in AD with ATH-1017.

We constantly strive to grow and optimize our portfolio through in-house discovery and plan on additional external business development activities enabled by our innovative internal research and development capabilities.

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 with proceeds from the sale and issuance of convertible preferred stock and convertible notes, and to a lesser extent from grant income and stock option exercises. From inception to December 31, 2019, we have raised aggregate cash proceeds of $18.4 million primarily from the issuance of our convertible preferred stock and convertible notes. Additionally, in the second quarter of 2020, we closed our Series B convertible preferred stock financing for net proceeds of $81.8 million. We have incurred significant operating losses to date. Our net losses were $5.1 million and $5.2 million for the years ended December 31, 2018 and 2019, respectively. As of December 31, 2019, we had an accumulated deficit of $21.1 million and cash and cash equivalents of $2.1 million.

We expect to continue to incur increasing operating losses for the foreseeable future as we:

- continue to advance ATH-1017 and our other product candidates through preclinical studies and clinical trials, including our planned potentially pivotal Phase 2/3 clinical trial for ATH-1017 for the treatment of mild-to-moderate AD;
- expand our pipeline of product candidates;
- continue to grow our discovery organization and invest in the ATH platform;
- ramp up manufacturing activities;
- attract, hire and retain additional personnel;
- obtain, maintain, expand and protect our intellectual property portfolio;
- operate as a public company;
- relocate to our new facility and build out lab space;
- implement operational, financial and management information systems;
- seek regulatory approval for any product candidates that successfully complete clinical trials; and
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We will require substantial additional funding to support our continuing operations and further the development of our product candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, which could include income from collaboration, licensing or similar arrangements,

for the foreseeable future. Adequate funding may not be available when needed or on terms acceptable to us, or at all. If we are unable to raise additional capital as needed, we may have to significantly delay, scale back or discontinue development of our product candidates. 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 flow from operating activities. Based upon our current operating plan, we estimate that our existing cash and cash equivalents and the net proceeds from this offering, will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next months.

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 the COVID-19 on our business, 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, 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.

Our Collaboration and Grant Agreements

Washington State University Research Foundation License Agreement and Amended and Restated Washington State University License Agreement

In December 2011, we entered into an exclusive license agreement with Washington State University Research Fund, or WSURF, which, after the dissolution of WSURF in 2013, was superseded by an amended and restated exclusive license agreement with Washington State University, or WSU, in September of 2015. Under this agreement, WSU granted us an exclusive license to make, use, sell, and offer for sale licensed products and licensed processes that embody the licensed patents (including WSU's rights to a patent jointly owned with Pacific Northwest Biotechnology, Inc.) and that form the underlying technology of the drug therapies we are developing. The term of the license begins on the effective date and continues until the earlier of the date in which no valid claim remains enforceable and the payment of royalties ceases for more than four consecutive quarters after such royalty payments begin.

We are obligated to pay to WSU the following if the related milestones are reached:

- $50,000 – At initiation of the first Phase 2 clinical trial in the United States, European Union or Japan for the first licensed product.

- $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.

We are obligated to pay WSU a royalty in the mid-single digits of net sales.

Additionally, under the agreement we have the right to sublicense the licensed rights, 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 tens of any non-sales based payments received, and low twenties of net sales based sublicense royalties.

Grant Liability

In 2014 and 2015, we received $250,000 and $500,000, respectively, from the Washington Life Sciences Discovery Fund, or LSDF, under the terms of two matching grant award agreements. In connection with the agreements, LSDF retained the right to receive cash payments of up to 2.0 times the amounts received, or $1.5 million, upon the occurrence of specified triggering events, including completion of this offering.

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 prospectus, 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.

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; 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. Following the completion of this offering, 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 short-term investments, grant income, periodic mark to market gains and losses on the derivative and grant liabilities carried at fair value, and interest expense on our convertible notes.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2019

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

	Year Ended December 31,		Dollar Change	% Change
	2018	2019		
	(in thousands)			
Operating expenses:				
Research and development	$ 3,589	$ 3,793	$ 204	6%
General and administrative	1,420	1,656	236	17
Total operating expenses	5,009	5,449	440	9
Loss from operations	(5,009)	(5,449)	(440)	9
Other income (expense), net	(88)	288	376	*
Net loss and comprehensive loss	$ (5,097)	$ (5,161)	$ (64)	1

** Not meaningful*

Research and Development Expenses

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

	Year Ended December 31,		Dollar	%
	2018	2019	Change	Change
	(in thousands)			
Direct costs:				
ATH-1017	$ 2,773	$ 2,619	$ (154)	(6)%
Preclinical programs	114	212	98	86
Total direct costs	2,887	2,831	(56)	(2)
Indirect costs:				
Personnel-related costs, including stock-based compensation	619	791	172	28
Facilities and other costs	83	171	88	106
Total research and development expenses	$ 3,589	$ 3,793	$ 204	6

Research and development expenses increased by $0.2 million, or 6%, from $3.6 million for the year ended December 31, 2018 to $3.8 million for the year ended December 31, 2019. The increase was driven primarily by an increase in personnel-related costs, and to a lesser extent, by increases in preclinical program costs as we expanded the number of research targets, as well as in facilities and other costs supporting our overall growth. In addition, expenses for ATH-1017 decreased by $0.2 million, primarily due to a decrease in clinical trial costs of $1.0 million related to the timing of activities in our Phase 1a and 1b clinical trials, partially offset by an increase in preclinical costs of $0.6 million as we completed certain toxicology studies in 2019, and by increases in manufacturing costs of $0.2 million as we began preparing for Phase 2 clinical trial drug supply production in late 2019.

General and Administrative Expenses

General and administrative expenses increased by $0.3 million, or 17%, from $1.4 million for the year ended December 31, 2018 to $1.7 million for the year ended December 31, 2019. The increase was primarily due to an increase in personnel-related costs as staffing increased to support our growth.

Other Income (Expense), Net

Other income (expense), net changed from an expense of $0.1 million for the year ended December 31, 2018 to income of $0.3 million for the year ended December 31, 2019. The change of $0.4 million was primarily due to income from a *Part the Cloud* research grant of $0.8 million received in 2019, partially offset primarily by an increase in interest expense on outstanding convertible notes of $0.3 million and to a lesser extent by a decrease in interest and other income and an increase in losses from changes in liabilities recorded at fair value.

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 and convertible notes, and to a lesser extent from grant income and stock option exercises. From our inception through December 31, 2019, we have raised aggregate net cash proceeds of $18.4 million primarily from the issuance of our convertible preferred stock and

convertible notes. As of December 31, 2019, we had $2.1 million in cash and cash equivalents and have not generated positive cash flows from operations. In the second quarter of 2020, we received an aggregate of approximately $81.8 million in net proceeds from our Series B convertible preferred stock financing. 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 $2.1 million of cash and cash equivalents at December 31, 2019 and the $81.8 million in net proceeds received upon closing of our Series B convertible preferred stock financing, will be sufficient to fund our operating expenses and capital expenditure requirements through at least the 12 months following the date of this prospectus. However, we believe our cash and cash equivalents as of the date of this prospectus, together with the net proceeds from this offering, will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next months. Even after this offering, 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:

	Year Ended December 31,	
	2018	2019
	(in thousands)	
Net cash used provided by (used in):		
Operating activities	$ (4,483)	$ (3,713)
Investing activities	2,007	1,506
Financing activities	1,464	946
Net decrease in cash and cash equivalents	$ (1,012)	$ (1,261)

Operating Activities

During the year ended December 31, 2019, net cash used in operating activities was $3.7 million. This consisted primarily of a net loss of $5.2 million, partially offset by non-cash charges of $0.8 million and an increase in our net operating assets of $0.7 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.

During the year ended December 31, 2018, net cash used in operating activities was $4.5 million. This consisted primarily of a net loss of $5.1 million, partially offset by non-cash charges of $0.4 million and an increase in our net operating assets of $0.2 million. The non-cash charges primarily consisted of stock-based compensation expense, non-cash interest expense 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 year ended December 31, 2019, cash provided by investing activities was $1.5 million. This consisted primarily of $2.5 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.

During the year ended December 31, 2018, cash provided by investing activities was $2.0 million. This consisted primarily of $7.3 million in proceeds received from short-term investments which matured during the period, partially offset by purchases of short-term investments of $5.3 million.

Financing Activities

During the year ended December 31, 2019, cash provided in financing activities was $0.9 million. This consisted primarily of net proceeds received from the issuance of our convertible notes of $0.9 million and to a lesser extent from exercises of stock options.

During the year ended December 31, 2018, cash provided in financing activities was $1.5 million. This consisted primarily of net proceeds received from the issuance of our convertible notes of $1.3 million, $0.1 million from exercises of stock options, and $0.1 million from the issuance of additional shares of Series A convertible preferred stock.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of December 31, 2019:

	Payments due by period				
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
	(in thousands)				
Convertible promissory notes	$ —	$ 2,452	$ —	$ —	$ 2,452
Total contractual obligations	$ —	$ 2,452	$ —	$ —	$ 2,452

We issued unsecured convertible promissory notes with aggregate principal amounts of $1.3 million and $0.9 million in 2018 and 2019, respectively. The convertible notes accrued interest at 5.0% per year with principal and interest due at maturity. The convertible notes automatically convert upon a qualified financing event at a conversion price equal to 85% of the price per share of the qualified financing. In May 2020, the outstanding principal balance of the convertible notes of $2.2 million and accrued interest of $0.1 million converted into 2,333,117 shares of our Series B-1 convertible preferred stock.

Under our license agreements, we have payment obligations that are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and are required to make royalty payments in connection with the sale of products developed under those agreements.

We received an aggregate of $0.8 million in grants from the LSDF. In connection with the agreements, LSDF retained the right to receive cash payments of up to 2.0 times the amounts received, or $1.5 million, upon the occurrence of specified triggering events, including an initial public offering. We carry a liability on our balance sheet equal to the fair value of this repayment obligation. As of December 31, 2019, we were unable to estimate with certainty the timing or likelihood of achieving any such milestones or triggering events, or making future product sales and, therefore, any related payments are not separately presented within our contractual obligations. For additional information regarding these agreements, including our payment obligations thereunder, see the sections of this prospectus titled "—Our Collaboration and Grant Agreements," "Business—Our Collaboration and Grant Agreements," as well as our financial statements and related notes included elsewhere in this prospectus.

We enter into agreements in the normal course of business with contract manufacturing organizations and contract research organizations for clinical trials, preclinical studies, manufacturing, and other services and products for operating purposes, which are generally cancelable upon written notice. These obligations and commitments are also not are not separately presented here within.

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. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Derivative Liability, Convertible Notes Discount and Amortization

Our convertible notes have conversion and redemption features that meet the definition of an embedded derivative and are therefore subject to derivative accounting. The initial fair value of the derivative is recorded as a discount to the convertible notes, with a corresponding derivative liability. The discount to the convertible notes is amortized using the effective interest method. The amortization of the discount is included in other income (expense), net in our statements of operations and comprehensive loss. The derivative liability related to these features is recorded at estimated fair value on a recurring basis. Any changes in fair value are reflected in other income (expense), net in our statements of operations and comprehensive loss at each period end while such instruments are outstanding. The derivative liability was remeasured to fair value until its settlement in May 2020 upon the conversion of the underlying convertible notes into shares of our Series B-1 convertible preferred stock.

Grant Liability

The grant liability associated with the grants from the LSDF is accounted for under Accounting Standards Codification, or 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 in our statements of operations and comprehensive loss at each period end. The fair value of the grant liability was estimated using 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 us, 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 we estimate. However, total payments under the agreements will not exceed $1.5 million.

Grant Income

In January 2019, the Alzheimer's Association awarded us a $1.0 million *Part the Cloud* research grant. Grant proceeds must be used to advance our ATH-1017 product candidate in the Alzheimer's disease setting. Under the terms of the agreement, we received $776,000 in 2019 and may potentially receive the remaining $224,000 in 2020 upon the completion of certain development milestones. Reporting of expenses incurred supported by the grant as well as research updates are sent to the Alzheimer's Association semi-annually. We recognize income related to the grant as qualifying expenses under the grant agreement are incurred, in grant income within other income (expense), net in our statement of operations and comprehensive loss. As of December 31, 2019, we had recognized $754,000 in grant income, which is included in other income (expense), net in our statements of operations and comprehensive loss, and had cash received in excess of qualifying expenses of approximately $22,000, which is included in accrued expenses on our balance sheets.

Research and Development Costs

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 expensed 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. We estimate 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, we will adjust the amounts recorded accordingly. We have not experienced any material differences between accrued or prepaid costs and actual costs since inception.

Stock-based Compensation

We maintain a stock-based compensation plan as a long-term incentive for employees, non-employee directors and consultants. The plan allows for the issuance of incentive stock options, non-qualified stock options, restricted stock units, and other forms of equity awards.

We recognize stock-based compensation expense for stock options on a straight-line basis over the requisite service period and account for forfeitures as they occur. Our stock-based compensation costs are based upon the grant date fair value of options estimated using the Black-Scholes option pricing model. To the extent any stock option grants are made subject to the achievement of a performance-based milestone, management evaluates when the achievement of any such performance-based milestone is probable based on the relative satisfaction of the performance conditions as of the reporting date.

The Black-Scholes option pricing model utilizes inputs which are highly subjective assumptions and generally require significant judgment. These assumptions include:

- *Fair Value of Common Stock*. See the subsection titled "—Common Stock Valuations" below.

- *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 we have been privately held and do not have any trading history for our 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. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our 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 mid-point between the vesting date and the end of the contractual term), as we do not have sufficient historical data to use any other method to estimate expected term.

- *Expected Dividend Yield*. We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

See Note 12 to our audited financial statements included elsewhere in this prospectus for more information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options. Certain of such assumptions involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation could be materially different.

We recorded stock-based compensation expense of $0.2 million and $0.3 million for the years ended December 31, 2018 and 2019, respectively. As of December 31, 2019, there was $0.4 million of total unrecognized stock-based compensation expense related to unvested stock options which we expect to recognize over a remaining weighted-average period of 1.41 years. We expect to continue to grant stock options and other equity-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase.

The intrinsic value of all outstanding options as of June 30, 2020 was $ million based on an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover of this prospectus, of which approximately $ million is related to vested options and approximately $ million is related to unvested options.

Common Stock Valuations

Historically, for all periods prior to this offering, since there has been no public market of our common stock to date, the fair value of the shares of common stock underlying our share-based awards was estimated on each grant date by our board of directors. To determine the fair value of our common stock underlying option grants, our board of directors considered, among other things, input from management, valuations of our common stock prepared by unrelated third-party valuation firms in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant,

and factors that may have changed from the date of the most recent valuation through the date of the grant. These factors include, but are not limited to:

- our results of operations and financial position, including our levels of available capital resources;
- our stage of development and material risks related to our business;
- progress of our research and development activities;
- our business conditions and projections;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- the lack of marketability of our common stock as a private company;
- the prices at which we sold shares of our convertible preferred stock to outside investors in arms-length transactions;
- the rights, preferences, and privileges of our convertible preferred stock relative to those of our common stock;
- the likelihood of achieving a liquidity event for our securityholders, such as an initial public offering or a sale of our company, given prevailing market conditions;
- the hiring of key personnel and the experience of management;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and biotechnology industry sectors.

For our valuations performed prior to December 31, 2019, we used the option pricing method, or OPM, back-solve method. In an OPM framework, the back-solve method for inferring the equity value implied by a recent financing transaction involves making assumptions for the expected time to liquidity, volatility and risk-free rate and then solving for the value of equity such that value for the most recent financing equals the amount paid. This method was selected as management concluded that the contemporaneous financing transaction was an arms-length transaction.

For our valuations performed subsequent to December 31, 2019, we used a hybrid method of the OPM and the Probability-Weighted Expected Return Method, or PWERM. PWERM considers various potential liquidity outcomes. Our approach included the use of an initial public offering scenario and a scenario assuming continued operation as a private entity. Under the hybrid OPM and PWERM method, the per share value calculated under the OPM and PWERM are weighted based on expected exit outcomes and the quality of the information specific to each allocation methodology to arrive at a final estimated fair value per share of the common stock before a discount for lack of marketability is applied.

Following the closing of this offering, our board of directors will determine the fair market value of our common stock based on its closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded.

Income Taxes

We recognize deferred income taxes for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. In evaluating our valuation allowance, we consider all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies, and recent financial performance. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance.

As of December 31, 2019, we had $9.4 million of federal net operating loss, or NOL, carryforwards and $1.0 million of tax credit carryforwards which expire over a period of 11 to 20 years. As of December 31, 2019, we had $9.2 million of such NOLs that do not expire.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, substantial changes in our ownership may limit the amount of NOL and research and development credit carryforwards that could be used annually in the future to offset taxable income. The tax benefits related to future utilization of federal and state NOL carryforwards, credit carryforwards, and other deferred tax assets may be limited or lost if cumulative changes in ownership exceeds 50% within any three-year period. We have not completed a Section 382/383 analysis under the Code regarding the limitation of NOL and credit carryforwards. If a change in ownership were to have occurred, the annual limitation may result in the expiration of NOL carryforwards and credits before utilization.

We record unrecognized tax benefits as liabilities or reduce the underlying tax attribute, as applicable, and adjust them when our judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available.

Recent Accounting Pronouncements

See Note 2 to our audited financial statements included elsewhere in this prospectus for additional information.

Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

As of December 31, 2019, we had cash and cash equivalents of $2.1 million. Because our investments are short-term in duration and are invested in instruments with a low risk profile to preserve our capital, we believe that 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 included elsewhere in this prospectus.

Foreign Currency

Our functional currency is the U.S. dollar. As of the date of this prospectus, 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 included elsewhere in this prospectus. However, in the third quarter of 2020, 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 included elsewhere in this prospectus.

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.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have at least $1.07 billion in annual revenue; (2) the last day of the fiscal year in which we are deemed to be a “large accelerated filer,” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of this offering.

BUSINESS

Overview

Athira is derived from the word Athir, the energy that reaches everyone. It captures our mission to develop therapies that can reach and positively impact everyone. We aim to restore neuronal health for those suffering from devastating neurological diseases, including Alzheimer's disease, so that patients can regain their memories, lives, and family relationships.

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 provide rapid 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 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. All of these characteristics are expected to 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 our Phase 1a and Phase 1b clinical trials, ATH-1017 for the treatment of Alzheimer's disease, or AD, was well tolerated with no serious adverse events. These clinical trials recruited 88 subjects, including 11 subjects with mild-to-moderate AD. Nonclinical studies and Phase 1 clinical trials with ATH-1017 demonstrated improvements in brain network activity indicating positive effects on brain function. In the AD subjects, multiple dosing of ATH-1017 significantly improved brain activity as measured by P300 latency, a functional measure that is highly correlated with cognition. By the end of 2020, we plan to initiate a pivotal Phase 2/3 clinical trial for ATH-1017, or LIFT-AD, for the treatment of mild-to-moderate AD with topline results expected by the end of 2022. By the end of 2020, we also plan to initiate 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.

The primary focus of our Phase 1a and Phase 1b clinical trials of ATH-1017 for the treatment of AD was to establish safety and drug exposure levels. ATH-1017 was well tolerated at all tested doses, produced predictable pharmacokinetics with dose-linear exposures, and did not accumulate over the course of treatment. Pharmacodynamic measures evaluating brain penetration, target engagement and brain function with electroencephalogram, or EEG, methods produced a strong suite of data justifying further investigation of ATH-1017 in future clinical trials. Individuals with AD typically experience a general slowing of EEG, including a reduction in higher frequency waves, such as gamma. Gamma power is typically associated with learning, memory and cognitive function. Administration of ATH-1017 treatment increased high frequency gamma power activity with a single dose in both young healthy volunteers and elderly healthy volunteers. Gamma power also improved in AD subjects. P300 latency, a functional measure of working memory processing speed that highly correlates with cognition, was also substantially improved. After a single dose of ATH-1017, all AD subjects tested had improved P300 latency and by the end of an 8-day treatment cycle, average latency across the AD treatment group had returned to levels close to those observed in healthy elderly subjects. Taken together, these results suggest that ATH-1017 has the potential to substantially improve synaptic connectivity and brain function in AD subjects.

AD is a significant unmet medical need with as many as 35 million cases estimated worldwide and no treatments that can significantly reduce the burden on people impacted by the disease. Failures of approaches targeting specific hypotheses of underlying AD pathology highlight the need for novel strategies to address the disease. Regardless of the underlying pathology, it has been established that the loss of synaptic density and breakdown of the neuronal network leads to cognitive impairment in subjects with AD and other forms of dementia. We believe the activation of the hepatocyte growth factor/MET, or HGF/MET growth factor in the brain will lead to increased synaptic density, network

recovery and information transmission in the brain, which could ultimately result in cognitive improvement and clinical benefit.

ATH-1017 is designed to address the broader dementia patient population beyond AD and we are planning to initiate a Phase 2 clinical trial for the treatment of Parkinson's disease dementia, or PDD, by the end of 2021. Dementia is a significant unmet medical need affecting over 50 million worldwide. Given underlying healthcare trends, specifically the aging population globally, dementia patients are expected to grow significantly and almost triple by 2050.

We are pioneering the use of small molecules to promote hepatocyte growth factor/MET, a naturally occurring regenerative system, in neurological disorders. While discovered in the liver, HGF is a critical growth factor across multiple organs, including in the brain. HGF/MET has long been known as a promising therapeutic target for CNS disorders; however, delivery of large proteins or gene therapy to the CNS to augment HGF/MET is challenging due to the invasive methods needed for them to bypass the BBB and the risk of potential adverse immune response. Our novel BBB-penetrating small molecules are designed to overcome many of these hurdles, allowing us to efficiently tap into the regenerative potential of HGF/MET. For therapeutic applications in CNS disorders, particularly AD, treatments that target neuronal growth factors can potentially accomplish several therapeutic goals, including rapid cognitive improvement and sustained neuroprotective effects.

We believe that our ability to enhance the body's repair mechanism of HGF/MET through our ATH platform has the potential to address a wide range of clinical applications ranging from CNS disorders, such as AD, PDD, multiple sclerosis, or MS, and amyotrophic lateral sclerosis, or ALS, to more peripheral conditions such as neuropathy. In addition, we believe that HGF/MET biology plays a role in neuropsychiatric disorders such as depression and anxiety. Currently we have two preclinical candidates for non-AD indications: ATH-1018, which is being advanced to address depression, and ATH-1019, which is being advanced to address peripheral neuropathy. Our ATH platform allows us the flexibility to engineer compounds that are BBB-penetrating or that generate specific activity in the periphery and molecules are suitable for subcutaneous or oral route of administration.

Our Team and Investors

Our leadership team includes experienced neuroscience biotech executives who have both developed and commercialized CNS drugs and founded successful companies. Dr. Kawas, our founder and chief executive officer, has been essential in creating our innovative translational development strategy. Dr. Hans Moebius, our chief medical officer, is a pioneer in the AD space and led the effort in getting Namenda, among other CNS drugs, approved. Dr. Mark Litton, our chief operating officer, is one of the co-founders and builders of Alder BioPharmaceuticals, which was acquired by Lundbeck A/S in October 2019. Dr. Kevin Church, our vice president of discovery, has over 10 years of research and management experience in the biotech space and is an expert in HGF biology.

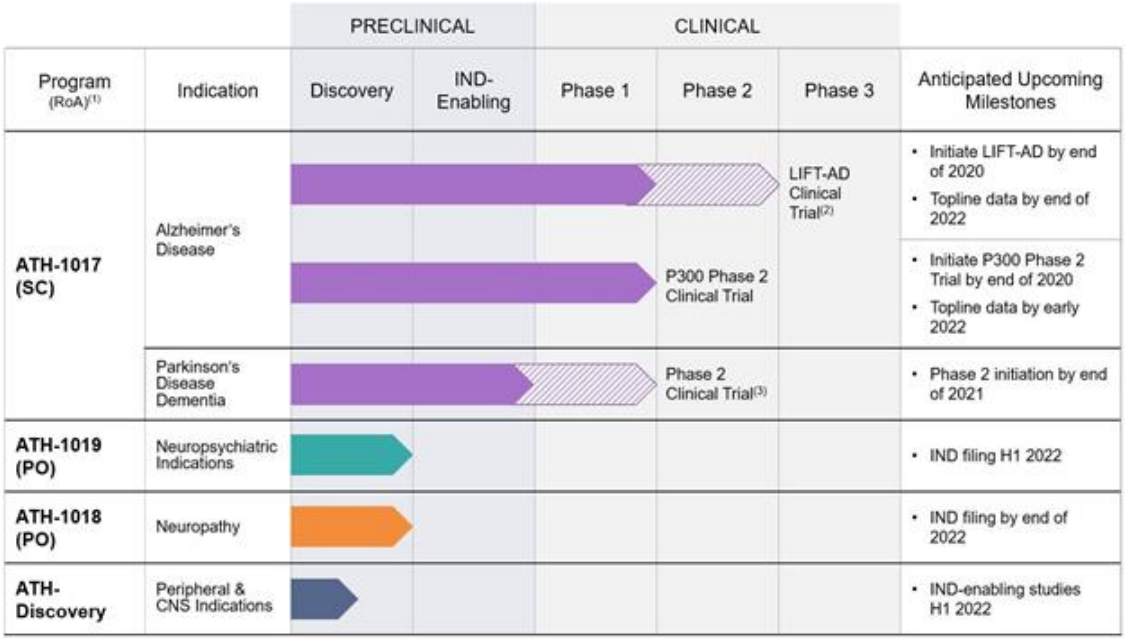
Our advisory board is a world-class team of leaders in the neuroregenerative, drug development and neurophysiology fields, including Dr. Larry Ereshefsky and Dr. Marwan Sabbagh. Dr. Ereshefsky is a pioneer in the application of translational drug development tools, including neurocircuitry/biomarker-based strategies, such as qEEG, ERP P300 latency, and cognitive and behavioral paradigms. Dr. Sabbagh, the Director of Cleveland Clinic Lou Ruvo Center for Brain Health, is considered to be one of the leading experts in AD and dementia.

Our team is further supported by a group of investors that share our vision, mission, and commitment to develop innovative therapies for neurodegeneration. Our key investors include Perceptive Advisors, RTW Investments, Viking Global Investors, Venrock Healthcare Capital Partners, Franklin Templeton, Rock Springs Capital, LifeSci Venture Partners, Surveyor Capital (a Citadel company), Highside Capital Management, Logos Capital, funds managed by Janus Henderson Investors, Sofinnova Investments, and Avidity Partners.

Our Pipeline

Figure 1 below illustrates the current development stage of our ATH compounds and discovery research programs. We are expanding our ATH platform to additional indications in the CNS and peripheral nervous system as we aim to improve neuronal health in multiple disorders.

Figure 1. Summary of Our Preclinical and Clinical ATH Programs.



(1) RoA: route of administration; SC: subcutaneous; PO: oral.

(2) ATH-1017 for AD, is moving from Phase 1b to a potentially pivotal Phase 2/3 clinical trial based on discussions with FDA.

(3) Following IND clearance, we plan to initiate a Phase 2 clinical trial in PDD based on results from Phase 1a and 1b clinical trials with ATH-1017.

Our Strategy

We intend to create, develop, and commercialize therapeutics with the potential to transform lives by repairing, restoring, and reversing the damage to nerve cells throughout the body. Key aspects of our business strategy to achieve these goals are to:

- *Rapidly advance ATH-1017 through clinical development for AD*. We believe ATH-1017 has the potential to rapidly improve cognition and durably improve the lives of the millions of people suffering from AD who currently have limited therapeutic options. We plan to initiate two clinical trials for AD by the end of 2020 to accelerate our development timelines and further inform our development decisions. The first of these clinical trials is LIFT-AD, our pivotal Phase 2/3 clinical trial evaluating the holistic impact of ATH-1017, with topline results expected by the end of 2022. The second clinical trial will be our P300 Phase 2 clinical trial for AD evaluating the overall effects of ATH-1017 on working memory processing speed and cognitive measures, with topline results expected by early 2022,.

- *Expand the development of ATH-1017 to include additional indications and delivery methods*. We are developing ATH-1017 as a treatment for mild-to-moderate AD, but over time we aim

to expand development to cover all stages of AD. 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 PDD to commence by the end of 2021. ATH-1017 is initially being developed to be delivered via pre-filled syringes, and we are exploring the development of alternative delivery devices, including multi-dose pen injectors, to increase patient comfort and ease of use for patients and caregivers, ultimately improving patient compliance and outcomes.

- *Focus on translational and functional endpoints to efficiently develop product candidates*. We intend to use highly translatable and predictive measures, such as EEG and event-related potential, or ERP, methods, early in development to guide clinical dose decisions, provide predictable measures for potential clinical benefit, and rapidly advance product candidates through clinical development. We have focused on changes in cognition and function, coupled with measures of brain function with EEG and ERP, allowing for more efficient and cost-effective clinical trials.

- *Continue developing additional pipeline programs and utilize our ATH platform for further drug discovery*. Our strategy is to only advance product candidates that show both strong translation and early predictive clinical data. We plan to continue growing our discovery organization in the field of neuronal health and regeneration by building on our strong foundational knowledge of neuronal network, behavior, and translatable measures. We believe that our ability to enhance the body's repair mechanism of HGF/MET through our ATH platform has the potential to address a wide range of clinical applications ranging from CNS disorders, such as AD, PDD, MS, and ALS, to more peripheral conditions such as neuropathy. In addition, we believe that HGF/MET biology plays a role in neuropsychiatric disorders such as depression and anxiety.

- *Optimize the value of ATH-1017 and other candidates in major markets*. We own worldwide rights to ATH-1017 as well as our pipeline of small molecule candidates. We plan to develop and pursue approval of ATH-1017 and other future candidates in major markets. Where appropriate, we may use strategic collaborations or partnerships to accelerate development and maximize the commercial potential of our programs.

Addressing the Key Aspects of Neuronal Health and Alzheimer's Disease

Maintenance of neuronal health is critical to preserving normal neuronal and brain function. Several neurodegenerative diseases, such as AD, PDD, MS, and ALS, share a common consequence of continued neuronal damage and death that ultimately lead to progressive impairment of the neuronal network and loss of both cognitive and general functions. Globally, these diseases affect millions of people.

AD, our initial focus, is a progressive dementia caused by widespread neurodegeneration. The causal pathophysiological mechanism of AD has yet to be identified. This fundamental lack of understanding, combined with the complex range of pathological features, has led to a history of late-stage drug development failures. Regardless of the underlying pathology, it has been established that the loss of synaptic density and breakdown of the neuronal network leads to cognitive impairment in subjects with AD and other forms of dementia.

There is a vast unmet need for effective pharmacological treatment for AD. Despite significant investments in drug discovery programs and strategies to treat AD there have been no approved therapeutics developed that can boost cognition, alter the course of the disease, and provide long-term symptomatic improvement. There are currently four marketed drugs for the management of AD symptoms: donepezil, galantamine, and rivastigmine (all acting on cholinergic pathways) and memantine (targeting the NMDA receptor and glutaminergic pathways). The long-term efficacy for these drugs has not been proven and they provide only temporary and modest clinical improvement.

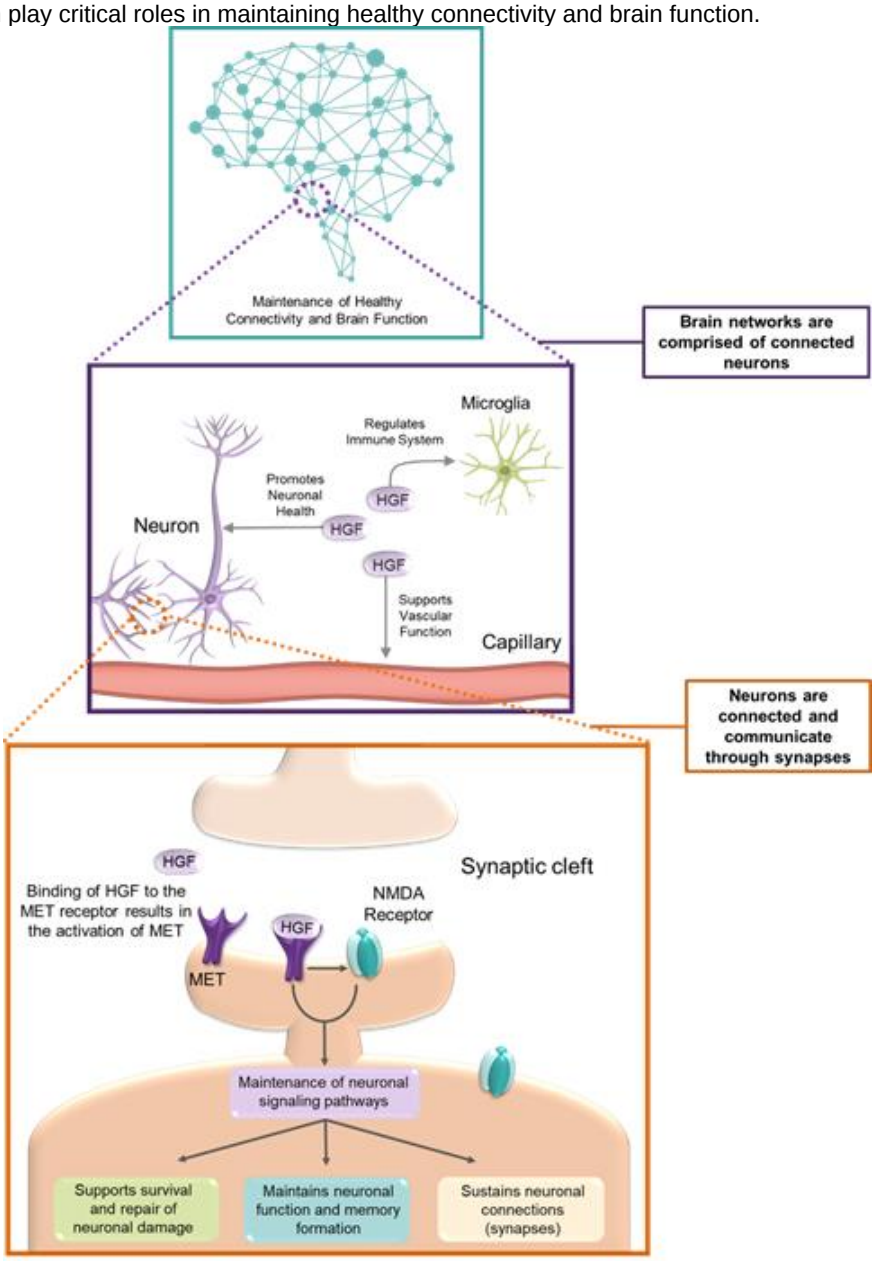
Additionally, there are currently a number of experimental therapeutic agents for AD in various stages of development with clinical testing directed towards amyloid-beta, or Aβ, clearance, and inhibition of Tau protein aggregation or phosphorylated-Tau, or pTau, clearance. Recent clinical failures involving Aβ clearance highlight the incomplete understanding of the pathological processes in AD and clearly demonstrate the need for novel strategies to fight the disease.

The HGF/MET Pathway – A Crucial System for Regeneration

The HGF/MET system has diverse roles relevant for synaptic function, network recovery, survival, and regeneration. We believe activation of HGF/MET offers a unique opportunity to address many aspects of AD pathology through a single target approach. Promoting the HGF/MET system has been shown to have multiple downstream beneficial effects relevant to improving symptoms and reversing the neurodegenerative process, making it an ideal target for complex neurodegenerative diseases, as illustrated below in Figure 2.

Figure 2. Normal HGF/MET System and Pathway. HGF is a protein ligand that binds to MET, which is a receptor expressed on the surface of neurons, glia, and vascular cells in the brain. HGF binding converts MET to an active state and initiates processes including changes in gene expression that help maintain normal cellular health and function. In the brain, the HGF/MET system contributes to neuronal signaling and healthy function including regulating N-methyl-D-aspartate, or NMDA, receptor activity, modulating glial activity to regulate inflammation, and helping maintain cerebral blood flow. These multiple

downstream effects of the HGF/MET system play critical roles in maintaining healthy connectivity and brain function.



The multi-modal effect of HGF/MET across the nervous, vascular, and immune systems may address the impact of neurodegenerative diseases where neuronal health, cerebral blood flow, and excess inflammation play a significant role in disease progression. Promotion of the HGF/MET system has the potential to directly halt neurodegeneration, induce regeneration, improve cerebral blood flow, and reduce inflammation.

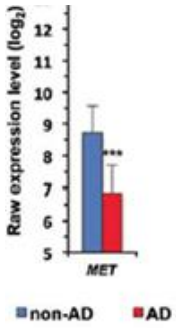
Significant Scientific Data Support HGF/MET's Role in Maintaining Neuronal Health and Function

Normal MET expression is crucial in maintaining the healthy adult brain. Multiple studies have demonstrated that the MET system is strictly regulated to have a stable expression pattern. MET is one of a small number of uniquely regulated genes with very high differential stability in its quantitative pattern of mRNA gene transcript levels across hundreds of structures throughout the neurotypical healthy adult brain. In fact, compared to approximately 17,000 other human genes, the MET receptor has the most differentially stable expression pattern in the cortex of the normal adult human brain. The cortex is a brain region that has important roles in learning, memory, and executive functioning, and this stable expression pattern demonstrates that the MET receptor is an important signature of a healthy brain.

Additionally, although MET expression is very stable in healthy adults, expression is reduced in AD subjects, particularly in the hippocampus, as illustrated below in Figure 3. Previous studies have shown that AD subjects have approximately 25%-75% less MET expression in different brain regions compared to healthy age-matched adults. This reduction highlights another rationale to rescue the activity of this critical regenerative system. The HGF/MET system is neuroprotective in models of neurodegenerative disorders, including AD, PDD, MS, and ALS. Amplification of the HGF/MET system has the potential to provide critical neuroprotective and neuroregenerative effects to rescue damaged and dysfunctional neurons and promote recovery of cognitive functions.

Figure 3. Neuronal MET Expression Is Reduced in the Hippocampus of AD Subjects. A study measuring MET mRNA levels in the hippocampus of AD subjects shows reduced MET expression compared to healthy samples, suggesting that the reduced activity of this critical regenerative system may potentially play a role in the progressive neurodegeneration in AD.

MET and mRNA Levels



Source: Hokama et al., 2014.

Multiple third-party studies have documented the regenerative impact of HGF/MET promotion in models of AD, PDD, MS, and ALS, with examples shown in Figure 4 below. Notably, promotion of the HGF/MET system improved memory in AD and PDD models and improvement in neuronal survival was reported in various disease models including MS and ALS. These studies indicate that an enhanced HGF/MET system has substantial beneficial effects and support the HGF/MET system as a therapeutic target in a diverse array of nervous system disorders.

Figure 4. Effects of HGF Treatment in Animal Models of CNS Disorders. Below is a list of preclinical studies conducted by third parties that shows the beneficial effects of HGF/MET on functional endpoint or processes that are critical in recovering neuronal health and function. These studies demonstrate that boosting the activity of the HGF/MET system, whether through direct injection of HGF or increasing expression of HGF by gene therapy techniques, promotes neuronal health and regeneration, and rescues memory and function in several animal models of CNS disorders.

Disease	Animal model (species)	HGF Delivery Method	Outcomes	Reference
AD	Aβ-injection (mouse)	HGF gene therapy	Improvement in memory, increased cerebral blood flow, increased BDNF expression	Takeuchi et. al. 2008
Parkinson's	6-OHDA (rat)	HGF gene therapy	Improved survival of dopaminergic neurons, improved motor function	Koike et. al. 2006
Brain ischemia	Transient ischemia (gerbil)	Injection of HGF protein	Improved neuronal survival	Miyazawa et. al. 2007
ALS	SOD1-G93) (mouse)	HGF gene therapy	Improved survival of motor neurons, prolonged lifespan	Sun et. al. 2002
Cerebral infarction	Embolism (rat)	Injection of HGF protein	Improvement in learning and memory, improved neuronal survival	Date et. al. 2004
Spinal cord injury	Trauma (rat)	HGF gene therapy	Promoted neuron survival and axonal regrowth, improved functional recovery	Kitamura et. al. 2007
MS	EAE (mouse)	Injection of HGF protein	Promoted remyelination of damaged axons, improved clinical scoring	Bai et al., 2012
Peripheral neuropathy	Nerve crush (mouse)	HGF gene therapy	Promoted regeneration of nerve tissue by recruitment of Schwann cells and remyelination	Ko et al., 2018

6-OHDA: 6-hydroxydopamine; BDNF: brain-derived neurotrophic factor; EAE: experimental autoimmune encephalomyelitis

As demonstrated by these studies, HGF/MET has long been known as a promising therapeutic target for CNS disorders, but the delivery of large proteins or gene therapy to the CNS to augment HGF/MET has been problematic and fraught with challenges. These approaches are not BBB-penetrating and require invasive methods to deliver to the CNS, which increases the risk of an immune reaction. Further, they are also expensive and more challenging to scale which might limit their availability to patients.

Challenges with Approved and Traditional Neuronal and AD Therapy Approaches

The development of neuronal therapies presents unique challenges including: an imperfect understanding of the biology, the presence of the BBB that restricts the flow of drugs to the brain, and a lack of translatability of preclinical study results in human trials. Currently approved neuronal therapies have limited efficacy, poor side effect profiles, and minimal impact on quality of life. There remains an urgent need for new and novel approaches to address most neuronal disorders including progressive and severe conditions such as AD, PDD, MS, and others.

Specific to AD, each of the currently approved therapies only works on a single neurotransmitter target with limited and transient effects on cognition and low tolerability, which negatively impacts compliance and minimally reduces the caregiver burden. Other therapies in development that target a slowdown in disease progression have a marginal benefit on clinical decline and are mainly focused on mild cognitive impairment, or MCI, and early-mild AD, and lack any immediate benefit in reducing the burden on people impacted by the disease. These approaches rely on the body's repair mechanisms, which may be damaged, and do not promote additional activation of regenerative pathways. This can lead to variability of treatment outcomes and longer clinical development timelines.

Further complicating drug development in AD has been the lack of utilization of biomarkers and measures that are able to detect early signs of efficacy and find promising candidates to take forward into larger trials. These methods have revolutionized clinical research in oncology and other therapeutic areas, but traditionally not in AD. Historically, AD testing in clinical trials has relied heavily on imaging techniques to assess changes in amyloid PET scans over several years, creating enormous costs and elongated timelines for the development process while not showing any direct correlation to cognitive functional improvement. We believe that these traditional methods can be replaced or supplemented by the use of rapid, non-invasive markers of brain activity and cognitive processing, like EEG and ERP.

Our Differentiated Approach

We believe our ATH platform of small molecules will promote neuronal health and function through stimulating the HGF/MET system. Our small molecules are BBB-penetrating, can be delivered non-invasively, have very low risk of an immune reaction and are more cost efficient to manufacture and distribute. Boosting the HGF/MET system leads to the following primary downstream effects:

- *Modulation of NMDA neurotransmitter system by enhancing synaptic localization and signaling*, leading to a rapid increase in brain network function. The NMDA receptor plays a key role in memory and learning. Other approaches work directly on the NMDA receptors and lack the specificity to modulate the NMDA receptor to the synaptic cleft, which is required to increase transmission of brain signals.

- *Restoration of traditional neuronal growth factor pathways* that are critical to neuronal survival, and activate brain systems that reduce oxidative stress, which is expected to reduce damage and slow down disease progression and improve network activity. Many therapies in development are focused only on slowing disease progression.

- *Improvement in cerebral blood flow, as well as reducing inflammation* by modulating inflammatory cytokine expression from the glia. Many other therapies only have a single mode of activity.

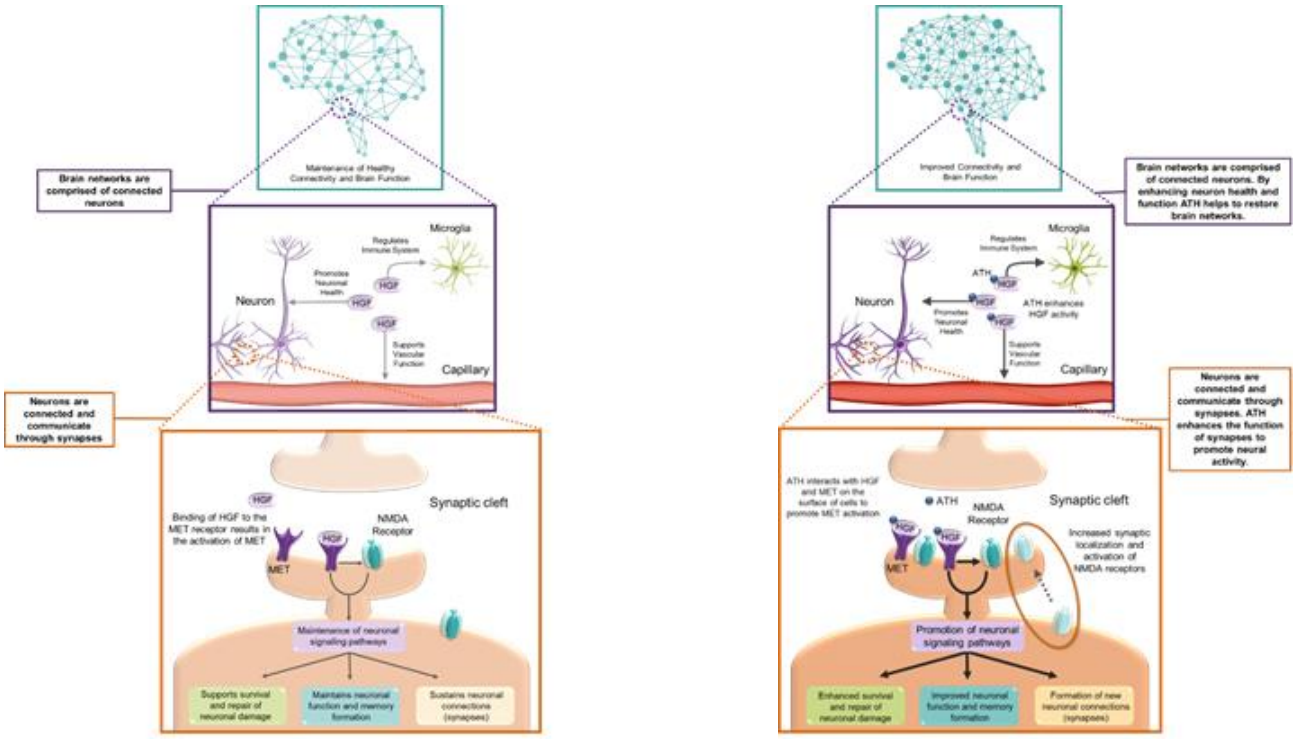
These factors positively impact neuronal health and function, not only by slowing down disease progression but also by improving brain network activity and function. We believe these effects position Athira, and initially ATH-1017, to address the complex pathology in neurodegenerative diseases.

We have designed ATH-1017 to enhance the ability of HGF to activate MET. This substantially increases MET activation levels, and amplifies the beneficial effects downstream of the HGF/MET system.

Figure 5. Our ATH Small Molecule Candidates Enhance the HGF/MET System and Promote Multiple Beneficial Effects with the Potential to Improve Connectivity and Brain Function in Neurodegenerative Diseases.

HGF Activity is Responsible for Healthy Brain Function and Is Reduced in AD

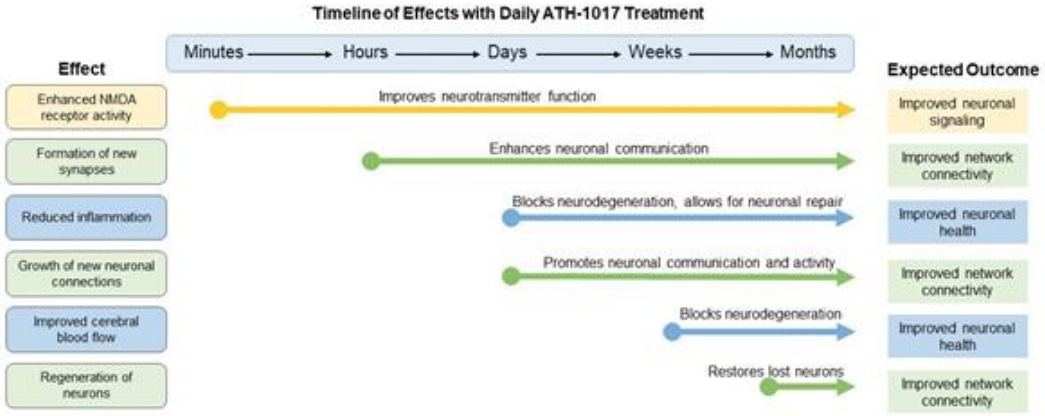
ATH-1017 Enhances HGF Activity to Promote Brain Health and Neuronal Regeneration



By promoting endogenous pro-survival and regenerative mechanisms orchestrated by HGF/MET signaling, our ATH platform represents a novel path to treat AD and neurodegeneration using a systemic approach. Activation of the HGF/MET system captures the modulation of the NMDA neurotransmitter pathway. Modulation of neurotransmitter systems serves as the basis for the four currently approved AD drugs. However, unlike these currently approved AD drugs, ATH-1017 is designed to also activate regenerative and anti-inflammatory pathways.

Figure 6. Our ATH Candidates Promote the HGF/MET System Leading to Both Rapid and Long-term Beneficial Effects. We expect that following administration of ATH-1017, the HGF/MET system will activate and lead to several downstream effects. These effects are expected to rapidly boost cognition

with multiple regenerative mechanisms leading to a stable and sustained recovery of the brain network and function.



For therapeutic applications in CNS disorders, particularly AD, treatments that target neuronal growth factors can potentially accomplish several therapeutic goals including rapid cognitive improvement and sustained neuroprotective effects.

Our Use of Highly Translatable and Predictive Measures to Guide Clinical Development

We believe EEG and ERP have the potential to revolutionize the paradigm in AD clinical trials. EEG and ERP methods are highly translatable and predictive measures that can guide clinical dose decisions and provide predictable measures of potential clinical benefit. These methods focus on changes in cognition and function, can result in more efficient and cost-effective clinical trials, and potentially provide an accelerated development path compared to traditional AD drug development programs.

EEG and ERP Methods Reflect Brain Activity and Function

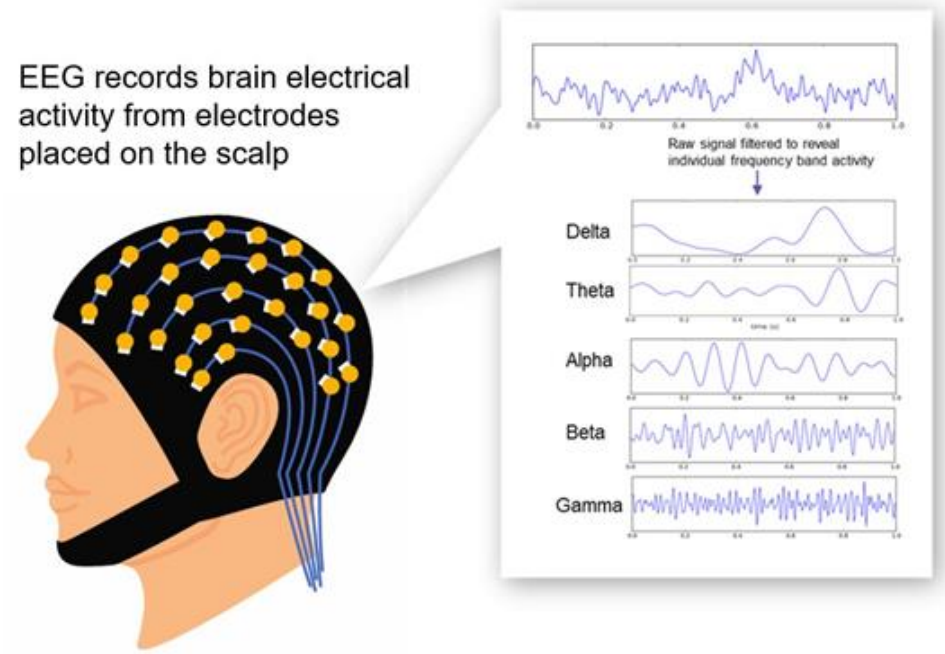
Our focused drug development approach aims to understand the potential clinical benefit of a product candidate at the early stages of clinical development by utilizing EEG and ERP methods. Commonly used in clinical research and clinical practice, EEG and ERP methods provide valuable insight into cognitive function, but have been largely overlooked in AD clinical trials. At Athira, we are innovatively using these non-invasive methods to gain early insight into potential therapeutic effects. Improvement in the brain network, as well as changes in neurotransmitter activity, can be captured in the electrical activity of the brain. EEG methods measure the brain's electrical activity from electrodes on the scalp. This noninvasive look at brain activity is highly informative and can give insight into the brain penetration and neuroactivity of therapeutics directed to the brain. EEG is a measure of the brain at rest, while ERP is measured from the same electrodes but only arises in response to a task-related stimulus. EEG/ERP methods can give substantial insight into the overall brain health and connectivity, as these measures are significantly altered in disorders that lead to cognitive impairment, such as AD. Certain EEG/ERP components are valuable measures of cognition, such as quantitative EEG, or qEEG, an assessment of high frequency gamma power brain waves, and the P300 latency component of ERP.

For ATH-1017, we incorporated a variety of translatable tools and measures into our clinical development plan. These measures, including both qEEG and P300 latency, have guided dose selection and provided predictive measures of cognitive improvement. By focusing on these direct measures of brain activity and cognition, we believe we will be able to more efficiently develop ATH-1017 for treatment of AD and broader dementia.

Quantitative Electroencephalogram: qEEG

EEG is a way to measure the electrical activity of the brain using small electrodes placed on the scalp. Neurons communicate and perform all functions using electrical impulses. EEG captures this electrical activity through the scalp and displays these electrical impulses as waves, as illustrated in Figure 7 below. The electrical activity will present at different frequencies or waves which provide various insights into neuronal health. We are most focused on the faster, higher frequency gamma waves which are associated with learning, memory formation and higher cognitive functions. qEEG is a method to quantitatively determine the amount of electrical signal that resides in each waveform, often described as power.

Figure 7. Noninvasive EEG Recordings Reflect Brain Activity and Function.

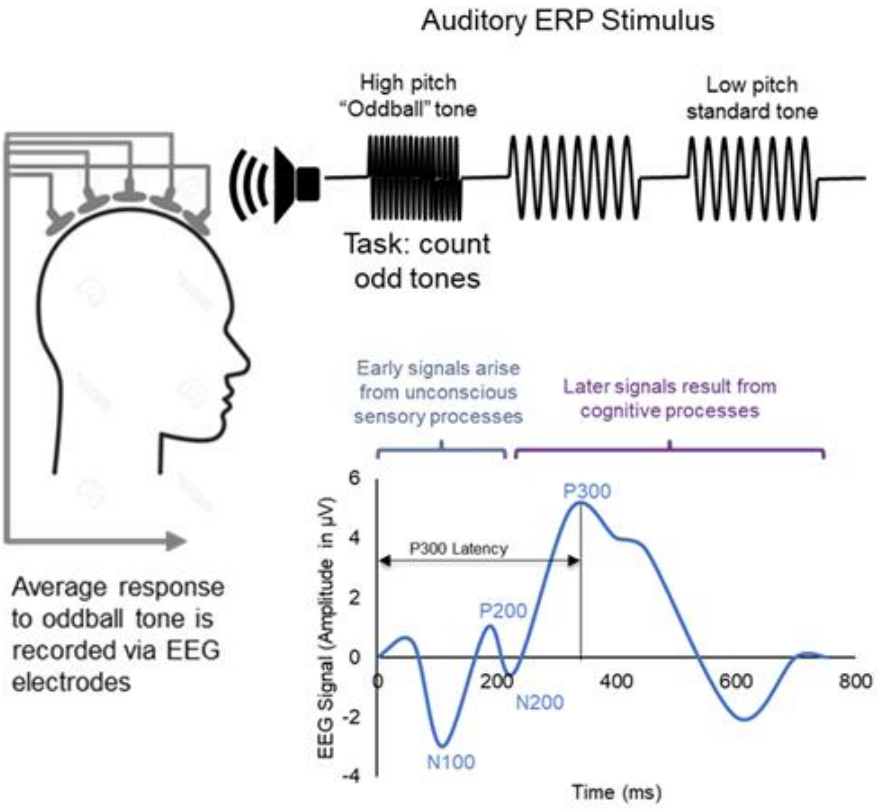


Changes in qEEG power or shifts in the amount of activity in each waveform can be caused by several factors including response to stimulus, cognitive state (healthy or dementia), and CNS-directed therapies. Because qEEG is a non-invasive direct measure of brain activity, it represents a valuable tool for investigating therapies in AD and broader dementia. Changes in qEEG signals following administration of therapies targeting the brain indicate the therapy has reached the brain and likely engaged the intended target. Additionally, AD subjects present a general slowing of qEEG, where activity in higher frequency waves, such as gamma, is reduced. If therapies can reverse this pattern in AD, and increase gamma power, this may suggest treatment has helped improve brain activity. We utilized qEEG in our ATH-1017 Phase 1 clinical trial in healthy young, healthy elderly, and AD subjects as a measure of CNS penetration and target engagement.

Event-related Potential: P300

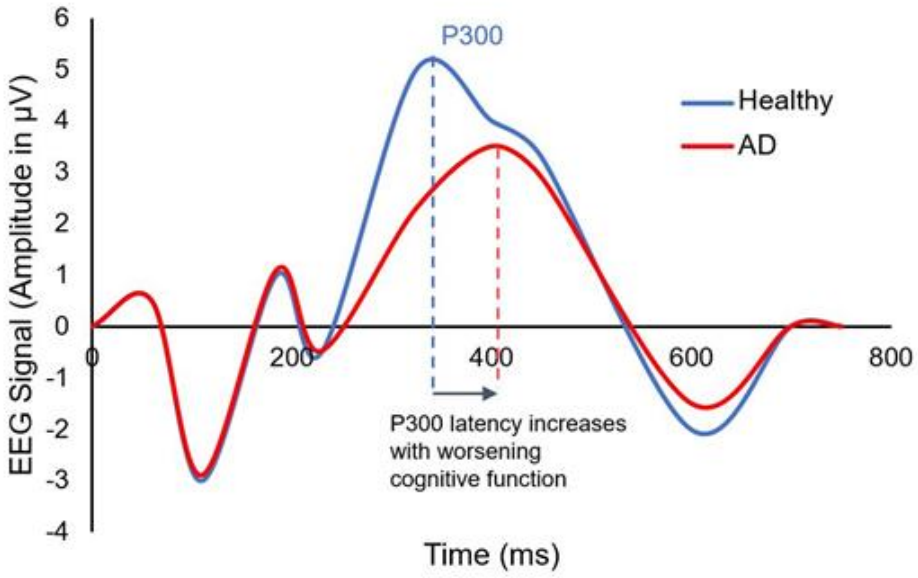
ERP refers to changes in the electrical activity of the brain in response to external stimuli. Recording brain activity while a subject is presented with a task reveals neural activity related to cognitive processing. Presenting subjects with a stimulus associated with a task, such as counting specific tones within a sequence, induces a series of electrical peaks that represent cognitive processing and memory access. P300 is the peak positive signal which is reported to typically arise 300 milliseconds after a tone stimulus and is the most studied component of the ERP waveform.

Figure 8. ERP Recording with an Auditory Oddball Paradigm.



The latency, or the amount of time that it takes to reach the peak of the positive wave following the stimulus, is typically reported to be 300 milliseconds in healthy, cognitively normal individuals. Numerous studies have shown that P300 latency is strongly correlated with cognition. P300 latency is increased and continues to worsen as AD and cognitive decline progresses. As an example, P300 latency is expected to be increased in subjects with severe AD, compared to subjects with mild AD. The connection between P300 latency and increased cognitive decline has been characterized in a number of diseases including AD, PDD, Lewy body dementia, Huntington's, major depressive disorder with cognitive impairment, and traumatic brain injury. Loss of synaptic connections and neuronal dysfunction are well characterized in AD, and likely are the primary causes of the increased P300 latency. Figure 9 below illustrates the latency of cognitive processing as demonstrated by the delayed peaks in P300 in AD subjects compared to healthy, age-matched subjects. While the P300 amplitude is often reported as lower in AD subjects compared to healthy, age-matched subjects, this measure is much less consistent and not as strongly correlated to cognition as latency.

Figure 9. ERP Waveforms in AD Subjects Show Increased P300 Latency.

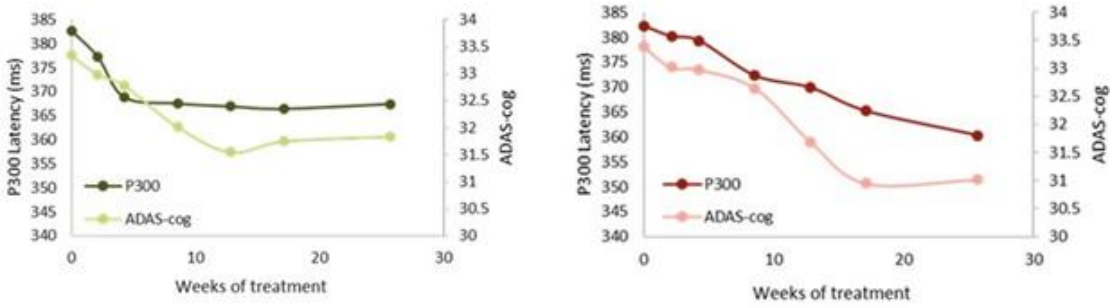


Insights from Approved Therapies

Companies with approved therapies have demonstrated parallel improvement in P300 latency and cognition as assessed by ADAS-cog, as shown in Figure 10 below. While these changes induced by acetylcholinesterase inhibitors are modest and often transient, these previously published results support the correlation of P300 latency and cognition in AD subjects.

Figure 10. Changes in P300 Latency Correlate with Cognitive Outcomes with Treatment of Approved Therapies in AD Subjects.

Donepezil **Rivastigmine**



Source: Adapted from Thomas et al., 2001.

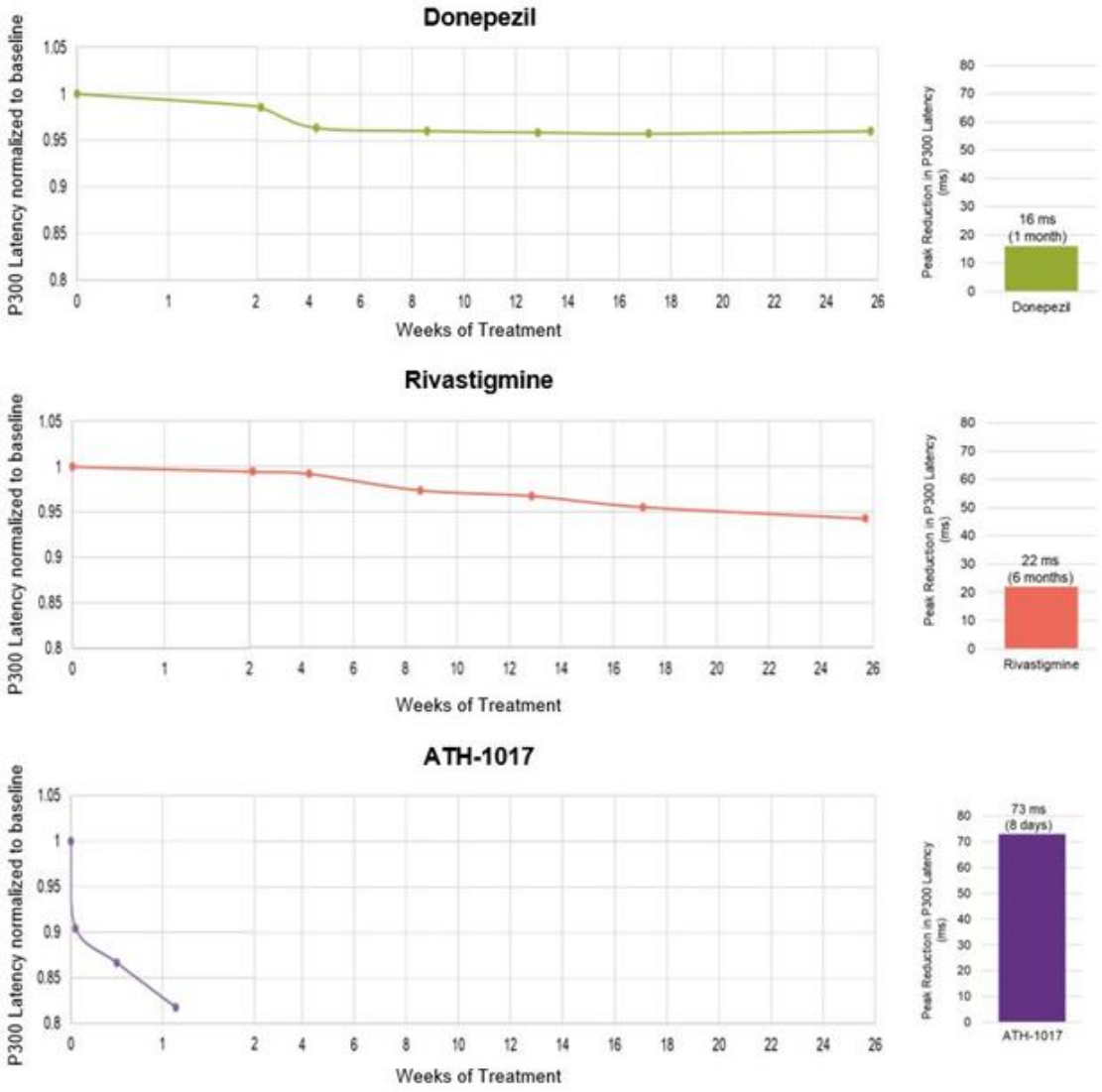
Figure 11. Studies Suggest Changes in P300 Latency Have Been Predictive of Changes in Cognition.

Treatment	P300 Latency Effect	Change in P300 Latency	Population	Cognitive Effect	Summary
ATH-1017	**Improved**	**(73) ms**	**AD**	**To be determined**	**Large magnitude improvement in P300 latency, expected to produce a correlated cognitive improvement.**
Donepezil	Improved	(16) ms	AD	Improved	P300 latency and cognition both improved in mild-to-moderate AD, though improvements were modest.
Rivastigmine	Improved	(22) ms	AD	Improved	P300 latency and cognition both improved in mild-to-moderate AD, though improvements were modest.
Memantine	Improved	(15) ms	AD	Improved	P300 latency and cognition both improved in moderate to severe AD, though improvements were modest.
Scopolamine	Worsened	50 ms	Healthy	Worsened	Scopolamine offers a counter example; P300 latency increases while cognitive performance is reduced.

Source: Results for donepezil and rivastigmine adapted from Thomas et al., 2001; results for memantine adapted from Sallach et al., 2011, and results for scopolamine adapted from Potter et al., 2000.

The magnitude of effects in P300 latency measures for current AD treatments is shown in Figure 12 below. We believe the large and rapid effect of ATH-1017 illustrated below further supports the likely translational therapeutic potential of ATH-1017 to impact cognition in AD.

Figure 12. ATH-1017 Had a Large and Rapid Effect on P300 Latency in AD Subjects.



Source: Data for donepezil and rivastigmine adapted from Thomas et al., 2001. ATH-1017 was not tested for the same duration as donepezil and rivastigmine (9 days for ATH-1017 vs 26 weeks).

Applications to our ATH Platform

In CNS disorders, fluid or imaging biomarkers have been extensively used in drug development. However, these can be invasive and expensive, and inconclusive in determining the connection of these biomarkers to cognition. We sought to develop a translational strategy for ATH that was highly correlated to brain function and cognition which led us to use EEG/ERP for the clinical development of ATH-1017. We believe these measures are particularly well-suited to provide insight into early therapeutic effects in AD, given that as cognitive decline progresses, subjects display a decrease in EEG gamma power, and a progressive increase in ERP P300 latency.

Utilizing EEG/ERP as non-invasive and efficient translatable measures early in clinical development allows us to rapidly assess therapeutic effects and helps to inform future clinical trial design. Positive changes in EEG and ERP P300 latency potentially indicate a positive cognitive effect of our ATH treatments, which increases our confidence that these effects may translate to clinical benefit in later-stage clinical trials.

ATH-1017 for the Potential Treatment of AD and Other Neuronal Diseases

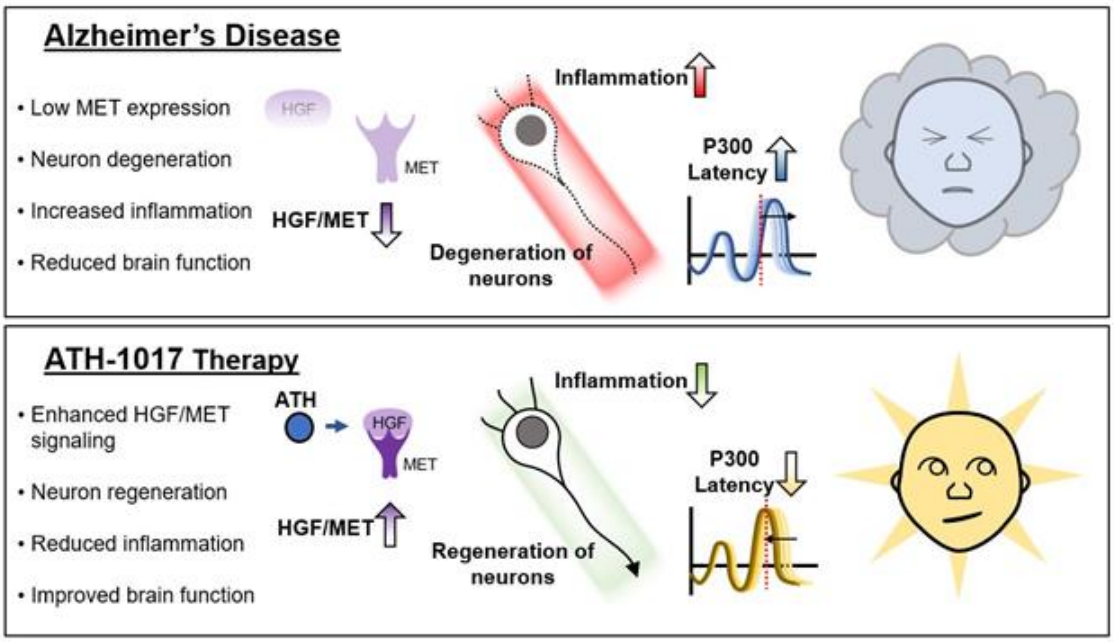
We are developing our lead product candidate, ATH-1017, for the treatment of neurodegenerative disorders, with an initial focus on AD. ATH-1017 is designed to improve neuronal health and promote regeneration, thereby improving symptoms in cognitively impaired subjects. As we continue to develop ATH-1017, we will plan to assess additional functional and behavioral benefits. In our Phase 1a and Phase 1b clinical trials, ATH-1017 for the treatment of AD was well tolerated with no serious adverse events across 88 subjects, including 11 subjects with mild-to-moderate AD. Additionally, ATH-1017 treatment led to improvements in brain network activity that indicated positive effects on brain function. In the AD subjects, multiple dosing of ATH-1017 significantly improved brain activity as measured by P300 latency. We identified ATH-1017 in 2016 and less than five years later, we are planning to initiate our Phase 2/3 Lift-AD trial, which has the potential to be a pivotal trial. By the end of 2020, we plan to initiate our potentially pivotal LIFT-AD clinical trial for ATH-1017 for the treatment of mild-to-moderate AD, with topline results expected by the end of 2022. By the end of 2020, we also plan to initiate our P300 Phase 2 clinical trial in mild-to-moderate AD to evaluate the overall effects of ATH-1017 on working memory processing speed and cognitive measurements, with topline results expected by early 2022, which will inform our strategy with respect to an additional Phase 3 clinical trial. We believe that ATH-1017 has the potential to provide meaningful benefit to individuals impacted by AD and substantially enhance overall quality of life for the subjects and their families.

Mechanism of Action

Growing evidence suggests that complex CNS disorders, such as AD, are unlikely to be caused by a single route of pathology. Modulation of a neuronal growth factor has gained considerable attention for the potential treatment of neurodegenerative disorders. Our lead candidate, ATH-1017, is a small molecule therapeutic specifically designed to promote the ability of HGF to activate MET. This promotion substantially increases MET activation levels and amplifies the beneficial downstream effects of the HGF/MET system, with several attributes relevant to AD:

- HGF/MET is a critical neurotrophic factor for normative brain function and it is reduced in AD subjects;
- promotion of the HGF/MET system has shown in several animal models the potential to directly halt neurodegeneration and induce regeneration, improve cerebral blood flow, and reduce inflammation; and
- we expect HGF/MET system activation to improve P300 latency, as observed in AD subjects after ATH-1017 treatment in our Phase 1a and Phase 1b clinical trials.

Figure 13. ATH-1017 Is Designed to Increase HGF/MET Activity and May Promote Regeneration of Neurons, Reduce Inflammation, Enhance Cognitive Processing Represented by a Decreased P300 Latency, and Improve Overall Brain Health and Function.



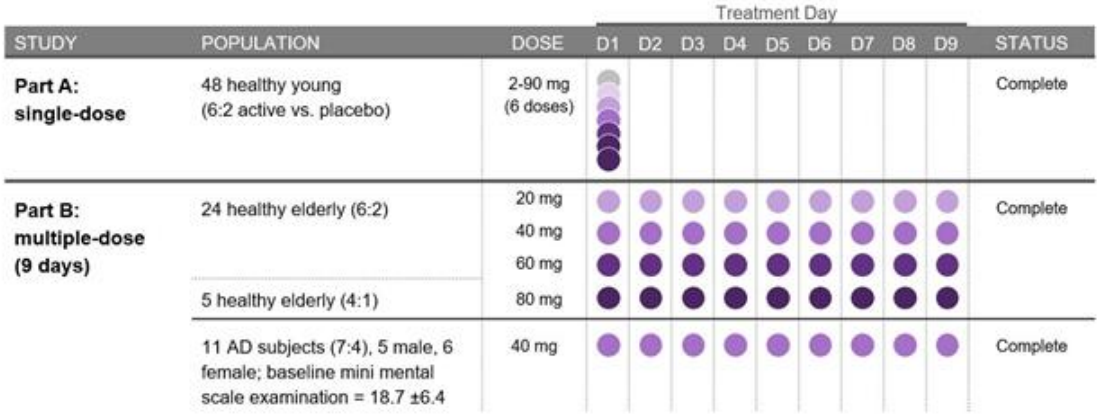
Unlike most approved or in development drugs, ATH-1017 has the potential to be regenerative, and is designed to slow, halt, or potentially reverse the effects of AD all while using a naturally modulated approach.

Clinical Results

Phase 1a and Phase 1b Clinical Trials

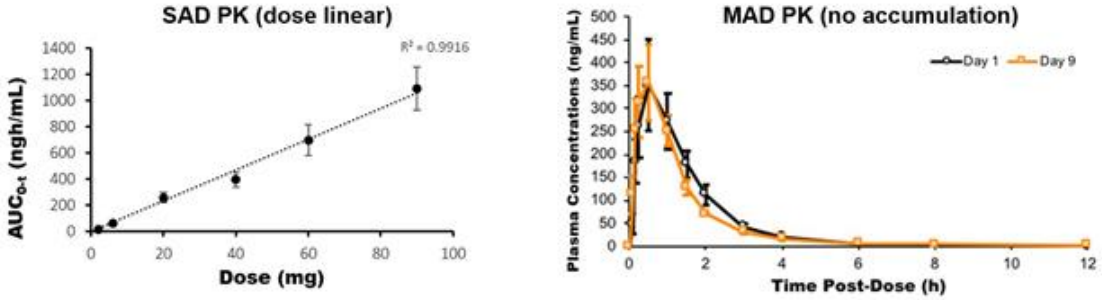
The IND for ATH-1017 in AD was filed in September 2017. Since then, we have completed our Phase 1a and Phase 1b clinical trials, which enrolled a total of 88 subjects, including 11 AD subjects, as illustrated below in Figure 14. The clinical trials were randomized, placebo-controlled and double-blind and consisted of daily single injections over a nine-day period. While the primary endpoints of our Phase 1a single ascending dose, or SAD, and Phase 1b multiple ascending dose, or MAD, trials were focused on safety and assessment of human pharmacokinetics, we also included measures to evaluate effects of ATH-1017 on brain activity in AD subjects. Together, these clinical trials assessed qEEG as a measure of brain circuitry and network activity and ERP as a measure of working memory access and cognitive processes in the brain.

Figure 14. 88 Subjects Included in the Phase 1a and Phase 1b Clinical Trials.



ATH-1017 was shown to be well tolerated with no serious adverse events across a wide dose range (2-90 mg) with single and multiple doses over 9 days. As shown in Figure 15, the PK profile is compelling, with linear dose relationship, no accumulation, and no sex or age effect. We did not have any subject dropout due to serious adverse events during these clinical trials.

Figure 15. ATH-1017 Demonstrated a Dose-Linear PK Profile and Did Not Accumulate with Multiple Doses.



Translation of ATH-1017 Changes in Brain Circuitry Activity

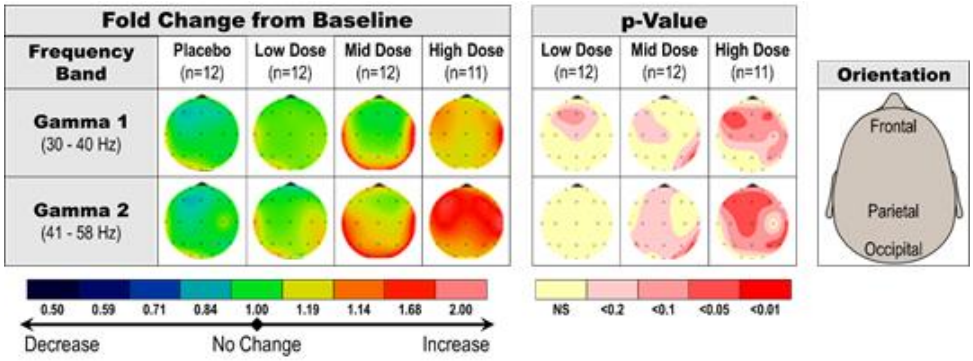
qEEG was used as a translational tool to recapitulate the changes in brain network activity from ATH-1017 that were observed in our preclinical models and to help guide dose selection for late-stage clinical development. We collected qEEG recordings from healthy young, healthy elderly, and AD subjects to determine qEEG changes after the administration of ATH-1017.

In the clinical trials, ATH-1017 increased the levels of the high frequency gamma power which is the frequency band that is associated with learning, memory, and cognitive function. Gamma is typically decreased in AD subjects. ATH-1017 showed dose-dependent and consistent changes in brain activity across all treated cohorts, consistent with the changes observed in non-clinical models.

Quantitative EEG Changes Observed in the Phase 1a SAD Clinical Trial

Rapid induction in the high frequency gamma power was observed after a single dose and is most likely explained by ATH-1017 promoting HGF/MET induced synaptic relocation of NMDA receptors and potentiation of NMDA receptor currents. A dose-dependent increase was observed across the low, mid, and high doses with statistically significant changes at the highest dose levels assessed. Figure 16 below shows the change in qEEG gamma power from baseline following administration of placebo, low dose ATH-1017 (2 and 6 mg, pooled), mid dose (20 and 40 mg, pooled), and high dose (60 and 90 mg, pooled).The p-value maps show the statistics based on analysis of covariance, or ANCOVA, analysis.

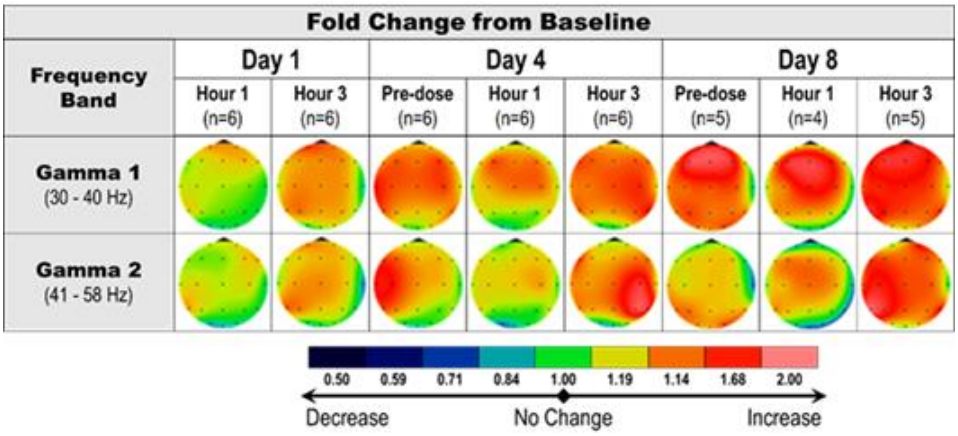
Figure 16. Single Dose of ATH-1017 Increased qEEG Gamma Power in Humans.



Quantitative EEG Changes Observed in Phase 1b MAD Clinical Trial in Healthy Elderly Subjects

The main qEEG effect of ATH-1017 administration at all doses (20, 40, and 60 mg) in the healthy elderly subjects was increased gamma power, both at 3 hours post-dose on Day 1 and across multiple data points collected on Days 4 and 8 for all assessed doses of ATH-1017. Figure 17 below shows the change in gamma power with once-daily administration of the 20 mg dose of ATH-1017 over 9 days. Similar results were observed for the 40 and 60 mg doses.

Figure 17. ATH-1017 Administration Increased qEEG Gamma Power in Elderly Subjects.

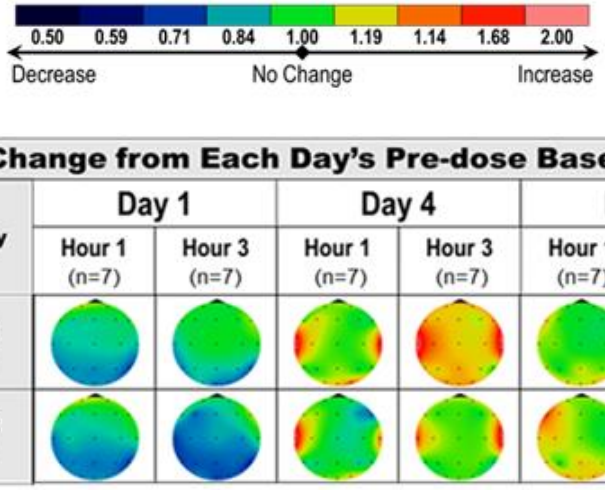


We also observed increased gamma power on Days 4 and 8 at the pre-dose recording: 24 hours after the last dose of ATH-1017, ATH-1017 was measured and shown to be completely cleared from the

plasma. These results suggest that the beneficial effects of ATH-1017 are sustained. The increase in gamma power was specific to the treatment groups as no increase was observed in subjects receiving placebo.

The multiple dose clinical trial in AD subjects (40 mg subcutaneous injection once daily over 9 days) suggested a potential effect in AD subjects. Analysis of qEEG indicates an acute induction of gamma power (Day 4 and Day 8) after multiple doses. Figure 18 below shows emerging recovery of acute gamma power induction after 4 days of ATH-1017 treatment which continues to increase after 8 days of treatment. This pattern was not observed in subjects receiving placebo, where there was no consistent change in acute gamma power induction.

Figure 18. ATH-1017 Administration Rescued Acute Gamma Power Signal in AD Subjects.



Overall, the qEEG results in humans are indicative of CNS penetration and target engagement, suggesting an active dose range of ATH-1017 from 20 to 90 mg.

Event-related Potential

In our Phase 1b clinical trial, ERP P300 recordings were collected from the MAD healthy elderly and AD subjects. Analysis of these P300 data demonstrated that one daily dose of ATH-1017 improved P300 latency over an 8-day dosing period, as shown in Figures 19-21. P300 latency, a functional measure of working memory processing speed that highly correlates with cognition, was dramatically improved. All AD subjects tested had improved P300 latency after a single dose of ATH-1017 and average latency across the AD treatment group had returned to levels close to those observed in healthy elderly subjects by the end of an 8-day treatment cycle. The acute effect observed on Day 1 is likely the result of the rapid augmentation of NMDA neurotransmitter receptors. The sustained effects on P300 latency observed in the pre-dose recordings on subsequent testing days (the arrows in Figure 19 show the average P300 latency value from the ATH-1017 group as a heat map) most likely reflect the long-term regeneration of neuronal connections and the improvement in brain function; at these time points, which are 24 hours after the last dose, ATH-1017 was measured and shown to be completely cleared from the plasma. These data indicate ATH-1017 treatment has recovered disruptions to brain function and network connectivity, likely through several components of the mechanism, including NMDA receptor modulation, increased connectivity through recovery of synaptic density, and improved overall neuronal health and function.

Figure 19. ATH-1017 Treatment Led to Continued and Sustained Improvement in P300 Latency. The arrows highlight the sustained P300 latency benefit due to ATH-1017 treatment.

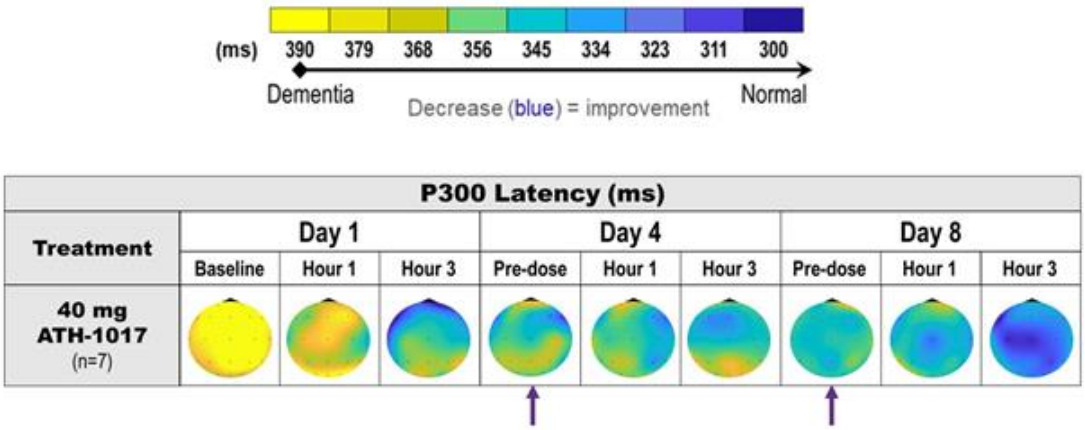


Figure 20. Quantification of the Change in P300 Latency from Baseline, ATH-1017 Significantly Reduced P300 Latency Compared to the Placebo Group on Day 8 Recordings. Data show average P300 latency values of 7 AD subjects treated with ATH-1017 vs. 8 AD subjects on placebo * p≤0.05

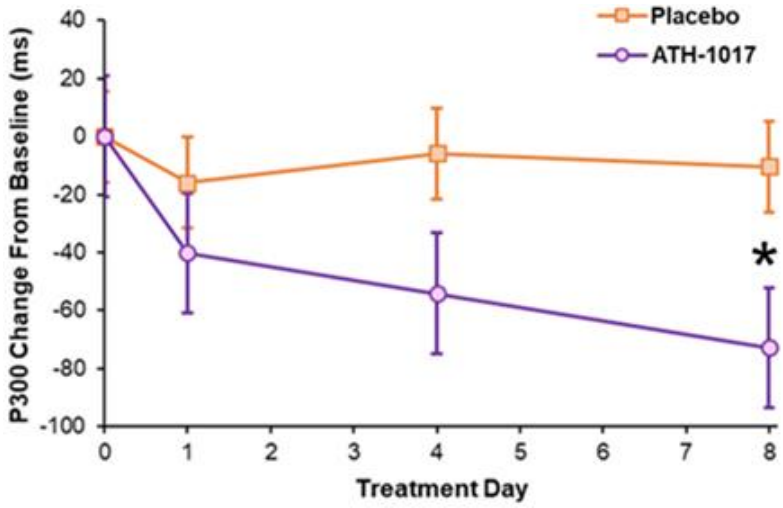
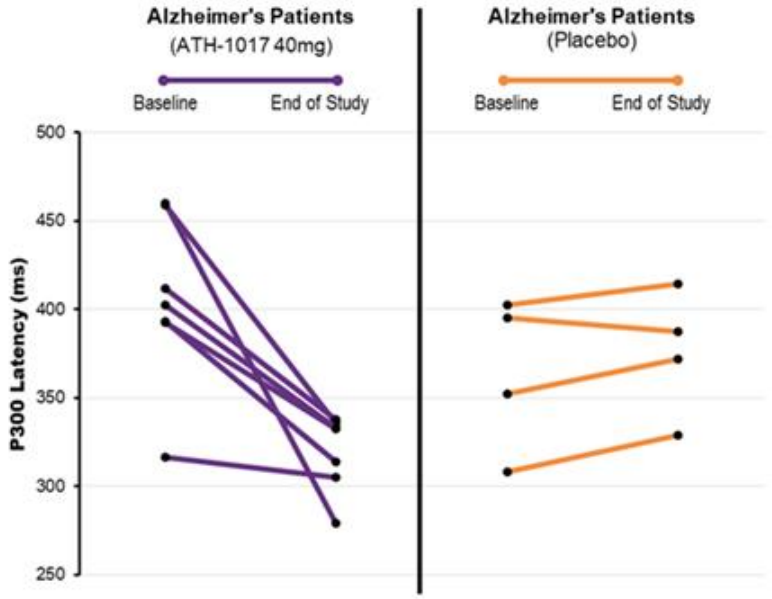


Figure 21. Data from Each Subject in the Clinical Trial Showing the Change in P300 Latency from Baseline, What Is Clear Is that Every Subject Receiving ATH-1017 Showed a Level of Improvement in P300 Latency and Subjects Receiving Placebo Had No Consistent Change.



Safety

ATH-1017 was well tolerated with no serious adverse events in our placebo-controlled double blind Phase 1a and Phase 1b clinical trials conducted to date where we enrolled 88 subjects including 11 subjects with mild-to-moderate AD.

Additionally, standard 26-week chronic GLP toxicology studies in rats and dogs showed no adverse findings in clinical observations, behavior, and clinical pathology laboratory parameters. Daily subcutaneous administration of ATH-1017 to rats for 26 weeks was tolerated. The only adverse finding was necrosis of the injection site subcutaneous tissue in male animals that largely resolved after the 28-day recovery period.

In summary, human exposures from the planned dose range of 20-80 mg for the Phase 2 clinical trials are well below the animal no observable adverse event level, or NOAEL, exposures. Furthermore, the NOAEL from the 26-week GLP toxicity study was defined by injection site reactions, which are monitorable and reversible, and may be less of a risk in humans due to greater surface area, a higher number of injection sites, and a lower volume of injection relative to body size.

Administration

ATH-1017 is delivered by once-daily subcutaneous injection. The ATH-1017 formulation is non-viscous, with a neutral pH, and is expected to be dispensed and administered at room temperature. These attributes and the use of small-gauge needles, and minimal volumes (≤ 1 mL) significantly optimize the ATH-1017 product profile for a subcutaneous route of administration. Subcutaneous injections are a common route of administration of chronic therapies, including those for diabetic or MS patients, and are

easy to administer for patients and/or caregivers while being generally well tolerated. With the progression of neurodegenerative disorders, oral administration can become challenging as:

- safe swallowing often becomes increasingly difficult;
- daily trays of multiple solid oral dosage forms add to patient/caregiver burden; and
- potential resistance to care can also impact compliance.

Subcutaneous injectables are expected to improve compliance and overall treatment outcomes. We have conducted a medication management research initiative, where we surveyed a number of caregivers and medical professionals to understand compliance challenges in the AD population. Top issues impeding compliance included forgetfulness, resistance to care, pill handling, and swallowing. The results of this study combined with the potential for a subcutaneous product profile to address several of these challenges, support ATH-1017 to be advanced as a once-daily subcutaneous injectable therapy for AD and dementia patients.

Development Plans for Alternative Delivery Devices for ATH-1017

ATH-1017 is initially being developed to be delivered via pre-filled syringes for Phase 2/3 clinical trials and initial market penetration. We are exploring the development of alternative delivery devices, including multi-dose pen injectors, to increase patient comfort and ease of use for patients and caregivers, with a view towards improving patient compliance and outcomes.

Development Strategy

LIFT-AD Pivotal Trial: A 26-Week Phase 2/3 Clinical Trial in Mild-to-Moderate AD Subjects

Based on the safety and translational Phase 1a and Phase 1b clinical trial results, including AD subjects, we plan to initiate LIFT-AD, a Phase 2/3 randomized, double-blind, placebo-controlled clinical trial. This clinical trial is designed to assess the efficacy, safety, and tolerability of two dose levels of ATH-1017 (low and high) in subjects with mild-to-moderate AD compared to placebo. The clinical trial is intended to enroll approximately 240 to 300 AD subjects. Subjects enrolled in the clinical trial will have a severity range within the conventional boundaries for mild-to-moderate AD, based on MMSE 14-24 inclusive. Clinical dementia rating, or CDR, is a 5-point scale used to assess cognition and function in AD and related dementias. CDR 1 or 2 are an additional inclusion criterion to ensure overt dementia. We plan to initiate the LIFT-AD potentially pivotal trial by the end of 2020, with topline results expected by the end of 2022.

Compared to therapies focused on AD progression, which traditionally require multi-year clinical trials to measure changes in disease progression, ATH-1017 is expected to induce a rapid boost in cognition, which enables us to design our trial with a 26-week treatment period and potentially accelerate the clinical development of ATH-1017.

The primary endpoint in this clinical trial will be the Global Statistical Test, or GST, and this outcome will provide proof-of-concept data. GST is based on actual psychometric performance tests of ADAS-cog-11 and ADCS-CGIC, both of which are key secondary endpoints and will potentially provide pivotal evidence to support registration. GST provides a more sensitive endpoint to the overall treatment effect of multiple variables and increases our chances of understanding the full impact of ATH-1017 clinical outcomes. If GST is positive, then the study will support proof of concept, and if the trial results for each of the separately measured endpoints — ADAS-cog-11 and ADCS-CGIC — are also positive, the LIFT-AD study will potentially provide pivotal evidence to support regulatory approval.

Further secondary endpoints will include the Controlled Oral Word Association Test, or COWAT, to specifically assess changes in executive memory function, the Disability Assessment for Dementia, or DAD, scale to assess instrumental activities of daily living, and the Neuropsychiatric Inventory, or NPI, to assess any changes in behavior.

Exploratory pharmaco-economic outcomes will be comprised of validated scales to capture resource utilization (RUD-lite 3.3), caregiver burden (Zarit Burden Interview) and the 5Q-5D-EL.

The clinical trial design for LIFT-AD was informed by our previous interactions and discussions with the FDA. In order to be considered a pivotal trial supportive of FDA approval for mild to moderate AD, LIFT-AD will need to achieve a statistically significant improvement separately on both the ADAS-Cog11 and ADCS-CGIC.

P300 Trial: A 26-Week Phase 2 Clinical Trial in Mild-to-Moderate AD Subjects

In addition to LIFT-AD, we are planning a randomized, placebo-controlled P300 Phase 2 clinical trial that will be initiated in parallel. This clinical trial is designed to test the same dose levels of ATH-1017 (low and high) in subjects with mild-to-moderate AD compared to placebo. We intend to enroll approximately 60 to 75 mild-to-moderate AD subjects using the same enrollment criteria as described above and include a 26-week treatment period.

The primary endpoint of this clinical trial is to establish the correlation of P300 latency changes due to ATH-1017 treatment to cognitive benefits, as previously shown for cholinergic drugs and cognitive therapies. This clinical trial will help define the safety profile and effect size of ATH-1017 in mild-to-moderate AD. Additionally, because this clinical trial is expected to have a faster readout due to a smaller sample size than LIFT-AD, it will help support strategic decisions around additional clinical trials, including any additional pivotal trials that we may initiate in parallel to the potentially pivotal LIFT-AD trial if the results from the P300 Phase 2 clinical trial do not meet our expectations. By the end of 2020, we plan to initiate the 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.

Expand Development of ATH-1017 to Include Additional Indications.

We are developing ATH-1017 as a treatment for mild-to-moderate AD patients, but over time, we aim to expand development to cover all stages of AD. Ultimately, we believe that ATH-1017 can address the broader dementia patient population.

Phase 2 Proof-of-Concept Clinical Trial in PDD Subjects

In addition to the two AD clinical trials, we are also planning to test the effects of ATH-1017 in PDD subjects. PDD is a disease that impacts neuronal health and leads to a progressive damage of the brain network, ultimately impacting function and cognition. Like AD, PDD subjects demonstrate an increase in their P300 latency, which increases the likelihood that ATH-1017 can potentially address dementia in PDD subjects. This clinical trial will be a randomized, placebo-controlled, Phase 2 proof-of-concept clinical trial in PDD subjects with a planned start by the end of 2021. The population severity will include Hoehn-Yahr stages 2 and 3, who will receive 40 mg ATH-1017 versus placebo. Endpoints will include P300 latency and Parkinson's Disease-Cognitive Rating Scale, or PD-CRS.

Preclinical Results

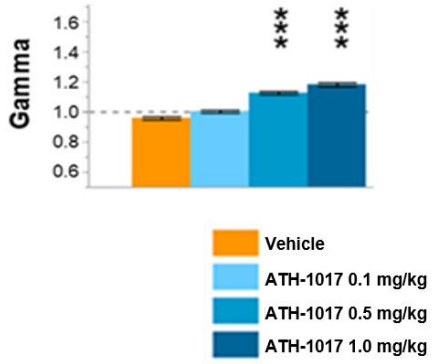
ATH-1017 was assessed in multiple preclinical studies, including in vitro assays and several animal models of memory deficits. ATH-1017 promoted the formation of new spines and functional synapses in hippocampal neurons *in vitro* (neuronal cultures). In the aged animal model of dementia, ATH-1017 increased synaptic density and in multiple models of dementia improved performance in tests of spatial memory.

Similar to the clinical findings, ATH-1017 treatment also increased the qEEG gamma power that is associated with cognitive processing and memory in a non-clinical AD animal model (APP1/PS1), as

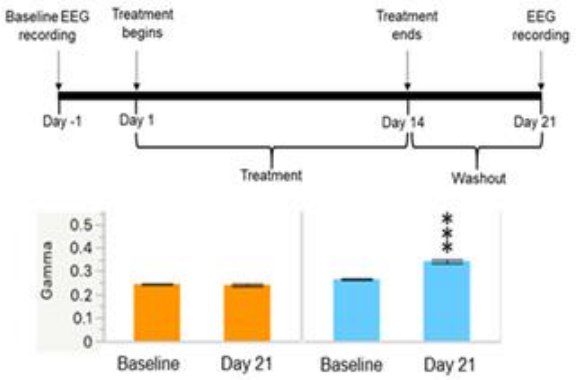
shown in Figure 22. Changes in gamma brain activity signals are highly translatable which helped guide our selection of the clinical doses.

Figure 22. ATH-1017 Treatment Induces Acute Increases in Gamma Power within One Hour of Administration (left); and Daily Treatment for Two Weeks Followed by a Seven-Day Washout Shows a Sustained Effect on Gamma Power (right).

ATH-1017 Induces an Acute Dose-Dependent Increase in Gamma Power



Two Weeks of ATH-1017 Treatment Induced Increased Gamma Power That Was Sustained After Seven Days of Washout



Our ATH Platform

Our ATH platform leverages the activity of a validated regenerative pathway, the HGF/MET system, that is critical for normal brain function. We believe that our ability to enhance the body's repair mechanism of HGF/MET through our ATH platform has the potential to address a wide range of clinical applications ranging from CNS disorders, such as AD, PDD, MS, and ALS, to more peripheral conditions such as neuropathy. In addition, we believe that HGF/MET biology plays a role in neuropsychiatric disorders such as depression and anxiety.

Key Aspects of Our ATH Platform

Our ATH platform utilizes proprietary technology to target and enhance the activity of a vital neuronal growth factor that promotes neuronal health and regeneration. We believe that our ATH platform has multiple advantages compared to previous strategies that have targeted growth factors, including:

- *Small molecules*. Previous attempts to promote neurotrophic factor activity with recombinant proteins or stem cells involved invasive surgeries or risked immune response. Our small molecules overcome these challenges, allowing for non-invasive systemic drug delivery through subcutaneous or oral routes that distribute to the nervous system.

- *Efficient and scalable manufacturing process*. Small molecules are manufactured using scalable chemical synthesis routes, representing a cost and time efficient process that does not require custom manufacturing infrastructure.

- *Avoids alteration of target system regulation*. ATH compounds are designed to enhance the activity of the target system with neither disruption to nor evasion of the normal regulatory processes that are in place to prevent hypo- or hyper-activation. This design aims to reduce safety risks.

We believe that the ATH platform represents a significant opportunity to develop therapeutics for the treatment of diseases of the nervous system and has the potential to drive significant advancement in regenerative medicine.

Our Therapeutic Discovery Process

We utilize a rigorous process to identify small-molecule compounds that activate regenerative systems.

- *Focus on activity*. Our drug screening process is an efficient blend of modern and traditional methods, starting with extensive modeling to create compound libraries. In our process, focus is placed on early activity assays, in which potential hits are rapidly advanced to further discovery.

- *Maximize hit potential*. When hits are identified, we employ a comprehensive set of studies to collect compound characteristics and optimize for drug-like characteristics with medicinal chemistry and structure-activity relationship studies to produce candidates ready for further development.

- *Gain insight to inform future therapeutic development*. We consider the drug discovery process as a cycle, with past work continuously informing future drug design, ultimately optimizing the process as we advance our knowledge and expertise.

This system has supported the identification of several candidates for development, including ATH-1017. We are using our ATH platform and discovery engine to explore potential development of therapeutic candidates in additional nervous system disorders including ALS, MS, and neuropsychiatric disorders, as well as in peripheral indications such as peripheral neuropathy. We are also actively exploring the potential of expanding the focus of our discovery engine to multiple molecular targets relevant to nervous system disorders.

Additional Development Opportunities

Our Neuropsychiatric Program (ATH-1019)

We are currently developing ATH compounds for neuropsychiatric conditions including depression and anxiety. The lifetime prevalence of common mental disorders is reported to be almost 30% and, despite the sizable number of available treatments, a large portion of subjects show an unsatisfactory or a lack of response to treatment. This context, combined with slow responses to common treatments, results in a major burden for patients, public healthcare, and disability systems. 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 has been shown to activate the HGF/MET system, and distribute to the CNS, and is neuroactive in animal models.

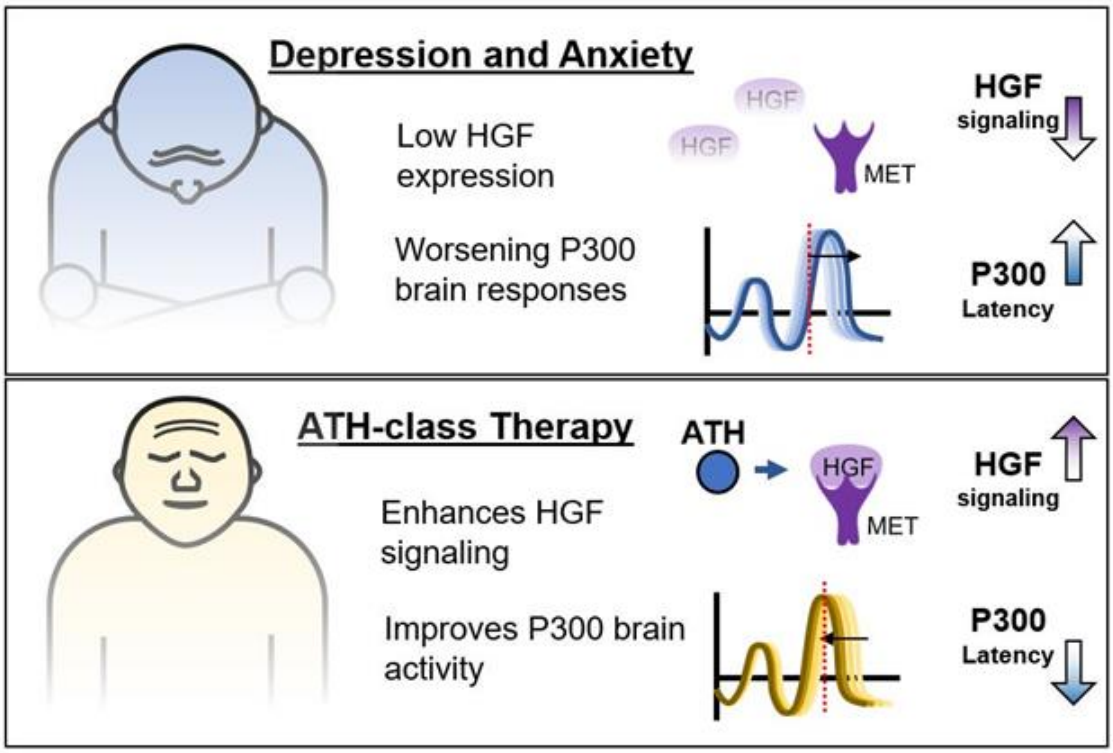
We believe the stimulating activity of ATH-1019 on the HGF/MET system is well-suited to address neuropsychiatric conditions because:

- HGF/MET signaling is deficient in neuropsychiatric patients and negatively correlated to disease severity;

- reductions in HGF/MET signaling is a causative agent of depression and anxiety behaviors in rodents; and

- enhancement of HGF concentrations in the brain has anti-depressive and anxiolytic effects in rodent models.

Figure 23. ATH-1019 Has the Potential to Rescue HGF/MET Signaling and Promote Activity to Address Depression and Anxiety.



Further, patients suffering from major depression display reduced function and connectivity of neural pathways, resulting in prolonged P300 latency compared to healthy controls. This effect is particularly apparent in those experiencing cognitive dysfunction. The extent of P300 latency slowing is strongly correlated with the severity of depression, and a normalization of P300 latency is associated with response to treatment. Our HGF activator for the treatment of AD, ATH-1017, normalized the P300 latency of AD subjects in a Phase 1b clinical trial within 8 days of treatment. While the patient populations in neuropsychiatric conditions and AD are substantially different, the root cause of the diseases may not be, and properties of P300 latency have been shown to be conserved across many diseases. These results highlight the ability of HGF/MET activators to impact P300 latency, which when combined with the preexisting research on the effects of activating the HGF/MET system in neuropsychiatric disorders indicates that treatment with HGF/MET activating compounds may be capable of improving patient outcomes in neuropsychiatric indications. We are advancing ATH-1019 to further development for neuropsychiatric indications including depression and anxiety and are targeting an IND submission to the FDA for depression and/or anxiety in the first half of 2022.

Our Neuropathy Program (ATH-1018)

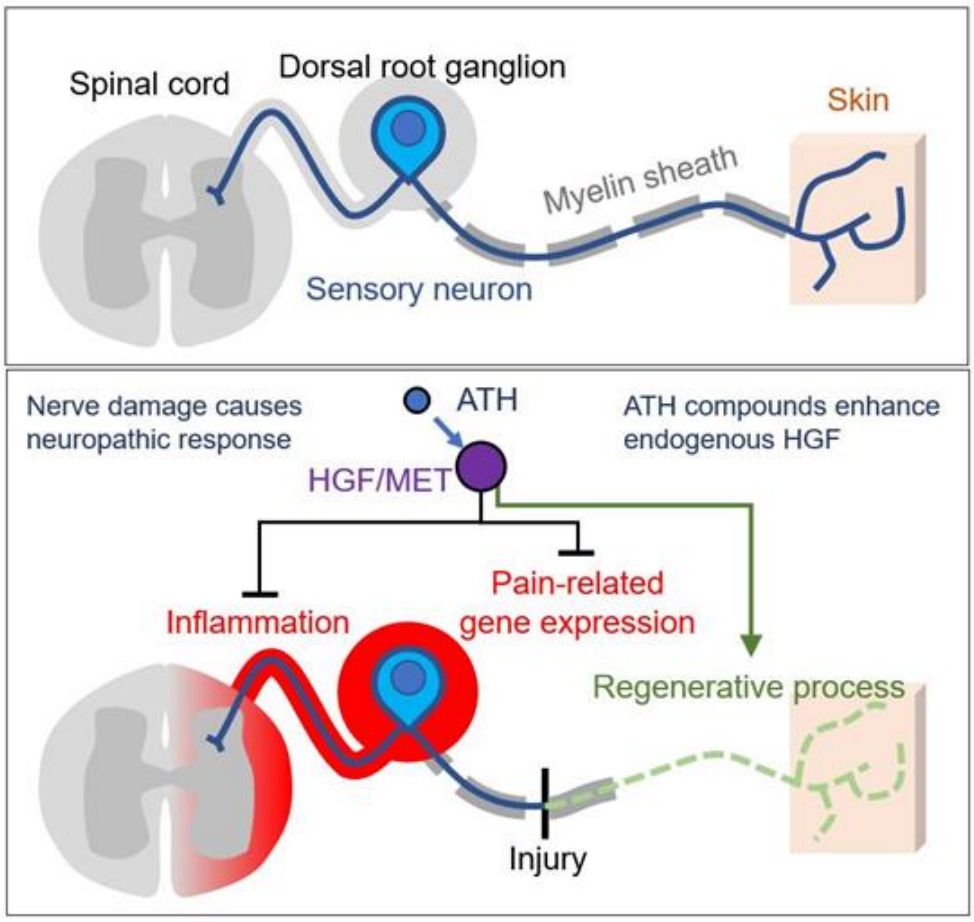
We have initiated a discovery program to evaluate ATH compounds for peripheral neuropathy. ATH-1018 is a novel, orally active candidate that has demonstrated ability to significantly promote the activity of the HGF/MET system. We are planning to administer ATH-1018 at doses that are expected to largely 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. Consideration of HGF/MET activators as a therapeutic approach for neuropathy was initiated following review of studies demonstrating that HGF/MET activating treatment repaired peripheral nerve injury and reduced neuropathy.

Despite a reported prevalence of up to 10% of the population, neuropathy has proven difficult to manage, and clinical outcomes are unsatisfactory. Management of pain symptoms with opiates serves as a common form of pain therapy and the only reliable one but is palliative only. As well, opiates are fraught with major clinical liabilities. Nerve injury and subsequent neuropathy are typically caused by lesion or disease, commonly diabetes, MS, or stroke. The nerve injury is then followed by an inflammatory response and upregulation of pain signaling factors, which lead to chronic neuropathy.

We believe the activity of ATH compounds, through enhancement of the HGF/MET system, is well-suited to address neuropathy given that HGF/MET signaling has been shown to:

- promote regeneration of damaged peripheral nerves, mediated through Schwann cell activity;
- inhibit inflammation by reduction of the expression of pro-inflammatory cytokines; and
- down-regulate the expression of pain-related genes in damaged peripheral neurons, including ATF3.

Figure 24. ATH-1018 Activity Has the Potential Both to Block Several Processes that Lead to Neuropathy and to Promote Neuronal Regeneration.



Furthermore, previous clinical trials have shown that with HGF plasmid therapy, designed to increase circulating HGF, promoting the HGF/MET system significantly reduced pain in patients with

diabetic peripheral neuropathy. We believe these clinical trials provide a proof of concept for the therapeutic target. However, our oral small-molecule candidates offer distinct advantages over plasmid therapies, including controlled dose and ease of administration. Targeting HGF/MET signaling for the treatment of neuropathy is supported by both preclinical and clinical research, and we are evaluating the next generation oral ATH compounds for activity to address neuropathy. Validated methods for the assessment of peripheral nerve function (neurography) and pain (VAS rating) are well established. 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.

Market Opportunity

AD and Dementia

ATH-1017 is being advanced for mild-to-moderate AD patients initially. The AD dementia market today in 2020 is reported to be 5.8 million Americans and is projected to reach nearly 14 million by 2050 in the U.S. Worldwide, as many as 35 million people are estimated to have AD and the patient population was projected in 2007 to grow to over 100 million by 2050. Our strategy is to ultimately position ATH-1017 as a treatment for dementia broadly. Spanning all dementias globally, an estimated 50 million people are reported to be affected today in 2020 and this number is projected to be 150 million by 2050. Many factors contribute to the growing numbers of the potentially treatable population, including “baby boomers” reaching age 65 and increasing life expectancy beyond 80.

Other Target Indications

Our immediate next pipeline opportunities include: ATH-1019 for neuropsychiatry and ATH-1018 for neuropathy. Neuropsychiatric indications, specifically depression, are estimated to affect 7% of all U.S. adults 18 and older representing an estimated addressable potential patient population of approximately 17 million adults as of 2017, and was projected in 2008 to reach approximately 37 million by 2050. Beyond depression, and with a reported lifetime prevalence of nearly 30% for all neuropsychiatric indications, the addressable 2020 patient population of adults 18 and older is reported to reach nearly 50 million in the U.S. alone.

The estimated prevalence of neuropathy in the U.S. averages approximately 10% but could be higher due to a larger undiagnosed population. Conservatively, and with nearly 10% of the U.S. population over 30 years old estimated to be diagnosed with some form of neuropathy, the reported addressable patient population today is approximately 30 million patients for peripheral neuropathy, a type of neuropathic pain, alone.

Potential Commercialization Plan

ATH-1017 is initially being developed as a regenerative medicine for AD. For the initial target patient population of mild-to-moderate AD patients, our commercialization strategy of ATH-1017 will consider the following key elements:

- an add-on therapy for patients on existing therapies;
- a monotherapy for patients who are not suitable for acetylcholinesterase inhibitors, or AChEIs;
- a monotherapy for patients who have stopped AChEIs due to loss of effect or side effects; and
- a treatment to other dementias such as PDD, Lewy body dementia and Frontal temporal dementia over time.

We aim to demonstrate the unique short- and long-term value provided by ATH-1017 by linking the core symptoms of dementia (cognition and behavioral and psychological symptoms of dementia) to both improved outcomes and reduced costs and the benefits of ATH-1017 through increased compliance rates in our initial indications.

We anticipate exploring two distribution strategies for ATH-1017, traditional wholesaler and specialty pharmacy. While the traditional wholesaler could be a suitable option, we believe that the additional patient services that could be provided through specialty pharmacy may offer more value to patients, caregivers, and their providers. Such services could include training on subcutaneous administration, patient counseling and assistance with reimbursement or insurance issues. This could also allow us to reduce the need for costly in house or field-based resources such as patient training or reimbursement support specialists.

Manufacturing

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 development and manufacturing organizations, or CDMOs, to manufacture and supply our preclinical and clinical materials during the development of our product candidates. We and various regulatory bodies have audited the CDMOs we contract with, and they have a proven track record of FDA-compliant manufacturing with an infrastructure to support large and commercial scale manufacturing.

We have enough ATH-1017 supply to begin our planned potentially pivotal LIFT-AD and our P300 Phase 2 clinical trials in AD. We believe the synthesis of ATH-1017 is reliable and reproducible and the synthetic routes 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 continue to optimize the manufacturing process to support future large-scale and commercial supply. ATH-1017 is purified as a stable solid and then released to additional CDMOs for formulation and packaging into final drug product for use in clinical testing.

The final drug product profile is a ready-to-use pre-filled syringe with a clear, non-viscous aqueous solution of ATH-1017. The syringes utilize materials and components that are readily available commercially. The ATH-1017 drug product has shown extended stability (at least 2 years) under storage conditions when stored in vials that were composed of identical materials to the syringes. Confirmatory stability studies in syringes are ongoing and data collected thus far support the translation of the extended stability from vials to syringes under refrigerated conditions as well as short-term dispensation and at-home storage in ambient conditions. Room temperature storage allows patients to avoid cumbersome storage requirements and reduces overall burden.

We plan to maintain our focus to identify and develop small molecule product candidates that are expected to have cost-effective manufacturing using third party CDMOs.

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.

Competition

The biotechnology and biopharmaceuticals industries are characterized by rapid technological advancement, significant competition, and an emphasis on intellectual property. As a clinical-stage biopharmaceutical company developing small molecules to restore neuronal health and stop neurodegeneration, with our most advanced product candidates focused on the treatment of AD and dementia, we face, and in the future may face increased, competitive pressures from both large and small pharmaceutical companies and from established and emerging biotechnology companies, as well as

academic, government, and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with current treatments and new treatments that may become available in the future. With the advancement of ATH-1017 as a novel small molecule therapeutic activating a neurotrophic factor pathway, the HGF/MET system, and its liquid formulation as a subcutaneous deliverable, we also consider as competitors companies developing small molecule AD therapies targeting neurotrophic factors with or without a subcutaneous route of administration. Despite the immediate commercialization plan to launch ATH-1017, if approved, in pre-filled syringes with future plans for device innovation, including potentially smart multi-dose pen injectors, we do not view the medical device industry as competition but rather potential partners enabling the manufacture and commercialization of ATH-1017.

Because of the range of potential competitors, many of our competitors, alone or with strategic partners, have greater access to financial resources, market presence, and resources and expertise in development, preclinical and clinical testing, manufacturing, commercialization, the regulatory approval process, and/or marketing and sales than we do. In addition, these same competitors, who may be in a clinical development stage, could also be competing with us for patient recruitment, clinical research organization, and operational resources. These entities also compete with us in the recruitment and retaining of qualified scientific and management personnel, as well as the acquisition of enabling or complementary technologies for advancing ATH-1017 across all competitors. Merger and acquisition activity in the biotechnology and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity could be substantially limited if our competitors develop and commercialize products that are more effective, safer, more convenient or less expensive than our comparable products. In geographies that are critical to our commercial success, competitors may also obtain regulatory approvals before us, resulting in our competitors building a strong market position in advance of the entry of our products. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of other treatments.

Key competitive forces that could potentially affect the success of our products, if approved, are safety, efficacy, price, adoption, convenience, time-to-market, level of promotional activity, intellectual property protection, and reimbursement likelihood from government and private payors. Despite these forces, we view our competitive advantage in not only our lead product candidate, ATH-1017, but also our novel pipeline of therapeutics with a focus on overall neuronal health. In particular, the following summarizes certain categories of our potential competition.

As a small molecule therapeutic targeting the HGF/MET system, we are aware of a number of potential competitors in this space, including ANG-3777, an HGF mimetic, developed by Angion for the treatment of kidney injury and Collategene developed by Mitsubishi Tanabe and AnGes as a gene therapy for the treatment of critical limb ischemia. ANG-3777 is currently in Phase 3 clinical trials while Collategene was launched in Japan in the third quarter of 2019. In addition, we are aware of p75 ligands being developed by PharmatrophiX for the treatment of neurodegenerative and other disorders, including AD, as well as VM-202, a regenerative plasmid DNA therapy candidate in development by Helixmith for the treatment of diabetic peripheral neuropathy. We are not aware of any direct competitors currently targeting the HGF/MET system for neurological conditions.

ATH-1017 is being advanced as either a monotherapy or an add-on therapy for patients on AChEIs. In addition to being a potential add-on therapy to currently approved therapies, we do not anticipate ATH-1017 to be a direct competitor to, but rather complementary to, other therapeutic developments focused on Aβ, pTau, AChE, BACE inhibitors, inflammation and others. Similarly, because ATH-1017 presents a novel mechanism of action, we do not view monoclonal antibody therapies currently under development by large pharmaceutical companies of which we are aware, including Biogen, Eli Lilly and Roche, as competitors, but potentially as complementary to our approach.

Intellectual Property

We own or have in-licensed numerous patents and patent applications and possess substantial know-how and trade secrets relating to the development and commercialization of our product candidates, including related manufacturing processes and technologies.

As of the date of this prospectus, our patent portfolio consists of nine owned or in-licensed U.S. issued patents, one owned or in-licensed U.S. pending patent application, 12 owned or in-licensed patents issued in jurisdictions outside of the United States, and nine owned or in-licensed pending patent applications in jurisdictions outside of the United States. The patents and patent applications issued and pending outside the United States are generally counterparts to the foregoing U.S. patents and patent applications and are held primarily in Europe, Canada, Japan, Australia, Hong Kong, India, and China. Our solely-owned and in-licensed patents and patent applications include, among others, claims directed to:

- ATH-1017 and related compounds;
- methods of using ATH-1017; and
- methods of using related compounds.

We intend to pursue, when possible, further composition, method of use, dosing, formulation, and device patent protection directed to the neuroregenerative products and processes we develop. We may also pursue patent protection with respect to manufacturing and drug development processes and technology.

Individual patents extend for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained. Generally, patents issued for applications filed in the United States are effective for 20 years from the earliest nonprovisional filing date. In addition, in certain instances, a patent term can be adjusted or extended to recapture a portion of the term effectively lost as a result of the USPTO delay and the FDA regulatory review period. The restoration period for FDA delay cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The duration of patents outside of the United States varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest nonprovisional filing date. Our in-licensed issued patents will expire on dates ranging from 2023 to 2035, exclusive of any patent term adjustment or patent term extension. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2032 to 2037, exclusive of any patent term adjustment or patent term extension.

We further seek to protect our technology and product candidates, in part, as trade secrets, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, contractors, consultants, collaborators, and advisors. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Our trademark portfolio currently consists of two pending trademark applications in the United States, two pending trademark applications in Australia, and two issued trademark registrations in the European Union.

Our Collaboration and Grant Agreements

Washington State University Research Foundation License Agreement and Amended and Restated Washington State University License Agreement

In December 2011, we entered into an exclusive license agreement with Washington State University Research Fund, or WSURF, which, after the dissolution of WSURF in 2013, was superseded by an amended and restated exclusive license agreement with Washington State University, or WSU, in

September of 2015. Under this agreement, WSU granted us an exclusive license to make, use, sell, and offer for sale licensed products and licensed processes that embody the licensed patents (including WSU's rights to a patent jointly owned with Pacific Norwest Biotechnology, Inc.) and that form the underlying technology of the drug therapies we are developing. The term of the license begins on the effective date and continues until the earlier of the date on which no valid claim remains enforceable or the payment of royalties ceases for more than four consecutive quarters after such royalty payments begin.

We are obligated to pay to WSU the following if the related milestones are reached:

- $50,000 – At initiation of the first Phase 2 clinical trial in the United States, European Union or Japan for the first licensed product.
- $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.

We are obligated to pay WSU a royalty in the mid-single digits of net sales.

Additionally, under the agreement we have the right to sublicense the licensed rights, 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 tens of any non-sales based payments received, and low twenties of net sales-based sublicense royalties.

Grant Liability

In 2014 and 2015, we received $250,000 and $500,000, respectively, from the Washington Life Sciences Discovery Fund, or LSDF, under the terms of two matching grant award agreements. In connection with the agreements, LSDF retained the right to receive cash payments of up to twice the amounts received, or $1.5 million, upon the occurrence of specified triggering events, including the completion of this offering.

Government Regulation

Government authorities in the United States, at the federal, state, and local level, and other countries extensively regulate, among other things, the research, development, nonclinical and clinical testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, and export and import of products such as those we are developing. Generally, before a new drug can be marketed, considerable data must be generated, which demonstrate the drug's quality, safety, and efficacy. Such data must then be organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, the approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies, and formulation studies in accordance with FDA's good laboratory practice requirements and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent IRB ethics committee, either centralized or with respect to each clinical site, before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with GCP requirements to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA after completion of all pivotal trials;
- determination by the FDA within 60 days of its receipt of an NDA to accept the filing for substantive review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP requirements to ensure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality, and purity, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the clinical trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which may review data and endpoints at designated check points, make recommendations and/or halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1*: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism, and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- *Phase 2*: The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- *Phase 3*: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

Post-approval clinical trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a clinical trial may move forward at designated check points based on access to certain data from the clinical trial.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 clinical trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and

unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

NDA Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development nonclinical and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality, and purity. Under the Prescription Drug User Fee Act (PDUFA) guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes 12 months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process, or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 clinical trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies, or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a REMS to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use. It could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may offer conditional approval subject to, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

Expedited Development and Review Programs

The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. With regard to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis, or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, a product may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

The Food and Drug Administration Safety and Innovation Act established a category of drugs referred to as "breakthrough therapies" that may be eligible to receive breakthrough therapy designation. A sponsor may seek FDA designation of a product candidate as a "breakthrough therapy" if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the

fast track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such drug.

Fast track designation, priority review, accelerated approval, and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on post-approval or Phase IV clinical studies, if applicable;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases, and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising, and promotion of drug products. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission and approval of certain marketing applications for products containing the same active ingredient. The FDCA permits patent term restoration of up to five years as compensation for a patent term lost during product development and FDA regulatory review process to the first applicant to obtain approval of an NDA for a new chemical entity in the United States. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application (ANDA) or an NDA submitted under Section 505(b)(2) (505(b)(2) NDA), submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

Other Healthcare Laws

Pharmaceutical manufacturers are subject to additional healthcare laws, regulation, and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal anti-kickback, anti-self-referral, false claims, transparency, including the federal Physician Payments Sunshine Act, consumer fraud, pricing reporting, data privacy, data protection, and security laws and regulations as well as similar foreign laws in the jurisdictions outside the U.S. Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; 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, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information; state and local laws which require the tracking of gifts and other remuneration and any transfer of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives; and state and local laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The risk of our being found in violation of these or other laws and regulations is increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts and their provisions are open to various interpretations. These laws and regulations are subject to change, which can increase the resources needed for compliance and delay drug approval or commercialization. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Also, we may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments. Actual or alleged violation of any such laws or regulations may lead to investigations and other claims and proceedings by regulatory authorities and in certain cases, private actors, and violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, significant administrative, civil and criminal penalties, damages, fines, 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, the curtailment or restructuring of operations, exclusion from participation in government healthcare programs and imprisonment.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance, and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product. As a result, the coverage determination process can require manufacturers to provide scientific details, information on cost-effectiveness, and clinical support for the use of a product to each payor separately. This can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

In addition, third-party payors are increasingly reducing reimbursements for pharmaceutical products and related services. The U.S. government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical products, in addition to questioning their safety and efficacy. Adoption of price controls and cost-

containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, that it will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available, or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. By way of example, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; it required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; it implemented a new methodology under which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; it expanded the eligibility criteria for Medicaid programs; it created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and it established a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Since January 2017, President Trump has signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have passed. For example, in 2017, Congress enacted the Tax Act, which eliminated 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, a process that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S.

Supreme Court granted the petitions for writs of certiorari to review the case, although it is unclear when a decision will be made or how the Supreme Court will rule. In addition, there may be other efforts to challenge, repeal, or replace the ACA. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business in the future.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030 unless additional congressional action is taken. The CARES Act, which was signed into law on March 27, 2020, and which is 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 end date of the sequester by one year, through 2030, in order to offset the 2020 suspension. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, to review the relationship between pricing and manufacturer patient programs, and to reform government program reimbursement methodologies for pharmaceutical products. For example, at the federal level, the Trump administration released a “Blueprint”, designed 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. On March 10, 2020, the Trump administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses; provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses; and place limits on pharmaceutical price increases. Additionally, the Trump administration’s budget proposal for the fiscal year 2021 includes a $135 billion 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 drugs. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. In addition, individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical 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, mechanisms to encourage importation from other countries and bulk purchasing. It is possible that additional governmental action may be taken to address the COVID-19 pandemic. Furthermore, there has been increased interest by third party payors and governmental authorities in reference to pricing systems and publication of discounts and list prices.

Employees

As of June 30, 2020, we had 15 employees, 14 of whom were full-time and eight of whom were engaged in research and development activities. Nine of our employees hold Ph.D. or M.D. degrees. Substantially all our employees are located in or around Seattle, Washington. None of our employees are represented by a labor union or covered under a collective bargaining agreement. We consider our relationship with our employees to be good.

Facilities

Our corporate headquarters are located in Seattle, Washington, where we currently lease approximately 1,270 square feet of laboratory and office space. Our Seattle lease expires in June 2021. We intend to relocate to facilities in Bothell, Washington starting in September 2020 as we add employees and scale our operations. We believe these facilities will be adequate for the foreseeable future and that suitable additional or substitute space will be available as and when needed.

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.

MANAGEMENT

Executive Officers and Directors

The following table sets forth information regarding our executive officers and directors as of June 30, 2020:

Name	Age	Position
Executive Officers		
Leen Kawas, Ph.D.	35	President, Chief Executive Officer and Director
Mark Litton, Ph.D.	52	Chief Operating Officer
Hans Moebius, M.D, Ph.D.	64	Chief Medical Officer
Kevin Church, Ph.D.	36	Vice President of Discovery
Non-Employee Directors		
Tadataka Yamada, M.D.	75	Chairman of the Board
Joseph Edelman	65	Director
John M. Fluke, Jr.	77	Director
Joseph W. Harding, Ph.D.	72	Director

(1) Member of the audit committee
(2) Member of the compensation committee
(3) Member of the nominating and corporate governance committee

Executive Officers

Leen Kawas, Ph.D., has served as our chief executive officer and as a member of our board of directors since January 2014. Previously, Dr. Kawas served as our vice president. Dr. Kawas serves on multiple boards, including the Washington Governor's Life Science Advisory Board, Scientific Review Board for the Alzheimer's Drug Discovery Foundation, and Alzheimer's Association – Washington Chapter Board. She also served as the co-chair of the International Alzheimer's Association Business Consortium. Dr. Kawas earned a Ph.D. in molecular pharmacology from Washington State University in 2011 and a pharmacy degree from the University of Jordan in 2008. We believe Dr. Kawas's scientific and professional training, her instrumental role in building Athira Pharma, Inc., and her extensive understanding of our business, operations and strategy qualify her to serve on our board of directors.

Mark Litton, M.B.A., Ph.D., has served as our chief operating officer since July 2019. Prior to joining Athira Pharma, Inc., Dr. Litton served as the president and chief operating officer of Alpine Immune Sciences, Inc., a publicly traded biotechnology company, from August 2018 to April 2019. Dr. Litton served as the chief business officer, treasurer, and secretary from 2004 to 2018 of Alder BioPharmaceuticals, Inc., a publicly traded biopharmaceutical company co-founded by Dr. Litton in 2004, which was acquired by Lundbeck A/S in October 2019. From 1999 to 2004, Dr. Litton served as vice president of business development for Celltech Group, where he was responsible for securing, commercializing, and partnering on numerous novel discoveries and therapeutic programs. In 1999, Dr. Litton joined Celltech Group as an employee of Chiroscience Group plc and was later promoted to vice president of business development after Chiroscience's merger with Celltech Group in 1999. From 1997 to 1999, Dr. Litton served as the manager of business development for Ribozyme Pharmaceuticals Inc. (now Sirna Therapeutics, Inc.), a biopharmaceutical company and wholly owned subsidiary of Alnylam Pharmaceuticals, Inc., where he helped form relationships with Eli Lilly and Company, Roche Bioscience and GlaxoWellcome plc (now GlaxoSmithKline plc) a biopharmaceutical company. From 1991 to 1994, Dr. Litton served as a research associate for DNAX Research Institute, a research facility of Schering-Plough (now Merck & Co., a publicly traded pharmaceutical company). Dr. Litton earned a Ph.D. in

immunology from Stockholm University in 1997, an M.B.A. from Santa Clara University in 1994 and a B.S. in biochemistry from the University of California Santa Cruz in 1990.

Hans Moebius, M.D., Ph.D., has served as our chief medical officer since April 2019. Prior to joining Athira Pharma, Inc., Dr. Moebius co-founded Exciva GmbH, a company focusing on targeted drug rescue, and served as its chief executive officer and chief medical officer from 2016 to 2019, and again as acting chief medical officer since April 2020. Dr. Moebius also served as scientific advisory board member at Rodin Therapeutics from October 2016 until the company was sold to Alkermes in December 2019. At Rodin Therapeutics, he also served as acting chief medical officer from December 2016 to April 2018. Prior to that, Dr. Moebius served as executive vice president of clinical research at CHASE Pharmaceuticals, until the company was acquired by Allergan in 2016. Dr. Moebius earned his Ph.D. in experimental pharmacology from the University of Heidelberg in 1983 and a B.S. in chemistry from the University of Kaiserslautern, Germany, in 1976. Dr. Moebius completed his medical studies at the Karls University of Heidelberg in 1982 and was board certified in neurology and psychiatry after completion of residencies at the Goethe University Frankfurt/Main from 1986-1991. During his research tenure at the Max-Planck-Institute for Brain Research from 1984-1986, he lectured in neuropathology and neuroscience. Dr. Moebius also holds the European Certificate in Pharmaceutical Medicine (ECPM) from the EUCOR Universities Basel/Switzerland, Freiburg/Germany and Strasbourg/France.

Kevin Church, Ph.D., has served in various roles at Athira since 2016, including research scientist, director of discovery, now as vice president of discovery. Dr. Church has research experience in diverse fields of study including neurodegenerative diseases, wound healing, and cancer. Dr. Church earned his Ph.D. in molecular biosciences from Washington State University in 2016, and prior to that earned his B.S. in microbiology from the University of Idaho in 2006. While in graduate school, Dr. Church was recognized for excellence in his graduate teaching assistantships. Dr. Church's graduate work primarily focused on the development of novel therapeutics for the treatment of pancreatic cancer, but also included research relating to the treatment of diabetic ulcers and neurodegenerative diseases such as Parkinson's disease dementia and Alzheimer's disease.

Non-Employee Board of Directors

Tadataka Yamada, M.D., has served on our board of directors since June 2019 and as the chair of our board of directors since January 2020. He is also a venture partner at Frazier Healthcare and co-founder of, and currently serves on the board of directors for, Phathom Pharmaceuticals, Passage Bio, Scout Bio, and Outpost Medicine. Dr. Yamada also serves on the board of directors of Agilent Technologies, Inc., as board of directors chair at the Clinton Health Access Initiative and is a member of the Council of the National Academy of Medicine. He is also a fellow of the Imperial College of Medicine, a master of the American College of Physicians, a fellow of the Royal College of Physicians, a member of the American Academy of Arts and Sciences and a past-president of the American Gastroenterological Association and the Association of American Physicians. Previously, Dr. Yamada held executive leadership roles at Takeda Pharmaceuticals, the Bill and Melinda Gates Foundation, GlaxoSmithKline, and at the University of Michigan in Ann Arbor. Dr. Yamada received his M.D. from New York University School of Medicine in 1971 and a B.A. in history from Stanford University 1967. In recognition of his contributions to medicine and science he has been elected to membership in the National Academy of Medicine (U.S.), the Academy of Medical Sciences (U.K.) and the National Academy of Medicine (Mexico). He has been awarded the Order of the Rising Sun, Gold and Silver Star by the Government of Japan, received an honorary appointment as Knight Commander of the Most Excellent Order of the British Empire (KBE), and been conferred the degree of D.Sc. h.c. from five universities. He has also been the recipient of numerous awards including the Distinguished Achievement Award in Gastrointestinal Physiology from the American Physiological Society, the Friedenwald Medal from the American Gastroenterological Association, and the Watanabe Prize in Translational Research from Indiana University and Eli Lilly & Co. We believe that Dr. Yamada's extensive background in medical and biopharmaceutical research, as well as his service as a director or officer of other healthcare companies, qualifies him to serve as chair of our board of directors.

Joseph Edelman has served on our board of directors since May 2020. Mr. Edelman is founder, chief executive officer, and portfolio manager of Perceptive Advisors. Prior to founding Perceptive Advisors, Mr. Edelman was a senior analyst at Aries Fund, a Paramount Capital Asset Management biotechnology hedge fund, from 1994 through 1998. Prior to that position, Mr. Edelman was a senior biotechnology analyst at Prudential Securities from 1990 to 1994. Mr. Edelman started his career in the healthcare sector of the securities industry as a biotechnology analyst at Labe, Simpson from 1987 to 1990. Mr. Edelman earned an M.B.A. from New York University in 1986 and a B.A., magna cum laude, in psychology from the University of California San Diego in 1980. We believe Mr. Edelman's experience as a board member and investor in many successful biotechnology companies qualifies him to serve on our board of directors.

John M. Fluke, Jr. has served on our board of directors since December 2014. Mr. Fluke is chairman of Fluke Capital Management, L.P., which he founded in 1976, and was chairman and chief executive officer of the John Fluke Manufacturing Co. until 1990. Mr. Fluke previously served on the boards of PACCAR Inc., CellCyte Genetics Corporation, Cell Therapeutics, Primus International, and American Seafoods Group. Mr. Fluke is a current trustee of the Greater Seattle Chamber of Commerce (formerly serving as its chairman) and previously served as chairman of the Washington State China Relations Council and a trustee emeritus of the Museum of Flight. He also previously served as chairman of the Washington Technology Center at the University of Washington, which is an organization responsible for managing technology transfers from public universities in Washington state to the private sector for commercialization. Mr. Fluke has also served as chairman of the trustees of Junior Achievement of Washington and president of the Seattle Council of Boy Scouts of America. Mr. Fluke earned an M.S. in electrical engineering from Stanford University in 1966 and a B.S. in electrical engineering from the University of Washington in 1964. We believe Mr. Fluke's extensive leadership experience and background as an investor in many successful companies qualifies him to serve on our board of directors.

Joseph Harding, Ph.D., has served on our board of directors since October 2011. Dr. Harding is co-inventor and co-founder of Athira Pharma, Inc. and has served on our board of directors since October 2011. He is the co-author of over 200 peer-reviewed publications and lead inventor of three issued and two published patents and a recent PCT application. Dr. Harding completed his Ph.D. in chemistry at the University of Delaware in 1974 and his B.S. in chemistry at Allegheny College in 1970. He was a postdoctoral fellow in neurochemistry with Frank Margolis at Roche Institute of Molecular Biology in 1974–76 and has been at Washington State University since 1976. Dr. Harding was the co-founder of Pacific Northwest Biotechnology. We believe Dr. Harding's extensive scientific research experience and background in scientific innovation qualify him to serve on our board of directors.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Board Composition and Risk Oversight

Our board of directors is currently composed of five members. Each of our directors other than Dr. Kawas is independent within the meaning of the independent director guidelines of the Nasdaq Global Market. All of the directors other than Dr. Kawas were elected to our board of directors pursuant to a voting agreement that will terminate automatically by its terms upon the completion of a qualified initial public offering. Our certificate of incorporation and bylaws to be in effect upon the completion of this offering provide that the number of our directors shall be at least one and will be fixed from time to time by resolution of our board of directors.

Immediately prior to the completion of this offering, our board of directors will be divided into three classes of directors. At each annual meeting of stockholders, a class of directors will be elected for a three-year term to succeed the class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held

during the years 2021 for the Class I directors, 2022 for the Class II directors and 2023 for the Class III directors.

- Our Class I directors will be and .
- Our Class II directors will be and .
- Our Class III directors will be and .

The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control. See the section of this prospectus titled “Description of Capital Stock—Anti-Takeover Effects of Delaware and Washington Law and Our Certificate of Incorporation and Bylaws” for a discussion of other anti-takeover provisions found in our certificate of incorporation.

Our board of directors has an active role, as a whole and also at the committee level, in overseeing the management of our risks. The board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including credit risks, liquidity risks and operational risks. Our compensation committee is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. Our audit committee is responsible for overseeing the management of our risks relating to accounting matters and financial reporting. Our nominating and corporate governance committee is responsible for overseeing the management of our risks associated with the independence of our board of directors and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed through discussions from committee members about such risks. Our board of directors believes its administration of its risk oversight function has not affected the board of directors’ leadership structure.

Director Independence

Upon the completion of this offering, we anticipate that our common stock will be listed on the Nasdaq Global Market. Under the rules of the Nasdaq Global Market, independent directors must comprise a majority of a listed company’s board of directors within a specified period of the completion of this offering. In addition, the rules of the Nasdaq Global Market require that, subject to specified exceptions, each member of a listed company’s audit, compensation and nominating and corporate governance committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. Under the rules of the Nasdaq Global Market, a director will only qualify as an “independent director” if, in the opinion of that company’s board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

To be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries.

In , our board of directors undertook a review of its composition, the composition of its committees and the independence of our directors and considered whether any director has a material relationship with us that could compromise his ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that, other than Dr. Kawas, none of our directors has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is “independent” as that term is defined under the rules of the Nasdaq Global Market. In , our board of directors also determined that , who comprise our audit committee; , who comprise

our compensation committee; and , who comprise our nominating and corporate governance committee, satisfy the independence standards for those committees established by applicable SEC rules and the rules of the Nasdaq Global Market. In making this determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

Board Leadership Structure

Dr. Yamada serves as the chairman of the board of directors, and Dr. Kawas serves as our president and chief executive officer. The roles of chief executive officer and chairman of the board of directors are currently separated in recognition of the differences between the two roles. We believe that it is in the best interests of our stockholders for the board of directors to make a determination regarding the separation or combination of these roles each time it elects a new chairman or appoints a chief executive officer, based on the relevant facts and circumstances applicable at such time. In 2014, when Dr. Kawas was first appointed as our president and chief executive officer, the Board determined it was in the best interests of our stockholders to continue to maintain an independent chairman to allow Dr. Kawas to focus on her primary responsibility for the operational leadership and strategic direction of our company.

Board Committees

Our board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and the responsibilities described below.

Audit Committee

The members of our audit committee are , and , each of whom is a non-employee member of our board of directors. Our audit committee chairman, , is our audit committee financial expert, as that term is defined under the SEC rules implementing Section 407 of the Sarbanes-Oxley Act of 2002, and possesses financial sophistication, as defined under the rules of the Nasdaq Global Market. Our audit committee oversees our corporate accounting and financial reporting process and assists our board of directors in monitoring our financial systems. Our audit committee operates under a written charter that specifies its duties and responsibilities and satisfies the applicable listing standards of the Nasdaq Global Market. Our board of directors has determined that each of , and is independent for audit committee purposes, as that term is defined in the rules of the SEC and the applicable Nasdaq rules, and have sufficient knowledge in financial and auditing matters to serve on the audit committee.

Our audit committee will:

- select, retain, compensate, evaluate, oversee and, where appropriate, terminate our independent registered public accounting firm;
- review and approve the scope and plans for the audits and the audit fees and approve all non-audit and tax services to be performed by the independent audit;
- evaluate the independence and qualification of the independent registered public accounting firm;
- review internal controls and integrity of financial statements;
- review financial information presentation, earnings press releases and guidance;
- oversee the design, implementation and performance of our internal audit function, if any;

- set hiring policies with regard to the hiring of employees and former employees of our independent auditor and oversee compliance with such policies;
- review, approve and monitor related party transactions;
- adopt and oversee procedures to address complaints regarding accounting, internal accounting controls or auditing matters;
- review and discuss with our management and the independent auditor our compliance with various laws;
- review and discuss with management our independent auditor guidelines and policies to identify, monitor, and address enterprise risks;
- engage independent legal, accounting and other advisors;
- provide appropriate funding for compensation to independent registered accounting firm, advisers and related expenses; and
- review the adequacy of the audit committee charter and recommend any proposed changes to our board of directors.

Compensation Committee

The members of our compensation committee are , and . is the chairman of our compensation committee. Our compensation committee oversees our compensation policies, plans and benefits programs. Our compensation committee operates under a written charter that specifies its duties and responsibilities and satisfies the applicable listing standards of the Nasdaq Global Market. The compensation committee will:

- review and approve the corporate goals and objectives applicable to the compensation of our chief executive officer;
- review and approve the compensation and benefits for our executive officers;
- review, approve, and administer employee compensation plans;
- advise on proposals to stockholders on executive compensation matters;
- oversee compensation plans and programs;
- review and discuss our compensation policies and practices and the risks related thereto;
- monitor compliance with any stock ownership guidelines;
- approve the creation or revision of any clawback policy allowing us to recoup compensation paid to employees;
- oversee regulatory compliance with respect to compensation matters;
- retain or obtain the advice of compensation consultants; and
- review the adequacy of the compensation committee charter and recommend any proposed changes to our board of directors.

Nominating and Corporate Governance Committee

The members of our nominating and corporate governance committee are , and . is the chairman of our nominating and corporate governance committee. Our nominating and corporate governance committee oversees and assists our board of directors in reviewing and recommending nominees for election as directors. Our nominating and corporate governance committee operates under a written charter that specifies its duties and

responsibilities and satisfies the applicable listing standards of the Nasdaq Global Market. The nominating and corporate governance committee will:

- establish procedures for the submission of candidates for election to our board of directors;
- conduct a periodic review of our succession planning process for the executive management team;
- review the structure and composition of each committee of our board of directors and make recommendations for changes to the committees;
- develop and recommend to the board of directors corporate governance guidelines and annually review the corporate governance guidelines and their application;
- oversee governance practices;
- oversee our director orientation and continuing education;
- oversee the evaluation of our board of directors and its committees;
- develop, approve, review and monitor compliance with our Code of Business Conduct and Ethics;
- administer policies and procedures for various constituencies that are involved with us to communicate with the non-management members of our board of directors; and
- review the adequacy of the nominating and corporate governance committee charter and recommend any proposed changes to our board of directors.

Our board of directors may from time to time establish other committees.

Director Compensation

Prior to this offering, we did not have a formal policy with respect to compensation payable to our non-employee directors for their service as directors. From time to time, we have granted equity awards to attract them to join our board of directors and for their continued service on our board of directors. We also have reimbursed our directors for expenses associated with attending meetings of our board of directors and its committees.

In 2020, our compensation committee retained Radford, a third-party compensation consultant, to provide our board of directors and its compensation committee with an analysis of publicly available market data and assistance in determining compensation to be provided to our non-employee directors on and after the effective date of the registration statement of which this prospectus forms a part. Based on the discussions with and assistance from Radford, prior to the completion of this offering, our board of directors intends to adopt, and we expect our stockholders will approve, an Outside Director Compensation Policy that will provide for certain compensation to our non-employee directors effective on and after the effective date of the registration statement of which this prospectus forms a part.

Cash Compensation

The Outside Director Compensation Policy will provide for the following cash compensation program for our non-employee directors, effective upon the effective date of the registration statement of which this prospectus forms a part:

- $ per for service as a non-employee director;
- $ per for service as non-executive chairman;
- $ per for service as chairman of the audit committee;
- $ per for service as a member of the audit committee;

- $ per for service as chairman of the compensation committee;
- $ per for service as a member of the compensation committee;
- $ per for service as chairman of the nominating and corporate governance committee; and
- $ per for service as a member of the nominating and corporate governance committee.

Each non-employee director who serves as a committee chair will receive only the cash retainer fee as the chair of the committee but not the cash retainer fee as a member of that committee. These fees to our non-employee directors will be paid quarterly in arrears on a prorated basis. Under our Outside Director Compensation Policy, we also will reimburse our non-employee directors for reasonable travel expenses to attend meetings of our board of directors and its committees.

Equity Compensation

Initial Award. Pursuant to our Outside Director Compensation Policy, each person who first becomes a non-employee director on or after the effective date of such policy will receive, on the first trading day on or after the date that the person first becomes a non-employee director, an initial award (or, the Initial Award) of stock options to purchase shares of our common stock. The Initial Award will be scheduled to vest in equal installments as to one 1/36th of the shares of our common stock subject at grant to the Initial Award on a monthly basis following the Initial Award's grant date, on the same day of the month as the grant date, subject to continued services to us through the applicable vesting dates. If the person was a member of our board of directors and also an employee, then becoming a non-employee director due to termination of employment will not entitle the person to an Initial Award.

Annual Award. Each non-employee director who has completed at least six months of continuous service as a non-employee director automatically will receive, on the first trading day immediately after the date of each annual meeting of our stockholders that occurs following the effective date of our Outside Director Compensation Policy, an annual award (or, the Annual Award) of stock options to purchase shares of our common stock. Each Annual Award will be scheduled to vest in equal installments as to 1/12th of the shares of our common stock subject at grant to the Annual Award on a monthly basis following the Annual Award's grant date, on the same day of the month as the grant date, or if earlier the day immediately before the day of the next annual meeting of stockholders that occurs after the grant date of the Annual Award, subject to continued services to us through the applicable vesting dates.

Change in Control. In the event of our change in control, as defined in our 2020 Equity Incentive Plan, each non-employee director's then outstanding equity awards covering shares of our common stock will accelerate vesting in full, provided that he or she remains a non-employee director through the date of our change in control.

Other Award Terms. Each Initial Award and Annual Award will be granted under our 2020 Equity Incentive Plan (or its successor plan, as applicable) and form of award agreement under such plan. These awards will have a maximum term to expiration of 10 years from their grant and a per share exercise price equal to 100% of the fair market value of a share of our common stock on the award's grant date.

Director Compensation Limits. Our Outside Director Compensation Policy will provide that in any fiscal year, a non-employee director may be paid cash compensation and granted equity awards with an aggregate value of no more than $ (with the value of equity awards based on its grant date fair value determined in accordance with U.S. Generally Accepted Accounting Principles for purposes of this limit), with such limit increased to $ for the fiscal year of his or her initial service as a non-employee director. Equity awards granted or other compensation provided to a non-employee director while he or she was an employee or consultant (other than a non-employee director), or granted or provided before the effective date of the registration statement of which this prospectus forms a part, will not count toward this annual limit.

Code of Business Conduct and Ethics

In 2020, we adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The code of business conduct and ethics will become effective on the date of effectiveness of the registration statement of which this prospectus forms a part. Following this offering, a copy of the code will be posted on the investor section of our website.

Compensation Committee Interlocks and Insider Participation

The members of our compensation committee are , and . None of the members of our compensation committee is an officer or employee of our company. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee (or other board committee performing equivalent functions or, in the absence of any such committee, the entire board of directors) of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Limitation of Liability and Indemnification Matters

Our certificate of incorporation and bylaws provide for the indemnification of our directors and officers to the fullest extent permitted under the Delaware General Corporation Law. In addition, our certificate of incorporation provides that our directors shall not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director and that if the Delaware General Corporation Law is amended to authorize corporate action further limiting the personal liability of directors, then the liability of our directors shall be limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

As permitted by the Delaware General Corporation Law, we have entered into separate indemnification agreements with each of our directors and certain of our officers that require us, among other things, to indemnify them against certain liabilities which may arise by reason of their status as directors or officers. We expect to obtain and maintain insurance policies under which our directors and officers are insured, within the limits and subject to the limitations of those policies, against certain expenses in connection with the defense of, and certain liabilities that might be imposed as a result of, actions, suits or proceedings to which they are parties by reason of being or having been directors or officers. The coverage provided by these policies may apply whether or not we would have the power to indemnify such person against such liability under the provisions of the Delaware General Corporation Law.

We believe that these provisions and agreements are necessary to attract and retain qualified persons as our officers and directors. At present, there is no pending litigation or proceeding involving our directors or officers for whom indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

EXECUTIVE COMPENSATION

This section discusses the material components of the executive compensation program for our executive officers who are named in the subsection titled "*—2019 Summary Compensation Table*" below. For 2019, our "named executive officers" and their positions were as follows:

- Leen Kawas, Ph.D., our president and chief executive officer;
- Mark Litton, Ph.D., our chief operating officer; and
- Kevin Church, Ph.D., our vice president of discovery.

2019 Summary Compensation Table

The following table represents information regarding the total compensation awarded to, earned by or paid to our named executive officers during 2019:

Name and Principal Position	Year	Salary ($)	Option Awards ($)(1)	Bonus ($)(2)	All Other Compensation ($)(3)	Total ($)
Leen Kawas, Ph.D., President and Chief Executive Officer	2019	284,999	—	—	2,016	287,015
Mark Litton, Ph.D., Chief Operating Officer	2019	12,000	180,480	—	—	192,480
Kevin Church, Ph.D., Vice President of Discovery	2019	113,666	11,650	10,000	—	135,316

(1) In accordance with SEC rules, amounts in this column reflect the aggregate grant date fair value of stock options granted during 2019 computed in accordance with ASC Topic 718, rather than the amounts paid or realized by the named executive officer. We provide information regarding the assumptions used to calculate the value of all stock options made to our directors in Note 12 to our audited financial statements included elsewhere in this prospectus.

(2) Reflects a discretionary bonus paid to Dr. Church.

(3) The amounts in this column represent reimbursements paid to Dr. Kawas to cover parking fees.

Outstanding Equity Awards at December 31, 2019

The following table shows grants of stock options and stock awards to each of our named executive officers outstanding at December 31, 2019.

		Number of Securities Underlying Unexercised Options			
Name	Vesting Commencement Date	Exercisable (#)	Unexercisable (#)	Option Exercise Prices ($)	Option Expiration Date
Leen Kawas, Ph.D.	1/20/2014	200,000	—	$ 0.02	08/28/2024
	08/29/2014	400,000	—	$ 0.02	08/28/2024
	10/24/2015	1,800,000	—	$ 0.06	10/23/2025
	12/01/2017	500,000	—	$ 0.17	01/21/2023
	01/01/2019	—	250,000(1)	$ 0.19	12/17/2023
Mark Litton, Ph.D.	07/01/2019	—	1,600,000(2)	$ 0.17	08/14/2029
Kevin Church, Ph.D.	07/01/2016	225,000	75,000(2)	0.13	06/19/2026
	09/01/2016	50,000		0.13	08/30/2026
	06/19/2017	25,000		0.15	06/19/2027
	01/01/2019	—	100,000(2)	0.17	12/17/2028

(1) Stock option vests over three years, with 1/3 vesting on each anniversary of the vesting commencement date, subject to continued service with us through the applicable vesting date.

(2) Stock option vests over four years, with 1/4 vesting on each anniversary of the vesting commencement date, subject to continued service with us through the applicable vesting date.

Executive Employment Arrangements

Each of our named executive officers has executed our standard form of confidential information, invention assignment and arbitration agreement.

Dr. Leen Kawas

Prior to the completion of this offering, we intend to enter into a confirmatory employment letter with Dr. Kawas, our president and chief executive officer. The confirmatory employment letter will have no specific term and will provide that Dr. Kawas is an at-will employee. Dr. Kawas's current annual base salary is $ and she is eligible for an annual target cash incentive payment equal to % of her annual base salary.

Dr. Mark Litton

Prior to the completion of this offering, we intend to enter into a confirmatory employment letter with Dr. Litton, our chief operating officer. The confirmatory employment letter will have no specific term and will provide that Dr. Litton is an at-will employee. Dr. Litton's current annual base salary is $ and he is eligible for an annual target cash incentive payment equal to % of his annual base salary.

Dr. Kevin Church

Prior to the completion of this offering, we intend to enter into a confirmatory employment letter with Dr. Kevin Church, our vice president of discovery. The confirmatory employment letter will have no specific term and will provide that Dr. Church is an at-will employee. Dr. Church's current annual base salary is $ and he is eligible for an annual target cash incentive payment equal to % of his annual base salary.

Executive Incentive Compensation Plan

Prior to the completion of this offering, our board of directors intends to adopt our Executive Incentive Compensation Plan. Our Executive Incentive Compensation Plan will be administered by our board of directors or a committee appointed by our board of directors. Unless and until our board of directors determines otherwise, our compensation committee will administer our Executive Incentive Compensation Plan. Our Executive Incentive Compensation Plan will allow us to grant incentive awards, generally payable in cash, to employees selected by the administrator, including our named executive officers, based upon any performance goals that may be established by the administrator.

Under our Executive Incentive Compensation Plan, the administrator will determine any performance goals applicable to an award, which goals may include, without limitation, goals related to . The performance goals may differ from participant to participant and from award to award. The administrator also may determine that a target award or portion of a target award will not have a performance goal associated with it but instead will be granted, if at all, as determined by the administrator.

The administrator of our Executive Incentive Compensation Plan, in its sole discretion and at any time, may increase, reduce or eliminate a participant's actual award, and/or increase, reduce or eliminate the amount allocated to any bonus pool for a particular performance period. The actual award may be below, at or above a participant's target award, in the discretion of the administrator. The administrator may determine the amount of any reduction on the basis of such factors as it deems relevant, and the administrator is not required to establish any allocation or weighting with respect to the factors it considers.

Actual awards generally will be paid in cash (or its equivalent) only after they are earned, and, unless otherwise determined by the administrator, a participant must be employed with us through the date the actual award is paid. The administrator of our Executive Incentive Compensation Plan reserves the right to settle an actual award with a grant of an equity award under our then-current equity compensation plan, which equity award may have such terms and conditions, including vesting, as determined by the administrator. Payment of awards occurs as soon as administratively practicable after they are earned, but no later than the dates set forth in our Executive Incentive Compensation Plan.

Awards under our Executive Incentive Compensation Plan are subject to any clawback policy of ours, which we may be required to adopt from time to time to comply with applicable laws. The administrator also may impose such other clawback, recovery or recoupment provisions with respect an award under our Executive Incentive Compensation Plan as the administrator determines necessary or appropriate, including for example, reduction, cancellation, forfeiture or recoupment upon a termination of a participant's employment for cause. Certain participants may be required to reimburse us for certain amounts paid under an award under our Executive Incentive Compensation Plan in connection with certain accounting restatements we may be required to prepare due to our material noncompliance with any financial reporting requirements under applicable securities laws, as a result of misconduct.

The administrator of our Executive Incentive Compensation Plan will have the authority to amend, alter, suspend or terminate our Executive Incentive Compensation Plan, provided such action does not impair the existing rights of any participant with respect to any earned awards. Our Executive Incentive Compensation Plan will remain in effect until terminated in accordance with its terms.

Employee Benefit Plans

2014 Equity Incentive Plan

Our board of directors adopted our 2014 Equity Incentive Plan, or our 2014 Plan, on August 29, 2014 and our stockholders approved our 2014 Plan on March 3, 2015. Prior to the effectiveness of the registration statement of which this prospectus forms a part, our 2014 Plan will be terminated and we will not grant any additional awards under our 2014 Plan thereafter. However, our 2014 Plan will continue to govern the terms and conditions of the outstanding awards granted under our 2014 Plan prior to its termination.

Our 2014 Plan allows for the grant of incentive stock options, within the meaning of Section 422 of the Code, nonstatutory stock options, stock appreciation rights, restricted stock awards and restricted stock units (each, an "award") to eligible employees, directors and consultants.

Authorized Shares

As of June 30, 2020, an aggregate of shares of our common stock is reserved for issuance under our 2014 Plan. As of June 30, 2020, there were stock options covering shares of our common stock outstanding under our 2014 Plan and no stock appreciation rights, restricted stock awards or restricted stock units outstanding under our 2014 Plan.

Plan Administration

Our board of directors or a committee thereof appointed by our board of directors administers the 2014 Plan. The administrator has authority and discretion to administer our 2014 Plan and to control its operation, including the authority to construe and interpret the terms of our 2014 Plan and the awards granted under it, determine the terms of awards, including the recipients, the number of shares subject to each award and the vesting schedule. The administrator may amend awards to reduce the exercise price of any outstanding options or stock appreciation rights, or provide that outstanding options or stock appreciation rights may be cancelled in exchange for awards of the same type (granted under the 2014 Plan or another equity plan of ours covering the same or different number of shares), restricted stock or restricted stock unit awards and/or cash or other consideration.

Stock Options

Stock options have been granted under our 2014 Plan. The term of an option is stated in the applicable award agreement, but may not exceed 10 years from the grant date. The administrator determines the exercise price of options, which generally may not be less than 100% of the fair market value of our common stock on the grant date, except as provided for in the 2014 Plan. The administrator determines the method of payment of the exercise price as well as the period of time after a participant's termination of service during which the participant may exercise his or her option, which generally must be at least 30 days (or at least six months in the event of the participant's termination of service due to death or disability) following such termination of service. Vested options generally terminate immediately if a participant's continuous service terminates due to "cause" (as defined in the 2014 Plan) unless the participant's award agreement provides otherwise. In no event will an option remain exercisable beyond its original term. If a participant does not exercise his or her option within the time specified in the award agreement, the option will terminate.

Transferability of Awards

Our 2014 Plan generally does not allow for the transfer of awards except by will or the laws of descent and distribution, and only the recipient of an award may exercise an option or stock appreciation right during his or her lifetime.

Certain Adjustments

In the event of certain changes in our capitalization, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under the 2014 Plan, the administrator will make proportionate adjustments to the number and class of shares that may be delivered under the 2014 Plan, the class and number of shares that may be issued on the exercise of incentive stock options, and the number, class and price of shares covered by each outstanding award. The administrator's determination regarding such adjustments will be final, binding and conclusive.

Dissolution or Liquidation

In the event of our dissolution or liquidation, all awards will terminate immediately prior to the completion of such proposed transaction.

Corporate Transactions

Our 2014 Plan provides that in the event of our merger or other corporate transaction (as defined in our 2014 Plan) and except as otherwise provided in the award agreements, the administrator may provide that outstanding awards may be assumed or continued, substituted with equivalent awards, accelerated as to its vesting to a date prior to the corporate transaction and terminated if not exercised (if applicable), cancelled without consideration to the extent not vested or exercised, or cancelled in exchange for a payment equal to the value of property the participant would have received upon exercise of the award less the exercise price payable in connection with such exercise. The administrator need not take the same action with respect to all awards or with respect to all participants.

Amendment and Termination

Our board of directors has the authority to amend, suspend or terminate our 2014 Plan at any time. No amendment, suspension or termination of our 2014 Plan will impair the rights of a participant, unless mutually agreed otherwise between the participant and the administrator in writing. As noted above, it is expected that prior to the effectiveness of the registration statement of which this prospectus forms a part, our 2014 Plan will be terminated, and we will not grant any additional awards under our 2014 Plan thereafter.

2020 Equity Incentive Plan

Prior to the completion of this offering, our board of directors intends to adopt, and we expect our stockholders will approve, our 2020 Equity Incentive Plan, or, the 2020 Plan. We expect that the 2020 Plan will be effective on the business day immediately prior to the effective date of our registration statement of which this prospectus forms a part. Our 2020 Plan will provide for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (or, the Code), to our employees and any of our parent or subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, and performance awards to our employees, directors and consultants and any of our parent or subsidiary corporations' employees and consultants.

Authorized Shares

A total of shares of our common stock will be reserved for issuance pursuant to our 2020 Plan. In addition, the shares reserved for issuance under our 2020 Plan will include (1) those shares reserved but unissued under our Plan (or, the Prior Plan) as of immediately prior to its termination, and (2) shares of our common stock subject to awards granted under our Prior Plan that, on or after the termination of the Prior Plan, expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us (provided that the maximum number of shares that may be added to the 2020 Plan pursuant to (1) and (2) is shares). The number of shares available for issuance under our 2020 Plan also will include an annual increase on the first day of each year for a period of ten years, beginning with our fiscal year , equal to the least of:

- shares;
- (%) of the outstanding shares of all classes of our common stock as of the last day of the immediately preceding fiscal year; and
- such number of shares as our board of directors may determine no later than the last day of our immediately preceding fiscal year.

Shares issuable under our 2020 Plan will be authorized, but unissued, or reacquired shares of our common stock. If an award expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an exchange program (as described below), or, with respect to restricted stock, restricted stock units, or performance awards, is forfeited to or repurchased due to failure to vest, the unpurchased shares (or for awards other than stock options or stock appreciation rights, the forfeited or repurchased shares) will become available for future grant or sale under the 2020 Plan. With respect to stock appreciation rights, only the net shares actually issued will cease to be available under the 2020 Plan and all remaining shares under stock appreciation rights will remain available for future grant or sale under the 2020 Plan. Shares that have actually been issued under the 2020 Plan under any award will not be returned to the 2020 Plan; except if shares issued pursuant to awards of restricted stock, restricted stock units, or performance awards are repurchased or forfeited, such shares will become available for future grant under the 2020 Plan. Shares used to pay the exercise price of an award or satisfy the tax withholding obligations related to an award will become available for future grant or sale under the 2020Plan. To the extent an award is paid out in cash rather than shares, such cash payment will not result in a reduction in the number of shares available for issuance under the 2020 Plan.

Plan Administration

Our board of directors or one or more committees appointed by our board of directors will have authority to administer our 2020 Plan. We expect that the compensation committee of our board of directors initially will administer our 2020 Plan. In addition, if we determine it is desirable to qualify transactions under our 2020 Plan as exempt under Rule 16b-3 of the Exchange Act, such transactions will be structured to satisfy the requirements for exemption under Rule 16b-3. Subject to the provisions of our 2020 Plan, the administrator has the power to administer our 2020 Plan and make all determinations deemed necessary or advisable for administering the 2020 Plan, including but not limited to, the power to determine the fair market value of our common stock, select the service providers to whom awards may be granted, determine the number of shares covered by each award, approve forms of award agreements

for use under the 2020 Plan, determine the terms and conditions of awards (including, but not limited to, the exercise price, the time or times at which awards may be exercised, any vesting acceleration or waiver or forfeiture restrictions and any restriction or limitation regarding any award or the shares relating thereto), construe and interpret the terms of our 2020 Plan and awards granted under it, prescribe, amend and rescind rules relating to our 2020 Plan, including creating sub-plans, modify or amend each award, and allow a participant to defer the receipt of payment of cash or the delivery of shares that otherwise would be due to such participant under an award. The administrator also has the authority to allow participants the opportunity under an exchange program to transfer outstanding awards granted under the 2020 Plan to a financial institution or other person or entity selected by the administrator, and to institute an exchange program by which outstanding awards granted under the 2020 Plan may be surrendered or cancelled in exchange for awards of the same type, which may have a higher or lower exercise price and/or different terms, awards of a different type and/or cash, or by which the exercise price of an outstanding award granted under the 2020 Plan is increased or reduced. The administrator's decisions, interpretations and other actions are final and binding on all participants and will be given the maximum deference permitted by applicable law.

Stock Options

Stock options may be granted under our 2020 Plan. The exercise price of options granted under our 2020 Plan must be equal to at least 100% of the fair market value of a share of our common stock on the date of grant. The term of an option may not exceed ten years. With respect to any participant who owns more than 10% of the voting power of all classes of our (or any of our parent's or subsidiary's) outstanding stock, the term of an incentive stock option granted to such participant must not exceed five years and the per share exercise price must equal at least 110% of the fair market value of a share of our common stock on the grant date. The administrator may grant incentive stock options under the 2020 Plan for a period of ten years from the earlier of the date our board of directors approves the 2020 Plan or the date that our stockholders approve the 2020 Plan. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, certain shares, cashless exercise, net exercise, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director or consultant, he or she may exercise his or her option for the period of time stated in his or her option agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the option will remain exercisable for six months. In all other cases, in the absence of a specified time in an award agreement, the option will remain exercisable for three months following the termination of service. An option, however, may not be exercised later than the expiration of its term. Subject to the provisions of our 2020 Plan, the administrator determines the terms of options.

Stock Appreciation Rights

Stock appreciation rights may be granted under our 2020 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. The term of a stock appreciation right may not exceed ten years. After the termination of service of an employee, director or consultant, he or she may exercise his or her stock appreciation right for the period of time stated in his or her stock appreciation rights agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the stock appreciation rights will remain exercisable for six months. In all other cases, in the absence of a specified time in an award agreement, the stock appreciation rights will remain exercisable for three months following the termination of service. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of our 2020 Plan, the administrator determines the terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per-share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Restricted Stock

Restricted stock may be granted under our 2020 Plan. Restricted stock awards are grants of shares of our common stock that may vest in accordance with terms and conditions established by the

administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of our 2020 Plan, will determine the terms and conditions of such awards. The administrator may impose whatever vesting conditions (if any) it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us), and the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock awards generally will have voting and dividend rights with respect to such shares upon grant, unless the administrator provides otherwise. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Restricted Stock Units

Restricted stock units may be granted under our 2020 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of our 2020 Plan, the administrator determines the terms and conditions of restricted stock units, including any vesting criteria and the form and timing of payment. The administrator may set vesting criteria based upon the achievement of company-wide, divisional, business unit, or individual goals (including, but not limited to, continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned restricted stock units in the form of cash, shares, or a combination of both. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

Performance Awards

Performance awards may be granted under the 2020 Plan. Performance awards are awards that may be earned in whole or in part on the attainment of performance goals or other vesting criteria that the administrator may determine, and that may be denominated in cash or stock. Subject to the terms and conditions of the 2020 Plan, the administrator determines the terms and conditions of performance awards, including any vesting criteria and form and timing of payment. The administrator may set vesting criteria based upon the achievement of company-wide, divisional, business unit, or individual goals (including, but not limited to, continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned performance awards in the form of cash, shares, or a combination of both. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

Outside Directors

All outside (non-employee) directors will be eligible to receive all types of awards (except for incentive stock options) under our 2020 Plan. Prior to the completion of this offering, we intend to implement a formal Outside Director Compensation Policy pursuant to which our outside directors will be eligible to receive equity awards under our 2020 Plan. Our 2020 Plan will provide that in any given fiscal year, no outside director may be granted awards (the value of which will be based on their grant date fair value) under our 2020 Plan and any other compensation (including without limitation any cash retainers and fees) that in the aggregate exceed $, provided that in the initial year of service such amount is increased to $. The grant-date fair values of awards granted under our 2020 Plan will be determined according to U.S. Generally Accepted Accounting Principles. Any awards or other compensation provided to an individual for his or her services as an employee or a consultant (other than an outside director), or prior to the effective date of the registration statement of which this prospectus forms a part, will not count toward this limit. This maximum limit provision does not reflect the intended size of any potential grants or a commitment to make grants to our outside directors under our 2020 Plan in the future.

Non-Transferability of Awards

Unless the administrator provides otherwise, our 2020 Plan generally does not allow for the transfer of awards other than by will or the laws of descent and distribution, and only the recipient of an award may exercise an award during his or her lifetime. If the administrator makes an award transferrable, such award will contain such additional terms and conditions as the administrator deems appropriate.

Certain Adjustments

In the event of certain changes in our capitalization, such as a dividend or other distribution, recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, reclassification, repurchase or exchange of our shares or other securities or other change in our corporate structure affecting our shares (other than ordinary dividends or other ordinary distributions), to prevent diminution or enlargement of the benefits or potential benefits available under our 2020 Plan, the administrator will adjust the number and class of shares that may be delivered under our 2020 Plan and/or the number, class and price of shares covered by each outstanding award and any numerical share limits set forth in our 2020 Plan.

Dissolution or Liquidation

In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and all awards will terminate immediately prior to the consummation of such proposed transaction.

Merger or Change in Control

Our 2020 Plan provides that in the event of our merger or change in control, as defined in our 2020 Plan, each outstanding award will be treated as the administrator determines, without a participant's consent. The administrator may provide that awards granted under the 2020 Plan will be assumed or substituted by substantially equivalent awards, be terminated immediately before the merger or change in control, become vested and exercisable or payable and be terminated in connection with the merger or change in control, be terminated in exchange for cash, other property or other consideration or any combination of the above. The administrator is not required to treat all awards, all awards held by a participant, all portions of awards, or all awards of the same type, similarly.

If a successor corporation or its parent or subsidiary does not assume or substitute an equivalent award for any outstanding award (or a portion of such award), then such award (or its applicable portion) will fully vest, all restrictions on such award (or its applicable portion) will lapse, all performance goals or other vesting criteria applicable to such award (or its applicable portion) will be deemed achieved at 100% of target levels and such award (or its applicable portion) will become fully exercisable, if applicable, for a specified period prior to the transaction, unless specifically provided otherwise under the applicable award agreement or other written agreement with the participant. The award (or its applicable portion) will then terminate upon the expiration of the specified period of time. If an option or stock appreciation right is not assumed or substituted, the administrator will notify the participant that such option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the option or stock appreciation right will terminate upon the expiration of such period.

If an outside director's awards are assumed or substituted for in our merger or change in control and the service of such outside director is terminated (other than upon his or her voluntary resignation that does not include a resignation at the request of the acquirer) on or following the merger or change in control, all such awards will fully vest, all restrictions on such awards will lapse, all performance goals or other vesting criteria applicable to such awards will be deemed achieved at 100% of target levels and such awards will become fully exercisable, if applicable, unless specifically provided otherwise under the applicable award agreement or other written agreement with the outside director.

Clawback

Awards are subject to any clawback policy of ours, which we may establish and/or amend from time to time to comply with applicable laws. The administrator also may specify in an award agreement that the participant's rights, payments and benefits with respect to an award will be subject to reduction, cancellation, forfeiture or recoupment upon the occurrence of certain specified events. Our board of directors may require a participant to forfeit, return or reimburse us all or a portion of the award and any amounts paid under the award in order to comply with any clawback policy of ours or applicable laws.

Amendment; Termination

The administrator has the authority to amend, suspend or terminate our 2020 Plan, provided such action does not materially impair the rights of any participant unless mutually agreed otherwise. Our 2020 Plan will remain in effect until terminated in accordance with its terms.

2020 Employee Stock Purchase Plan

Prior to the completion of this offering, we expect that our board of directors will adopt, and our stockholders will approve, a 2020 Employee Stock Purchase Plan, or the ESPP. Our ESPP will be effective upon the later of its adoption by our board of directors or one business day immediately before the effective date of the registration statement of which this prospectus forms a part.

Authorized Shares

A total of shares of our common stock will be available for issuance under our ESPP. In addition, our ESPP will provide for annual increases in the number of shares of our common stock available for issuance under our ESPP on the first day of each of our fiscal years beginning with our fiscal year 2021, equal to the least of:

- shares;
- percent (%) of the outstanding shares of all classes of our common stock on the last day of our immediately preceding fiscal year; and
- such other number of shares as our board of directors may determine as of no later than the last day of our immediately preceding fiscal year.

Shares issuable under the ESPP will be authorized, but unissued, or reacquired shares of our common stock.

Plan Administration

Our board of directors or a committee appointed by our board of directors may administer the ESPP. We anticipate that our compensation committee will administer our ESPP. The administrator will have full and exclusive discretionary authority to construe, interpret, and apply the terms of the ESPP, delegate ministerial duties to any of our employees, designate separate offerings under the ESPP, designate our subsidiaries as participating in the ESPP, determine eligibility, adjudicate all disputed claims filed under the ESPP and establish procedures that it deems necessary or advisable for the administration of the ESPP, including, but not limited to, adopting such procedures, sub-plans, and appendices to the enrollment agreement as are necessary or appropriate to permit participation in the ESPP by employees who are non-U.S. nationals or employed outside the U.S. The administrator's findings, decisions, and determinations are final and binding on all participants to the maximum extent permitted by law.

Eligibility

Generally, any of our employees are eligible to participate in our ESPP if they are customarily employed by us or any of our participating subsidiaries for at least 20 hours per week and more than five

months in any calendar year. The administrator, in its discretion, before an enrollment date for all options granted on such enrollment date in an offering, may determine that an employee who (1) has not completed at least two years of service (or a lesser period of time determined by the administrator) since the employee's last hire date, (2) customarily works not more than 20 hours per week (or a lesser period of time determined by the administrator), (3) customarily works not more than five months per calendar year (or a lesser period of time determined by the administrator), (4) is a highly compensated employee within the meaning of Code Section 414(q), or (5) is a highly compensated employee within the meaning of Code Section 414(q) with compensation above a certain level or who is an officer or subject to disclosure requirements under Section 16(a) of the Exchange Act, is or is not eligible to participate in an offering. However, an employee may not be granted an option to purchase stock under our ESPP if the employee (1) immediately after the grant, would own stock and/or hold outstanding options to purchase such stock possessing 5% or more of the total combined voting power or value of all classes of our (or any of our parent's or subsidiary's) capital stock, or (2) holds rights to purchase stock under all of our employee stock purchase plans that accrue at a rate that exceeds $25,000 worth of stock for each calendar year.

Participants may end their participation at any time during an offering period and will be paid their accrued contributions that have not yet been used to purchase shares of our common stock. Participation ends automatically upon termination of employment with us.

Offering Periods and Purchase Periods

Our ESPP includes a component, or the 423 Component, that is intended to qualify as an "employee stock purchase plan" under Code Section 423, and a component that does not comply with Code Section 423, or the Non-423 Component. For purposes of this summary, a reference to our ESPP generally will mean the terms and operations of the 423 Component. Our ESPP will provide for - month offering periods. Each offering period will have one purchase period with the same duration as the offering period. The offering periods will be scheduled to begin on the first trading day on or after and of each year, except for the first offering period, which will begin on the first trading day on or after the effective date of the registration statement of which this prospectus forms a part and end on the first trading day on or after , 2021. The administrator is authorized to change the duration of future offering periods and purchase periods under our ESPP, including the starting and ending dates of offering periods and purchase periods and the number of purchase periods in any offering periods, provided that no offering period will have a duration exceeding 27 months. If the fair market value of a share of our common stock on a purchase date is less than the fair market value on the first trading day of the offering period, participants in that offering period will be withdrawn from that offering period following their purchase of shares on that purchase date and automatically will be enrolled in a new offering period.

Contributions

Our ESPP permits participants to purchase shares of our common stock through payroll deductions of up 15% of their eligible compensation, which includes a participant's base straight time gross earnings but excludes payments for overtime and shift premium, incentive compensation, bonuses, commissions, equity compensation and other similar compensation.

Exercise of Purchase Right

Amounts deducted and accumulated by a participant under our ESPP are used to purchase shares of our common stock at the end of each purchase period. The purchase price of the shares will be 85% of the lower of (1) the fair market value of a share of our common stock on the first trading day of the offering period and (2) the fair market value of a share of our common stock on the exercise date. A participant will be permitted to purchase a maximum of shares during each offering period.

Non-transferability

A participant may not transfer the contributions credited to his or her ESPP account or rights granted under our ESPP, other than by will or the laws of descent and distribution.

Certain Adjustments

Our ESPP provides that if any dividend or other distribution (whether in the form of cash, our common stock, other securities, or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, reclassification, repurchase, or exchange of our common stock or other securities of ours, or other change in our corporate structure affecting our common stock occurs (other than any ordinary dividends or other ordinary distributions), the administrator will make adjustments to the number and class of shares that may be delivered under our ESPP and/or the purchase price per share and number of shares covered by each option granted under our ESPP that has not yet been exercised, and the numerical share limits under our ESPP. In the event of our proposed dissolution or liquidation, any offering period in progress will be shortened by setting a new purchase date and will terminate immediately before the completion of such proposed transaction, unless determined otherwise by the administrator.

Merger or Change in Control

In the event of our merger or change in control, as defined in our ESPP, a successor corporation may assume or substitute for each outstanding option. If the successor corporation does not assume or substitute for the options, the offering period then in progress will be shortened, and a new exercise date will be set to occur before the date of the proposed merger or change in control. The administrator will notify each participant that the exercise date has been changed and that the participant's option will be exercised automatically on the new exercise date unless prior to such date the participant has withdrawn from the offering period.

Amendment and Termination

The administrator has the authority to modify, amend, suspend, or terminate our ESPP except that, subject to certain exceptions described in our ESPP, no such action may adversely affect any outstanding rights to purchase shares of our common stock under our ESPP. Our ESPP will terminate automatically 20 years after the later of the date of the ESPP's adoption by our board of directors or the business day immediately prior to the effective date of our registration statement of which this prospectus forms a part, unless we terminate it earlier.

401(k) Plan

We maintain a 401(k) retirement savings plan for the benefit of our employees, including our named executive officers, who satisfy certain eligibility requirements. Our 401(k) plan provides eligible employees with an opportunity to save for retirement on a tax-advantaged basis. Under our 401(k) plan, eligible employees may elect to defer a portion of their compensation, within the limits prescribed by the Code and the applicable limits under the 401(k) plan on a pre-tax basis, through contributions to the 401(k) plan. All of a participant's contributions into the 401(k) plan are 100% vested when contributed. The 401(k) plan permits us to make contributions to eligible participants. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Code. As a tax-qualified retirement plan, pre-tax contributions to the 401(k) plan and earnings on those pre-tax contributions are not taxable to the employees until distributed from the 401(k) plan.

Limitation of Liability and Indemnification Matters

Our certificate of incorporation and bylaws, each to be effective upon completion of this offering, will provide that we will indemnify our directors and officers, and may indemnify our employees and other agents, to the fullest extent permitted by the Delaware General Corporation Law, which prohibits us from limiting the liability of our directors for the following:

- any breach of the director's duty of loyalty to us or to our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; and
- any transaction from which the director derived an improper personal benefit.

If Delaware law is amended to authorize corporate action further limiting the personal liability of a director, then the liability of our directors will be limited to the fullest extent permitted by Delaware law, as so amended. Our certificate of incorporation does not eliminate a director's duty of care and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, remain available under Delaware law. This provision also does not affect a director's responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our bylaws, we will also be empowered to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

In addition to the indemnification required in our certificate of incorporation and bylaws, we have entered into indemnification agreements with each of our current directors, officers and some employees. These agreements provide for the indemnification of our directors, officers and some employees for certain expenses and liabilities incurred in connection with any action, suit, proceeding or alternative dispute resolution mechanism, or hearing, inquiry or investigation that may lead to the foregoing, to which they are a party, or are threatened to be made a party, by reason of the fact that they are or were a director, officer, employee, agent or fiduciary of us, or any of our subsidiaries, by reason of any action or inaction by them while serving as an officer, director, agent or fiduciary, or by reason of the fact that they were serving at our request as a director, officer, employee, agent or fiduciary of another entity. In the case of an action or proceeding by or in the right of us or any of our subsidiaries, no indemnification will be provided for any claim where a court determines that the indemnified party is prohibited from receiving indemnification. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of transactions since January 1, 2017 to which we have been a party in which the amount involved exceeded $120,000 and in which any of our executive officers, directors, promoters or beneficial holders of more than 5% of our capital stock had or will have a direct or indirect material interest, other than compensation arrangements which are described under the section of this prospectus titled “Executive Compensation.”

Related-Person Transactions Policy

We have a formal, written policy, which will become effective on the date of effectiveness of the registration statement of which this prospectus forms a part, that our executive officers, directors (including director nominees), holders of more than 5% of any class of our voting securities and any member of the immediate family of or any entities affiliated with any of the foregoing persons, are not permitted to enter into a related-person transaction with us without the prior approval or, in the case of pending or ongoing related-person transactions, ratification of our audit committee. For purposes of our policy, a related-person transaction is a transaction, arrangement or relationship where we were, are or will be involved and in which a related-person had, has or will have a direct or indirect material interest.

Certain transactions with related persons, however, are exempted from pre-approval including, but not limited to:

- compensation of our executive officers and directors that is otherwise disclosed in our public filings with the SEC;
- compensation, benefits and other transactions available to all of our employees generally;
- transactions where a related-person’s interest derives solely from his or her service as a director of another entity that is a party to the transaction;
- transactions where a related-person’s interest derives solely from his or her ownership of less than 10% of the equity interest in another entity that is a party to the transaction; and
- transactions where a related-person’s interest derives solely from his or her ownership of a class of our equity securities and all holders of that class received the same benefit on a pro rata basis.

No member of the audit committee may participate in any review, consideration or approval of any related-person transaction where such member or any of his or her immediate family members is the related-person. In approving or rejecting the proposed agreement, our audit committee shall consider the relevant facts and circumstances available and deemed relevant to the audit committee, including, but not limited to:

- the benefits and perceived benefits to us;
- the materiality and character of the related-person’s direct and indirect interest;
- the availability of other sources for comparable products or services;
- the terms of the transaction; and
- the terms available to unrelated third parties under the same or similar circumstances.

Sales of Securities

The following table sets forth a summary of the sale and issuance of our securities to related persons since January 1, 2017, other than compensation arrangements which are described under the sections of this prospectus titled “Management—Director Compensation” and “Executive Compensation.” For a description of beneficial ownership see the section of this prospectus titled “Principal Stockholders.”

	Shares of Series B Convertible Preferred Stock	Principal Amount of Convertible Notes ($)	Shares of Series B-1 Convertible Preferred Stock Issued on Conversion of Convertible Notes	Shares of Common Stock Underlying Warrants
5% stockholders:				
Perceptive Life Sciences Master Fund Ltd.	13,043,478			3,260,869(1)
Entities affiliated with RTW Investments, LP	12,173,913(2)			3,043,477(3)
Entities affiliated with Franklin Templeton Investments	6,086,956(4)			1,521,738(5)
Viking Global Opportunities Illiquid Investments Sub-Master LP	8,695,652			2,173,913(1)
Executive officers and directors:				
Joseph Edelman(6)	13,043,478			3,260,869(1)
Mark Litton, Ph.D.		250,00(7)	260,236(8)	
John M. Fluke, Jr.(9)		50,000	53,379	

(1) This warrant was fully exercised prior to June 30, 2020.

(2) Consists of 2,512,696 shares of our Series B convertible preferred stock held by RTW Innovation Master Fund, Ltd., 7,922,087 shares of our Series B convertible preferred stock held by RTW Master Fund, Ltd., and 1,739,130 shares of our Series B convertible preferred stock held by RTW Venture Fund Limited.

(3) Consists of warrants to purchase 628,174 shares of our common stock held by RTW Innovation Master Fund, Ltd., warrants to purchase 1,980,521 shares of our common stock held by RTW Master Fund, Ltd., and warrants to purchase 434,782 shares of our common stock held by RTW Venture Fund Limited.

(4) Consists of 2,587,975 shares of our Series B convertible preferred stock held by Franklin Strategic Series – Franklin Biotechnology Discovery Fund and 3,498,981 shares of our Series B convertible preferred stock held by Franklin Templeton Investment Funds – Franklin Biotechnology Discovery Fund.

(5) Consists of warrants to purchase 646,993 shares of our common stock held by Franklin Strategic Series – Franklin Biotechnology Discovery Fund and warrants to purchase 874,745 shares of our common stock held by Franklin Templeton Investment Funds – Franklin Biotechnology Discovery Fund.

(6) Joseph Edelman is chief executive officer and portfolio manager of Perceptive Advisors, an affiliate of Perceptive Life Sciences Master Fund Ltd., and may be deemed to beneficially own such shares.

(7) Consists of $100,000 in aggregate principal amount of convertible notes held jointly by Dr. Litton and Alicia Litton, his wife, and $150,000 in aggregate principal amount of convertible notes held by the Irrevocable Trust of OSL, the Irrevocable Trust of SWL, and the Irrevocable Trust of WGL, each of which are trusts held for the benefit of Dr. Litton’s children.

(8) Consists of 104,095 shares of our Series B-1 convertible preferred stock held jointly by Dr. Litton and Alicia Litton, his wife, and an aggregate 156,141 shares of our Series B-1 convertible preferred stock held by the Irrevocable Trust of OSL, the Irrevocable Trust of SWL, and the Irrevocable Trust of WGL, each of which are trusts held for the benefit of Dr. Litton’s children.

(9) Consists of convertible notes and shares of our Series B convertible preferred stock held by Fluke Capital Management, L.P., of which John M. Fluke, Jr. has a beneficial ownership interest.

Convertible Notes

From December 2018 to January 2020, we issued and sold $3.8 million in aggregate principal amount of our convertible notes. The notes accrue interest at a rate of 5% per month. Dr. Litton, our chief operating officer, and Alicia Litton, his wife, purchased $100,000 in aggregate principal amount of the notes. In addition, notes in an aggregate principal amount of $150,000 were purchased by the Irrevocable

Trust of OSL, the Irrevocable Trust of WGL, and the Irrevocable Trust of SWL, each of which are trusts held for the benefit of Dr. Litton's children. [Fluke Capital Management, L.P., of which John M. Fluke, Jr., a member of our board of directors, has a beneficial ownership interest, also purchased notes in an aggregate principal amount of $50,000]. All outstanding notes to purchase our common stock converted into shares of our Series B-1 convertible preferred stock at a conversion price of $0.9775 per share in connection with our Series B financing in May 2020. The Series B financing is described below.

Series B Financing

From May 2020 to June 2020, we issued and sold to investors an aggregate of 74,328,105 shares of Series B convertible preferred stock at $1.15 per share for aggregate proceeds of $85.5 million, an aggregate of 4,067,148 shares of Series B-1 convertible preferred stock at a conversion price of $0.9775 per share upon conversion of outstanding convertible notes, and warrants to purchase 18,582,009 shares of our common stock at an exercise price of $0.01 per share. Perceptive Life Sciences Master Fund Ltd., entities affiliated with RTW Investments, LP, and Viking Global Opportunities Illiquid Investments Sub-Master LP are each significant stockholders of the company and participated in the Series B financing. Perceptive Advisors LLC serves as the investment manager of Perceptive Life Sciences Master Fund Ltd. Joseph Edelman, a member of our board of directors, is the managing member of Perceptive Advisors LLC and he may be deemed to have shared voting and dispositive power over our securities held by Perceptive Life Sciences Master Fund Ltd.

Investors' Rights Agreement

We have entered into an investors' rights agreement with certain of our stockholders, including Dr. Kawas, our chief executive officer, Dr. Litton, our chief operating officer, and Fluke Capital Management, L.P., of which John M. Fluke, Jr., a member of our board of directors, has a beneficial ownership interest. In addition, Perceptive Life Sciences Master Fund Ltd., entities affiliated with RTW Investments, LP, and Viking Global Opportunities Illiquid Investments Sub-Master LP are parties to the agreement. As of June 30, 2020, the holders of shares of our common stock, including common stock issuable upon conversion of outstanding convertible preferred stock, or their transferees, are entitled to rights with respect to the registration of their shares under the Securities Act.

Voting Agreement

The election of the members of the board of directors is governed by a voting agreement with certain of our stockholders, including Dr. Kawas, our chief executive officer, and Perceptive Life Sciences Master Fund Ltd. The parties to the voting agreement have agreed, subject to certain conditions, to vote their shares to elect as directors as follows:

- one nominee designated by Perceptive Life Sciences Master Fund Ltd., currently Mr. Edelman;
- four nominees, one of which must be our chief executive officer, designated by a majority vote of our common stock, currently Dr. Kawas, Dr. Yamada, and Messrs. Fluke and Harding;
- one nominee not otherwise an affiliate of the company designated by Perceptive Life Sciences Master Fund Ltd., currently vacant; and
- one nominee not otherwise an affiliate of the company or of any investor, who is mutually acceptable to the other members of the board of directors.

Upon the consummation of this offering, the obligations of the parties to the voting agreement to vote their shares to elect these nominees will terminate, and none of our stockholders will have any special rights regarding the nomination, election or designation of members of the board of directors. Our existing certificate of incorporation contains provisions that correspond to the voting agreement; however, the certificate of incorporation that will be effective immediately prior to the closing of this offering will not include such provisions.

Other Transactions

We have issued a promissory note to Dr. Kawas in the aggregate principal amount of $60,000. As of June 30, 2020, the outstanding balance of the note was approximately . Such note will be repaid prior to the public filing of the registration statement of which this prospectus forms a part.

We have entered into employment agreements with our executive officers. For a description of these agreements, see the section of this prospectus titled “Executive Compensation – Executive Employment Arrangements.”

We have granted stock options and issued common stock to our executive officers and to certain of our non-executive directors. For a description of these grants and issuances, see the sections of this prospectus titled “Management – Director Compensation” and “Executive Compensation.”

We have entered into indemnification agreements with our directors and executive officers. For a description of these agreements, see the section of this prospectus titled “Management – Limitation of Liability and Indemnification Matters.”

PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of June 30, 2020 by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock;
- each of the named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The percentage of beneficial ownership prior to the offering shown in the table is based upon shares of common stock outstanding as of June 30, 2020 assuming the automatic conversion of all outstanding shares of convertible preferred stock into an aggregate of shares of common stock. The percentage of beneficial ownership after this offering shown in the table is based on shares of common stock outstanding after the closing of this offering, assuming no exercise of the underwriters' option to purchase additional shares.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules take into account shares of common stock issuable pursuant to the exercise or conversion of stock options or warrants or convertible notes that are either immediately exercisable or convertible or exercisable or convertible on or before the 60th day after June 30, 2020. Certain of the options granted to our named executive officers may be exercised prior to the vesting of the underlying shares. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for each person or entity listed in the table is c/o Athira Pharma, Inc., 4000 Mason Road, Suite 300, Seattle, Washington 98195.

	Shares Beneficially Owned Prior to the Offering		Shares Beneficially Owned After the Offering	
	Number of Shares	Percentage	Number of Shares	Percentage
5% and Greater Stockholders:				
Leen Kawas (1)	13,343,333			
Perceptive Life Sciences Master Fund Ltd. (2)	16,304,347			
Entities affiliated with RTW Master Fund, Ltd. (3)	15,217,390			
Viking Global Opportunities Illiquidity Investments Sub-Master LP (4)	10,869,565			
Entities affiliated with Franklin Templeton Investments (5)	7,608,694			
Named Executive Officers and Directors:				
Leen Kawas (1)	13,343,333			
Mark Litton (6)	660,236			
Kevin Church (7)	400,000			
Tadataka Yamada (8)	227,777			
Joseph Edelman (9)	16,304,347			
John M. Fluke, Jr. (10)	1,614,327			
Joseph Harding (11)	5,408,000			
All directors and executive officers as a group (8 persons) (12)	38,070,520			

* Represents beneficial ownership of less than 1% of our outstanding common stock.

(1) Consists of 2,100,000 shares held of record by Hamdan Family GST Trust, 8,860,000 shares held of record by Dr Kawas and options to purchase 2,383,333 shares that are exercisable within 60 days of June 30, 2020, all of which will be vested as of August 29, 2020.

(2) Consists of 16,304,347 shares held of record by Perceptive Life Sciences Master Fund Ltd., or Perceptive. The business address of Perceptive is 499 Park Avenue, 25th Floor, New York, NY 10022. Perceptive Advisors LLC serves as the investment manager of Perceptive. Joseph Edelman is the managing member of Perceptive Advisors LLC and he may be deemed to have shared voting and dispositive power over such shares.

(3) Consists of (a) 7,922,087 shares and a warrant to acquire 1,980,521 shares held of record by RTW Master Fund, Ltd., (b) 2,512,696 shares and a warrant to acquire 628,174 shares held of record by RTW Innovation Master Fund, Ltd. and (c) 1,739,130 shares and a warrant to acquire 434,782 shares held of record by RTW Venture Fund Limited. The business address of each of the entities is c/o Intertrust Corp. Serv. (Cayman) Ltd., 190 Elgin Avenue, George Town, Grand Cayman KY1-9005 E9.

(4) Consists of 10,869,565 shares held of record by Viking Global Opportunities Illiquidity Investments Sub-Master LP, or Viking. The business address of Viking is 55 Railroad Avenue, Greenwich, CT 06830.

(5) Consists of (a) 2,587,975 shares and a warrant to acquire 646,993 shares held of record by Franklin Strategic Series – Franklin Biotechnology Discovery Fund and (b) 3,498,981 shares and a warrant to acquire 874,745 shares held of record by Franklin Templeton Investment Funds – Franklin Biotechnology Discovery Fund. The business address of each of the entities is One Franklin Parkway, San Mateo, California, CA 94403

(6) Consists of options to purchase 112,500 shares that are exercisable within 60 days of June 30, 2020, all of which will be vested as of August 29, 2020.

(7) Consists of options to purchase 400,000 shares that are exercisable within 60 days of June 30, 2020, all of which will be vested as of August 29, 2020.

(8) Consists of options to purchase 227,777 shares that are exercisable within 60 days of June 30, 2020, all of which will be vested as of August 29, 2020.

(9) Consists of the shares referenced in footnote (2) above.

(10) Consists of 53,379 shares held of record by Fluke Capital Management, L.P, 486,575 shares held of record by Mr. Fluke's spouse, 911,040 shares held by Mr. Fluke, and options to purchase 163,333 shares that are exercisable within 60 days of June 30, 2020, all of which will be vested as of August 29, 2020.

(11) Consists of 5,208,000 shares held of record by Mr. Harding and options to purchase 200,000 shares that are exercisable within 60 days of June 30, 2020, all of which will be vested as of August 29, 2020.

(12) Consists of 34,183,577 shares held of record and options to purchase 3,486,943 shares that are exercisable within 60 days of June 30, 2020, all of which will be vested as of August 29, 2020.

DESCRIPTION OF CAPITAL STOCK

This section provides a summary of the rights of our common stock and preferred stock. This summary is not complete. For more detailed information, please see our certificate of incorporation and bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part.

Upon the closing of this offering and the filing of our certificate of incorporation to be effective immediately prior to this offering, our authorized capital stock will consist of shares of common stock, par value $0.0001 per share, andshares of preferred stock, par value $0.0001 per share.

Immediately prior to the closing of this offering, all the outstanding shares of convertible preferred stock will automatically convert into an aggregate of shares of common stock, the outstanding warrants to purchase shares of our Series B convertible preferred stock will convert into warrants to purchase an aggregate of shares of our common stock and the outstanding warrants will exercise into an aggregate of shares of our common stock.

Common Stock

Outstanding Shares

Based on shares of common stock outstanding as of June 30, 2020, the conversion of convertible preferred stock outstanding as of June 30, 2020 into an aggregate of shares of our common stock upon the completion of this offering, the issuance of an aggregate of shares of our common stock upon the exercise of outstanding warrants immediately prior to the completion of this offering, the issuance of shares of our common stock in this offering, and no exercise of the underwriters' option to purchase additional shares and no exercise of options, there will be shares of common stock outstanding upon the closing of this offering. As of June 30, 2020, assuming the conversion of all outstanding convertible preferred stock into common stock upon the closing of this offering and the issuance of shares of common stock upon the net exercise of certain outstanding warrants to purchase shares of our Series B convertible preferred stock and common stock immediately prior to the closing of this offering that would otherwise expire, we had approximately 141 record holders of our common stock.

Voting Rights

Each share of common stock is entitled to one vote per share on all matters (including the election of directors) submitted to a vote of stockholders, unless otherwise required by law or our certificate of incorporation. Our certificate of incorporation and bylaws to be in effect upon the completion of this offering do not provide for cumulative voting rights. Because of this, the holders of a plurality of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose. With respect to matters other than the election of directors, at any meeting of the stockholders at which a quorum is present or represented, the affirmative vote of a majority of the voting power of the shares present in person or represented by proxy at such meeting and entitled to vote on the subject matter shall be the act of the stockholders, except as otherwise required by law. The holders of a majority of the stock 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.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. For more information see the section of this prospectus titled "Dividend Policy."

Liquidation

Upon a liquidation event, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering, upon payment and delivery in accordance with the underwriting agreement, will be, fully paid and nonassessable.

Preferred Stock

Upon the closing of this offering, our board of directors will have the authority, without further action by the stockholders, to issue shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, redemption rights, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing change in our control or other corporate action. Upon closing of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Registration Rights

Under our investors' rights agreement, as amended, following the closing of this offering, the holders of approximately shares of common stock and common stock issuable upon conversion of outstanding convertible preferred stock, or their transferees, have the right to require us to register the offer and sale of their shares, which we refer to as registration rights. Additionally, the holders of shares of common stock issuable upon exercise of warrants to purchase our Series B convertible preferred stock and common stock, and the holders of shares of common stock issuable upon exercise of options to purchase our common stock, or their transferees, have registration rights.

Demand Registration Rights

At any time after six months after the date of this prospectus, the holders of at least 40% of the shares having demand registration rights have the right to demand that we use best efforts to file a registration statement for the registration of the offer. We are only obligated to file up to two registration statements in connection with the exercise of demand registration rights. These registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances and our ability to defer the filing of a registration statement with respect to an exercise of such demand registration rights for up to 120 days under certain circumstances.

Form S-3 Registration Rights

At any time after we are qualified to file a registration statement on Form S-3, the holders of at least 30% of the shares having demand registration rights have the right to demand that we file a registration statement on Form S-3 so long as the aggregate number of shares to be offered and sold under such registration statement on Form S-3 is at least $5 million. We are not obligated to file any registration statements within 30 days of a registration statement that we propose. These investor registration rights are subject to specified conditions and limitations, including our ability to defer the filing of a registration statement with respect to an exercise of such Form S-3 registration rights for up to 90 days under certain circumstances.

Piggyback Registration Rights

At any time immediately prior to the closing of this offering, if we propose to register the offer and sale of any of our securities under the Securities Act either for our own account or for the account of other stockholders, a stockholder with registration rights will have the right, subject to certain exceptions, to include their shares of common stock in the registration statement. These registration rights are subject to specified conditions and limitations, and any proposed offering in connection therewith may be terminated or withdrawn by us at our sole discretion.

Expenses of Registration

We will pay all expenses relating to any demand registrations, Form S-3 registrations and piggyback registrations, other than underwriting discounts and selling commissions and up to $50,000 of fees and disbursements of one counsel to the selling stockholders.

Termination

The registration rights terminate upon the earliest of (1) a merger or acquisition; (2) as to a given holder of registration rights, when such holder of registration rights can sell all of such holder's registrable securities in a three month-period pursuant to Rule 144 promulgated under the Securities Act; and (3) the date that is three years after the closing of this offering.

Anti-Takeover Effects of Delaware and Washington Law and Our Certificate of Incorporation and Bylaws

Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a publicly held Delaware corporation from engaging in a "business combination" with any "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder

- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

- Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

Washington Business Corporation Act

The laws of Washington, where our principal executive offices are located, impose restrictions on certain transactions between certain foreign corporations and significant stockholders. In particular, the Washington Business Corporation Act, or WBCA, prohibits a "target corporation," with certain exceptions, from engaging in certain "significant business transactions" with a person or group of persons which beneficially owns 10% or more of the voting securities of the target corporation, an "acquiring person," for a period of five years after such acquisition, unless the transaction or acquisition of shares is approved by a majority of the members of the target corporation's board of directors prior to the time of acquisition. Such prohibited transactions may include, among other things:

- any merger or consolidation with, disposition of assets to, or issuance or redemption of stock to or from, the acquiring person;

- any termination of 5% or more of the employees of the target corporation as a result of the acquiring person's acquisition of 10% or more of the shares; and

- allowing the acquiring person to receive any disproportionate benefit as a stockholder.

After the five-year period, a significant business transaction may take place as long as it complies with certain fair price provisions of the statute or is approved at an annual or special meeting of stockholders.

We will be considered a "target corporation" so long as our principal executive office is located in Washington, and: (1) a majority of our employees are residents of the state of Washington or we employ more than one thousand residents of the state of Washington; (2) a majority of our tangible assets, measured by market value, are located in the state of Washington or we have more than $50 million worth of tangible assets located in the state of Washington; and (3) any one of the following: (a) more than 10% of our stockholders of record are resident in the state of Washington; (b) more than 10% of our shares are owned of record by state residents; or (c) 1,000 or more of our stockholders of record are resident in the state.

If we meet the definition of a target corporation, the WBCA may have the effect of delaying, deferring or preventing a change of control.

Certificate of Incorporation and Bylaws

Provisions of our certificate of incorporation and bylaws 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, our certificate of incorporation and bylaws will

- permit our board of directors to issue 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 our board of directors into three classes, each of which stands for election once every three years;
- 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 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 also meet specific requirements as to the form and content of a stockholder's notice;
- not provide for 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 board of directors, the chairman of the board of directors, our chief executive officer or president;
- provide that stockholders will be permitted to amend certain provisions of our bylaws only upon receiving at least two-thirds of the 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; and
- provide that, unless we otherwise consent in writing, a state or federal court located within the State of Delaware shall be the sole and exclusive forum for (1) any derivative action or proceeding brought on behalf of the company, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to the company or our stockholders, (3) any action asserting a claim against the company arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation and bylaws (as either may be amended from time to time), or (4) any action asserting a claim against the company governed by the internal affairs doctrine; and
- Provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

The amendment of any of these provisions would require approval by the holders of at least two-thirds of our then outstanding common stock, voting as a single class.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is . The transfer agent and registrar's address is .

Listing

We intend to apply to have our common stock approved for quotation on the Nasdaq Global Market under the trading symbol "ATHA."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and although we expect that our common stock will be approved for listing on the Nasdaq Global Market, we cannot assure you that there will be an active public market for our common stock following this offering. We cannot predict what effect sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. Future sales of substantial amounts of common stock in the public market, including shares issued upon exercise of outstanding options or warrants, or the perception that such sales may occur, however, could adversely affect the market price of our common stock and also could adversely affect our future ability to raise capital through the sale of our common stock or other equity-related securities at times and prices we believe appropriate.

Upon completion of this offering, based on our shares outstanding as of June 30, 2020, the conversion of convertible preferred stock outstanding as of June 30, 2020 into an aggregate of shares of our common stock upon the completion of this offering, the issuance of an aggregate of shares of our common stock upon the exercise of outstanding warrants immediately prior to the completion of this offering, and the issuance of shares of our common stock in this offering, shares of our common stock will be outstanding, or shares of common stock if the underwriters exercise their option to purchase additional shares in full. All of the shares of common stock expected to be sold in this offering will be freely tradable without restriction or further registration under the Securities Act unless held by our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining outstanding shares of our common stock will be deemed "restricted securities" as that term is defined under Rule 144. Restricted securities may be sold in the public market only if their offer and sale is registered under the Securities Act or if the offer and sale of those securities qualify for an exemption from registration, including exemptions provided by Rules 144 and 701 under the Securities Act, which are summarized below.

As a result of the lock-up agreements and market stand-off provisions described below and the provisions of Rules 144 or 701, and assuming no extension of the lock-up period and no exercise of the underwriters' option to purchase additional shares, the shares of our common stock that will be deemed "restricted securities" will be available for sale in the public market following the completion of this offering as follows:

- shares will be eligible for sale on the date of this prospectus; and
- shares will be eligible for sale upon expiration of the lock-up agreements and market stand-off provisions described below, beginning more than 180 days after the date of this prospectus.

We may issue shares of our common stock from time to time for a variety of corporate purposes, including in capital-raising activities through future public offerings or private placements, in connection with exercise of stock options or warrants, vesting of restricted stock units and other issuances relating to our employee benefit plans and as consideration for future acquisitions, investments or other purposes. The number of shares of our common stock that we may issue may be significant, depending on the events surrounding such issuances. In some cases, the shares we issue may be freely tradable without restriction or further registration under the Securities Act; in other cases, we may grant registration rights covering the shares issued in connection with these issuances, in which case the holders of our common stock will have the right, under certain circumstances, to cause us to register any resale of such shares to the public.

Lock-up Agreements and Market Standoff Provisions

We, our directors and officers and substantially all of the holders of our equity securities have agreed, subject to certain exceptions, not to offer, sell or transfer any common stock or securities convertible into or exchangeable or exercisable for common stock for 180 days after the date of this prospectus without first obtaining the written consent of Goldman Sachs & Co. LLC and Jefferies LLC, on

behalf of the underwriters, or us, as applicable, after the date of this prospectus. Goldman Sachs & Co. LLC and Jefferies LLC may, in their sole discretion, and subject to FINRA Rule 5131, release any of the securities subject to the lock-up agreements with the underwriters at any time. These agreements are described below under the section of this prospectus titled “Underwriting.”

Rule 144

In general, under Rule 144, beginning 90 days after the effective date of this prospectus, a person who is not our affiliate for purposes of the Securities Act and has not been our affiliate at any time during the preceding three months will be entitled to sell any shares of our common stock that such person has beneficially owned for at least six months, including the holding period of any prior owner other than one of our affiliates, without being required to comply with the notice, manner of sale or public information requirements or volume limitation provisions of Rule 144. Sales of our common stock by any such person would be subject to the availability of current public information about us if the shares to be sold were beneficially owned by such person for less than one year.

In addition, under Rule 144, a person may sell shares of our common stock acquired from us immediately upon the completion of this offering, without regard to the registration requirements of the Securities Act or the availability of public information about us, if:

- the person is not our affiliate and has not been our affiliate at any time during the preceding three months; and
- the person has beneficially owned the shares to be sold for at least one year, including the holding period of any prior owner other than one of our affiliates.
- Beginning 90 days after the date of this prospectus, our affiliates who have beneficially owned shares of our common stock for at least six months, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:
    - 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering, assuming no exercise of the underwriters’ option to purchase additional shares; and
    - the average weekly trading volume in our common stock on the Nasdaq Global Market during the four calendar weeks preceding the date of filing of a notice on Form 144 with respect to the sale.

Rule 701

In general, under Rule 701 a person who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been one of our affiliates during the immediately preceding 90 days may sell these shares in reliance upon Rule 144, but without being required to comply with the notice, manner of sale or public information requirements or volume limitation provisions of Rule 144. Rule 701 also permits affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the effective date of this prospectus before selling such shares pursuant to Rule 701.

As of June 30, 2020, there were shares of our outstanding common stock issued in reliance on Rule 701 as a result of exercises of stock options. All of these shares, however, are subject to lock-up agreements or market stand-off provisions as discussed above, and, as a result, these shares will only become eligible for sale at the earlier of the expiration of the lock-up period or upon obtaining the consent of Goldman Sachs & Co. LLC and Jeffries LLC, on behalf of the underwriters to release all or any portion of these shares from the lock-up agreements.

Stock Options

As of June 30, 2020, options to purchase an aggregate of shares of our common stock were outstanding. We intend to file one or more registration statements on Form S-8 under the Securities Act to register the offer and sale of all shares of our common stock subject to outstanding stock options and all shares issued or issuable under our stock plans. We expect to file the registration statement covering these shares after the date of this prospectus, which will permit the resale of such shares by persons who are non-affiliates of ours in the public market without restriction under the Securities Act, subject, with respect to certain of the shares, to the provisions of the lock-up agreements and market stand-off provisions described above.

Registration Rights

Upon completion of this offering, the holders of approximately shares of our common stock will be eligible to exercise certain rights to cause us to register their shares for resale under the Securities Act, subject to various conditions and limitations. These registration rights are described under the section of this prospectus titled “Description of Capital Stock—Registration Rights.” Upon the effectiveness of a registration statement covering these shares, the shares would become freely tradable, and a large number of shares may be sold into the public market, which may adversely affect the market price of our common stock.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES FOR NON-U.S. HOLDERS OF COMMON STOCK

The following is a summary of the material U.S. federal income tax consequences of the ownership and disposition of our common stock acquired in this offering by a "non-U.S. holder" (as defined below), but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the United States Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income tax consequences different from those set forth below. We have not sought, and do not intend to seek, any ruling from the Internal Revenue Service, or IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This summary also does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction or under U.S. federal gift and estate tax rules, except to the limited extent set forth below. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies, regulated investment companies, real estate investment trusts or other financial institutions;
- persons subject to the alternative minimum tax or the tax on net investment income;
- tax-exempt organizations;
- pension plans and tax-qualified retirement plans;
- controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than five percent of our capital stock (except to the extent specifically set forth below);
- certain former citizens or long-term residents of the United States;
- persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment); or
- persons deemed to sell our common stock under the constructive sale provisions of the Code.

In addition, if a partnership, entity or arrangement classified as a partnership or flow-through entity for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership or other entity. A partner in a partnership or other such entity that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock through a partnership or other such entity, as applicable.

You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our common stock arising under the U.S. federal gift or estate tax rules or under the laws of any state, local, non-U.S. or other taxing jurisdiction or under any applicable tax treaty.

Non-U.S. Holder Defined

For purposes of this discussion, you are a "non-U.S. holder" if you are a beneficial owner of our common stock that, for U.S. federal income tax purposes, is not a partnership or:

- an individual who is a citizen or resident of the United States;
- a corporation or other entity taxable as a corporation created or organized in the United States or under the laws of the United States or any political subdivision thereof, or otherwise treated as such for U.S. federal income tax purposes;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust (1) whose administration is subject to the primary supervision of a U.S. court and that has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (2) that has made a valid election under applicable Treasury Regulations to be treated as a U.S. person.

Distributions

As described in the section of this prospectus titled "Dividend Policy," we have never declared or paid cash dividends on our common stock, and we do not anticipate paying any dividends on our common stock following the completion of this offering. However, if we do make distributions on our common stock, those payments will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, the excess will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock.

Subject to the discussions below on effectively connected income and Foreign Account Tax Compliance Act, or FATCA, withholding, any dividend paid to you generally will be subject to U.S. federal withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty between the United States and your country of residence. In order to receive a reduced treaty rate, you must provide the applicable withholding agent with an IRS Form W-8BEN or W-8BEN-E or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate. A non-U.S. holder of shares of our common stock eligible for a reduced rate of U.S. federal withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by filing an appropriate claim for refund with the IRS. If the non-U.S. holder holds our common stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to the applicable withholding agent, either directly or through other intermediaries.

Dividends received by you that are treated as effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, such dividends are attributable to a permanent establishment or fixed base maintained by you in the United States) are generally exempt from the 30% U.S. federal withholding tax, subject to the discussion below on backup withholding and FATCA withholding. In order to obtain this exemption, you must provide the applicable withholding agent with a properly executed IRS Form W-8ECI or other applicable IRS Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to U.S. federal withholding tax, are taxed at the same rates applicable to U.S. persons, net of certain deductions and credits, subject to an applicable income tax treaty providing otherwise. In addition, if you are a corporate non-U.S. holder,

dividends you receive that are effectively connected with your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty between the United States and your country of residence. You should consult your tax advisor regarding the tax consequences of the ownership and disposition of our common stock, including any applicable tax treaties that may provide for different rules.

Gain on Disposition of Common Stock

Subject to the discussion below regarding backup withholding and FATCA withholding, you generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with your conduct of a U.S. trade or business (and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by you in the United States);
- you are an individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met; or
- our common stock constitutes a United States real property interest by reason of our status as a "United States real property holding corporation," or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

We believe that we are not currently and will not become a USRPHC for U.S. federal income tax purposes, and the remainder of this discussion so assumes. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our U.S. and worldwide real property interests plus our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, your common stock will be treated as U.S. real property interests only if you actually (directly or indirectly) or constructively hold more than five percent of such regularly traded common stock at any time during the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

If you are a non-U.S. holder described in the first bullet above, you will be required to pay tax on the gain derived from the sale (net of certain deductions and credits) under regular U.S. federal income tax rates, and a corporate non-U.S. holder described in the first bullet above also may be subject to the branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. If you are an individual non-U.S. holder described in the second bullet above, you will be subject to tax at 30% (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale, which gain may be offset by U.S. source capital losses for the year, provided you have timely filed U.S. federal income tax returns with respect to such losses. You should consult your tax advisor regarding any applicable income tax or other treaties that may provide for different rules.

Federal Estate Tax

Our common stock beneficially owned by an individual who is not a citizen or resident of the United States (as defined for U.S. federal estate tax purposes) at the time of his or her death will generally be includable in the decedent's gross estate for U.S. federal estate tax purposes. Such stock, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax treaty provides otherwise.

Backup Withholding and Information Reporting

Generally, we must report annually to the IRS the amount of dividends paid to you, your name and address, and the amount of tax withheld, if any. A similar report will be sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Payments of dividends on or of proceeds from the disposition of our common stock made to you may be subject to information reporting and backup withholding at a current rate of 24% unless you establish an exemption, for example, by properly certifying your non-U.S. status on a properly completed IRS Form W-8BEN or W-8BEN-E or another appropriate version of IRS Form W-8. Notwithstanding the foregoing, backup withholding and information reporting may apply if the applicable withholding agent has actual knowledge, or reason to know, that you are a U.S. person.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Foreign Account Tax Compliance Act

Provisions of the Code commonly referred to as FATCA, Treasury Regulations issued thereunder and official IRS guidance generally impose a U.S. federal withholding tax of 30% on dividends on, and the gross proceeds from a sale or other disposition of our common stock, paid to a “foreign financial institution” (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on, and the gross proceeds from, a sale or other disposition of our common stock paid to a “non-financial foreign entity” (as specially defined under these rules), unless such entity provides the withholding agent with a certification identifying the substantial direct and indirect U.S. owners of the entity, certifies that it does not have any substantial U.S. owners, or otherwise establishes an exemption.

The withholding obligations under FATCA generally apply to dividends on our common stock and subject to the proposed Treasury Regulations described in the next sentence, will apply to the payment of gross proceeds of a sale or other disposition of our common stock. The Treasury Department has released proposed Treasury Regulations (the preamble to which specifies that taxpayers are permitted to rely on them pending finalization) which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a disposition of our common stock. The withholding tax will apply regardless of whether the payment otherwise would be exempt from U.S. nonresident and backup withholding tax, including under the other exemptions described above. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this section. Prospective investors are encouraged to consult with their own tax advisors regarding the application of FATCA withholding to their investment in, and ownership and disposition of, our common stock.

The preceding discussion of U.S. federal tax considerations is for general information only. It is not tax advice to investors in their particular circumstances. Each prospective investor should consult its own tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC and Jefferies LLC are the representatives of the underwriters.

Underwriters	Number of Shares
Goldman Sachs & Co. LLC	
Jefferies LLC	
Stifel, Nicolaus & Company, Incorporated	
JMP Securities LLC	
Total	

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional shares from us.

	No Exercise	Full Exercise
Per Share	$	$
Total	$	$

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $ per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We and our officers, directors, and holders of substantially all of our common stock and securities convertible into or exchangeable for our common stock have agreed or will agree with the underwriters, subject to certain exceptions, not to dispose of or hedge any of our or their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of Goldman Sachs & Co. LLC and Jefferies LLC. This agreement does not apply to any existing employee benefit plans. See the section of this prospectus titled "Shares Eligible for Future Sale" for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for the shares. The initial public offering price has been negotiated among the company and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be the company's historical performance, estimates of the business potential and earnings prospects of the company, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

We intend to apply to list our common stock on the Nasdaq Global Market under the symbol "ATHA".

In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A “covered short position” is a short position that is not greater than the amount of additional shares for which the underwriters’ option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. “Naked” short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our common stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of our common stock. As a result, the price of our common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the Nasdaq Global Market, in the over-the-counter market or otherwise.

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately $. We have agreed to reimburse the underwriters for certain of their expenses in an amount up to $.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

At our request, the underwriters have reserved up to % of the shares of common stock offered hereby, at the initial public offering price, to offer to directors, officers, employees, business associates and other persons related to us. The underwriters will receive the same underwriting discount on any shares purchased pursuant to this program as they will on any other shares sold to the public in this offering. The number of shares of common stock available for sale to the general public will be reduced to the extent these individuals purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus. Shares purchased by our directors and officers will be subject to a 180-day lock-up agreement with the underwriters in this offering.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their

respective affiliates may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with the issuer. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

In May 2020, we issued a warrant to JMP Securities LLC to purchase up to 1,010,955 shares of our Series B convertible preferred stock in connection with our Series B convertible preferred stock financing. This warrant will be automatically exercised into shares of our common stock immediately prior to the closing of this offering. The warrant (and the shares of common stock once exercised) are subject to the 180-day lock-up restrictions pursuant to FINRA Rule 5110(g) and a 180-day lock-up agreement with the underwriters in this offering.

European Economic Area and United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom (each a "Relevant State"), no common shares, or Shares, have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the Shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation), except that offers of Shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of Shares shall require the company or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to any Shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase or subscribe for any Shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

United Kingdom

Each Underwriter has represented and agreed that:

- it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (as amended, the

"FSMA")) received by it in connection with the issue or sale of the shares in circumstances in which Section 21(1) of the FSMA does not apply to the company; and

- it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (1) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong), or the Companies Ordinance, or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or the Securities and Futures Ordinance, or (2) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (3) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (1) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, under Section 274 of the SFA, (2) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (3) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore, or Regulation 32.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

Solely for the purposes of its obligations pursuant to Section 309B of the SFA, we have determined, and hereby notify all relevant persons (as defined in the CMP Regulations 2018), that the shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This offering document does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the "Exempt Investors") who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This offering document contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this offering document is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Dubai International Financial Centre

This offering document relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This offering document is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth in this prospectus and has no responsibility for the offering document. The securities to which this offering document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this offering document you should consult an authorized financial advisor.

Switzerland

We have not and will not register with the Swiss Financial Market Supervisory Authority, or FINMA, as a foreign collective investment scheme pursuant to Article 119 of the Federal Act on Collective Investment Scheme of 23 June 2006, as amended, or CISA, and accordingly the securities being offered pursuant to this prospectus have not and will not be approved, and may not be licenseable, with FINMA. Therefore, the securities have not been authorized for distribution by FINMA as a foreign collective investment scheme pursuant to Article 119 CISA and the securities offered hereby may not be offered to the public (as this term is defined in Article 3 CISA) in or from Switzerland. The securities may solely be offered to “qualified investors,” as this term is defined in Article 10 CISA, and in the circumstances set out in Article 3 of the Ordinance on Collective Investment Scheme of 22 November 2006, as amended, or CISO, such that there is no public offer. Investors, however, do not benefit from protection under CISA or CISO or supervision by FINMA. This prospectus and any other materials relating to the securities are strictly personal and confidential to each offeree and do not constitute an offer to any other person. This prospectus may only be used by those qualified investors to whom it has been handed out in connection with the offer described in this prospectus and may neither directly or indirectly be distributed or made available to any person or entity other than its recipients. It may not be used in connection with any other offer and shall in particular not be copied and/or distributed to the public in Switzerland or from Switzerland. This prospectus does not constitute an issue prospectus as that term is understood pursuant to Article 652a and/or 1156 of the Swiss Federal Code of Obligations. We have not applied for a listing of the securities on the SIX Swiss Exchange or any other regulated securities market in Switzerland, and consequently, the information presented in this prospectus does not necessarily comply with the information standards set out in the listing rules of the SIX Swiss Exchange and corresponding prospectus schemes annexed to the listing rules of the SIX Swiss Exchange.

LEGAL MATTERS

The validity of the shares of the common stock offered hereby will be passed upon for us by Wilson Sonsini Goodrich & Rosati, Professional Corporation, Seattle, Washington. Cooley, LLP, Seattle Washington, is acting as counsel for the underwriters. Investment funds associated with Wilson Sonsini Goodrich & Rosati, Professional Corporation, hold shares of our common stock and preferred stock convertible into our common stock representing an aggregate of 108,695 shares of our common stock, which is less than 1% of our outstanding shares of common stock.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements as of December 31, 2018 and December 31, 2019 and for each of the two years in the period ended December 31, 2019, as set forth in their report. We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered by this prospectus. This prospectus constitutes only a part of the registration statement. Some items are contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits. Statements contained in this prospectus concerning the contents of any contract or document referred to are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit.

You may obtain copies of this information by mail from the Public Reference Section of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website at www.sec.gov that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC.

As a result of this offering, we will become subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, will file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at www.athira.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

ATHIRA PHARMA, INC.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Athira Pharma, Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Athira Pharma, Inc. (the Company) as of December 31, 2018 and 2019, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit and cash flows for the years then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2019, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2018.

Seattle, Washington
July 24, 2020

ATHIRA PHARMA, INC.

Balance Sheets
(in thousands, except share and per share data)

	As of December 31,	
	2018	2019
Assets		
Current assets:		
Cash and cash equivalents	$ 3,317	$ 2,056
Short-term investments	1,500	—
Prepaid expenses and other current assets	74	97
Current portion of unsecured related party note receivable	6	7
Total current assets	4,897	2,160
Unsecured related party note receivable	36	29
Total assets	$ 4,933	$ 2,189
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 121	$ 421
Accrued expenses	451	852
Total current liabilities	572	1,273
Grant liability	936	1,036
Derivative liability	539	999
Convertible notes, net	722	1,553
Total liabilities	2,769	4,861
Commitments and contingencies (Note 9)		
Convertible preferred stock, $0.0001 par value per share; 22,184,536 shares authorized; 20,756,536 issued and outstanding at December 31, 2018 and 2019; aggregate liquidation preference of $16,288 at December 31, 2018 and 2019	17,051	17,051
Stockholders' deficit:		
Common stock, $0.0001 par value per share, 80,000,000 shares authorized; 28,227,500 and 28,877,500 shares issued and outstanding at December 31, 2018 and 2019, respectively	3	3
Additional paid-in capital	1,036	1,361
Accumulated deficit	(15,926)	(21,087)
Total stockholders' deficit	(14,887)	(19,723)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 4,933	$ 2,189

See accompanying notes.

ATHIRA PHARMA, INC.

Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year Ended December 31,	
	2018	**2019**
Operating expenses:		
Research and development	$ 3,589	$ 3,793
General and administrative	1,420	1,656
Total operating expenses	5,009	5,449
Loss from operations	(5,009)	(5,449)
Other income (expense), net	(88)	288
Net loss and comprehensive loss	$ (5,097)	$ (5,161)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.19)	$ (0.18)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	27,511,082	28,285,902
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)		$
Weighted-average shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)		

See accompanying notes.

ATHIRA PHARMA, INC.

Statements of Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share and per share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance as of December 31, 2017	20,676,536	$ 16,951	25,720,000	$ 3	$ 728	$ (10,829)	$ (10,098)
Issuance of common stock upon exercise of stock options	—	—	2,407,500	—	112	—	112
Issuance of convertible preferred stock for cash of $1.25 per share	80,000	100	—	—	—	—	—
Issuance of restricted stock awards for advisory services	—	—	100,000	—	—	—	—
Stock-based compensation	—	—	—	—	196	—	196
Net loss	—	—	—	—	—	(5,097)	(5,097)
Balance as of December 31, 2018	20,756,536	$ 17,051	28,227,500	$ 3	$ 1,036	$ (15,926)	$ (14,887)
Issuance of common stock upon exercise of stock options	—	—	650,000	—	72	—	72
Stock-based compensation	—	—	—	—	253	—	253
Net loss	—	—	—	—	—	(5,161)	(5,161)
Balance as of December 31, 2019	20,756,536	$ 17,051	28,877,500	$ 3	$ 1,361	$ (21,087)	$ (19,723)

See accompanying notes.

ATHIRA PHARMA, INC.

Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2018	2019
Operating activities		
Net loss	$ (5,097)	$ (5,161)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	196	253
Non-cash interest expense on convertible notes	—	88
Accretion of discounts on convertible notes	9	258
Change in fair value of derivative liability	—	71
Change in fair value of grant liability	164	100
Changes in operating assets and liabilities:		
Prepaid expenses	(46)	(23)
Accounts payable and accrued expenses	291	701
Net cash used in operating activities	(4,483)	(3,713)
Investing activities		
Purchases of available-for-sale securities	(5,250)	(995)
Maturities of available-for-sale securities	7,250	2,495
Principal payments received on related party note receivable	7	6
Net cash provided by investing activities	2,007	1,506
Financing activities		
Proceeds from exercise of common stock options	112	72
Proceeds from sales of convertible preferred stock, net of issuance costs	100	—
Proceeds from issuance of convertible notes, including derivative	1,266	884
Issuance costs of convertible notes	(14)	(10)
Net cash provided by financing activities	1,464	946
Net decrease in cash and cash equivalents	(1,012)	(1,261)
Cash and cash equivalents, beginning of year	4,329	3,317
Cash and cash equivalents, end of year	$ 3,317	$ 2,056

See accompanying notes.

1. Description of Business and Financial Condition

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, Washington. The Company is a late clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and stop neurodegradation.

Risks and Uncertainties

The Company is subject to a number of inherent risks which include, but are not limited to, the need to obtain adequate additional funding, possible failure of clinical trials or other events demonstrating a lack of clinical safety or efficacy of its product candidates, dependence on key personnel, reliance on third-party service providers for manufacturing or drug product and conduct of clinical trials, the ability to successfully secure its proprietary technology, and risks related to the regulatory approval and commercialization of a product candidate. Additionally, the development and commercialization of new drug products is highly competitive. There are a number of large pharmaceutical and biotechnology companies developing products for the treatment of neurodegenerative diseases that may have significantly greater financial resources and expertise in drug product development. Products or technologies developed by competitors may diminish or render obsolete the Company's existing products under development.

Liquidity and Capital Resources

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company has incurred net operating losses since its inception and had an accumulated deficit of $21.1 million as of December 31, 2019. The Company had cash and cash equivalents of $2.1 million as of December 31, 2019 and has not generated positive cash flows from operations. To date, the Company has been able to fund its operations primarily through the issuance of convertible notes and convertible preferred stock. In the second quarter of 2020, the Company received an aggregate of $81.8 million in net proceeds from the issuance of Series B convertible preferred stock. The Company's currently available cash and cash equivalents as of December 31, 2019, together with the proceeds received from the Series B convertible preferred stock financing in the second quarter of 2020, will be sufficient to meet its anticipated cash requirements and management considers that there are no conditions or events, in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern for a period of at least one year from the date the financial statements are issued.

Management expects operating losses to continue for the foreseeable future. There can be no assurance that the Company will ever earn revenues or achieve profitability, or if achieved, that they will be sustained on a continuing basis. In addition, the manufacturing, clinical and preclinical development activities as well as the commercialization of the Company's therapies, if approved, will require significant additional financing. The Company may be unable to secure such financing when needed, or if available, such financings may be under terms that are unfavorable to the Company or the current stockholders. If the Company is unable to raise additional funds when needed, it may be required to delay, reduce the scope of, or eliminate development programs, which may adversely affect its business and operations.

2. Significant Accounting Policies

Basis of Presentation

The financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP").

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.

Cash and Cash Equivalents

The Company considers highly liquid investments with original maturities of three months or less to be cash equivalents.

Short-term Investments

Short-term investments consist entirely of fixed income certificates of deposit with original maturities of greater than 90 days but not more than one year. These securities are classified as available-for-sale and reported at estimated fair value with unrealized gains and losses, if any, included in accumulated other comprehensive loss in stockholders' deficit. The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method.

If the estimated fair value of a security is below its carrying value, the Company evaluates whether it is more likely than not that it will sell the security before its anticipated recover in market value and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs the evidence to the contrary. Realized gains, realized losses and declines in the value of investments judged to be other than temporary, are included in other income (expense), net.

Concentration of Credit Risk

The Company is exposed to credit risk from its deposits of cash in excess of amounts insured by the Federal Deposit Insurance Corporation. The Company has not experienced any losses on its deposits of cash since inception.

Fair Value Measurements

The carrying amounts of certain financial instruments, including cash and cash equivalents, short-term investments, and 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 Life Services Discovery Fund ("LSDF") and the derivative liability were estimated using Level 3 unobservable inputs.

Grant Liability

The grant liability associated with the grants from the Washington LSDF is accounted for under Accounting Standards Codification ("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. The Company estimates the fair value of the grant liability by using 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.

Derivative Liability, Convertible Notes Discount and Amortization

The Company's convertible notes (see Note 8) have conversion and redemption features that meet the definition of an embedded derivative and are therefore subject to derivative accounting. The initial fair value of the derivative is recorded as a discount to the convertible notes, with a corresponding derivative liability. The discount to the convertible notes is amortized using the effective interest method. The amortization of the discount is included in other income (expense), net in the statements of operations and comprehensive loss. The derivative liability related to these features is recorded at estimated fair value on a recurring basis. Any changes in fair value are reflected in other income (expense), net in the statements of operations and comprehensive loss at each period end while such instruments are outstanding. The derivative liability was settled in May 2020 upon conversion of the underlying convertible notes into Series B-1 convertible preferred stock. See Note 17.

Grant Income

In January 2019, the Alzheimer's Association awarded the Company a $1.0 million *Part the Cloud* research grant. Grant proceeds must be used to advance the Company's ATH-1017 product candidate in the Alzheimer's disease setting. Reporting of expenses incurred supported by the grant as well as research updates are sent to the Alzheimer's Association semi-annually. Under the terms of the agreement, the Company received $776,000 in 2019 and may potentially receive the remaining $224,000 in 2020 upon the completion of certain development milestones. The Company recognizes income related to the grant as qualifying expenses under the grant agreement are incurred. As of December 31, 2019, the Company had recognized $754,000 in grant income, which is included in other income (expense), net in the statement of operations and comprehensive loss, and had cash received in excess of qualifying expenses of approximately $22,000, which is included in accrued expenses on the balance sheets.

Research and Development Expenses

Research and development expenses consist primarily of direct and indirect costs incurred for research activities, including development of the 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 will adjust the amounts recorded accordingly. The Company has not experienced any material differences between accrued or prepaid costs and actual costs since inception.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, consisting of employee salaries, related benefits, and stock-based compensation expense for 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. General and administrative costs are expensed as incurred.

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.

Stock-based payments issued to non-employees are recorded at their fair values, subject to periodic adjustments as the underlying equity instruments vest. Compensation expense is recognized over the vesting term on a straight-line basis, which reflects the service period. Options granted to non-employee service providers are valued at estimated fair value using the Black-Scholes option-pricing model and are remeasured over the vesting term as earned. Awards of restricted stock to non-employees are adjusted through stock-based compensation expense at each reporting period end until the shares vest to reflect the current fair value of such awards.

Income Taxes

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

In assessing the Company's ability to realize deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences are deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future income, tax planning strategies in making this assessment.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. The Company accrues interest and penalties related to unrecognized tax benefits in its provision for incomes taxes.

Comprehensive Loss

Comprehensive loss consists of net loss and other gains and losses affecting stockholders' deficit that, under U.S. GAAP, are excluded from net loss. The Company has no items of other comprehensive loss. As such, net loss equals comprehensive loss.

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.

Unaudited Pro Forma Net Loss Per Share Attributable to Common Stockholders

The unaudited pro forma basic and diluted net loss per share attributable to common stockholders has been computed to give effect to the conversion of all shares of convertible preferred stock into common stock, the exercise of outstanding warrants for shares of common stock, and the repayment of the grant liability upon the closing of a firm-commitment underwritten public offering ("IPO") resulting in at least $50.0 million in gross proceeds. The unaudited pro forma net loss per share attributable to common stockholders does not include the shares to be sold from the proposed IPO.

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.

Related Party Transactions

As of December 31, 2018 and 2019, the Company had an unsecured note receivable outstanding from its chief executive officer of approximately $42,000 and $36,000, respectively. The note bears interest at 1.45% and requires monthly payments with final repayment in April 2025. The note is included in current portion of unsecured related party note receivable and unsecured related party note receivable in the accompanying balance sheets. Interest income is recognized using the effective interest method, and is included in other income (expense), net in the statements of operations and comprehensive loss.

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 opt out of the extended transition period provided in the JOBS Act. 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.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02, *Leases*. The ASU requires entities to recognize in the balance sheet a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term. The Company will adopt the standard on January 1, 2021 using the modified retrospective method in the year of adoption and electing certain transition practical expedients. The Company is currently evaluating the guidance to determine the potential impact on its financial condition, results of operations and cash flows, and financial statement disclosures, and expects that the adoption of the ASU will increase assets and liabilities related to the Company's operating leases in the balance sheets.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments: Credit Losses (Topic 326)* as clarified in ASU 2019-04 and ASU 2019-05. 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 statements.

In August 2018, the FASB issued ASU 2018-15, *Intangible − Goodwill and Others − Internal-Use Software (Subtopic 350-40) Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. The objective of the ASU is to align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The ASU will become effective beginning January 1, 2021, with early adoption permitted. The Company does not expect the adoption of this ASU to have a significant impact on its financial condition, results of operations, cash flows and financial statement disclosures. In August 2018, the FASB issued ASU No. 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.

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 326) Improvements to Nonemployee Share-Based Payment Accounting*. The new ASU simplifies 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 the Company's financial condition, results of operations and cash flows.

3. Short-term Investments

Short-term investments consisted of available-for-sale securities as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2018				
Certificates of deposit	$ 1,500	$ —	$ —	$ 1,500
December 31, 2019				
Certificates of deposit	$ —	$ —	$ —	$ —

All short-term investments had contractual maturities of less than one year.

4. 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 fair value hierarchy of the Company's assets and liabilities carried at fair value and measured on a recurring basis was as follows (in thousands):

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Short-term investments – Certificates of Deposit	$ —	$ 1,500	$ —	$ 1,500
Total	$ —	$ 1,500	$ —	$ 1,500
Liabilities:				
Grant liability	—	—	936	936
Derivative liability (see Note 8)	—	—	539	539
Total	$ —	$ 1,500	$ 1,475	$ 2,975

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Grant liability	$ —	$ —	$ 1,036	$ 1,036
Derivative liability (see Note 8)	—	—	999	999
Total	$ —	$ —	$ 2,035	$ 2,035

The following table presents the activity for grant liability for the years ended December 31, 2018 and 2019 (in thousands):

	Year Ended December 31,	
	2018	2019
Fair value at beginning of period	$ 772	$ 936
Change in fair value of grant liability	164	100
Fair value at end of period	$ 936	$ 1,036

The following table presents the activity for derivative liability for the years ended December 31, 2018 and 2019 (in thousands):

	Year Ended December 31,	
	2018	2019
Fair value at beginning of period	$ —	$ 539
Derivative liability recorded upon issuance of convertible notes	539	389
Change in fair value of derivative liability	—	71
Fair value at end of period	$ 539	$ 999

The losses resulting from the change in fair value of the grant liability and the bifurcated conversion and redemption features related to the derivative liability are classified as other income (expense), net in the accompanying 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.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	As of December 31,	
	2018	2019
Research and development expenses	$ 299	$ 536
Employee compensation and benefits	72	230
Professional services and other	80	86
Total accrued expenses	$ 451	$ 852

6. Other Income (Expense), Net

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

	Year Ended December 31,	
	2018	2019
Part the Cloud research grant	$ —	$ 754
Interest and other income	85	51
Interest expense	(9)	(346)
Change in fair value of derivative liability	—	(71)
Change in fair value of grant liability	(164)	(100)
Total other income (expense), net	$ (88)	$ 288

7. 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 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 December 31, 2019.

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

- $50,000 – At initiation of the first Phase 2 clinical trial in the United States, European Union or Japan for the first licensed product.
- $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.

As of December 31, 2019, none of these milestones had been reached.

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 December 31, 2019, 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-tens of any non-sales based payments received, and low twenties of net sales based sublicense royalties. As of December 31, 2019, the Company had 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 the Washington LSDF under the terms of two matching grant award agreements. In connection with the agreements, LSDF retained the right to receive cash payments of up to 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.

As of December 31, 2019, no triggering events have occurred and no payments to LSDF have been made.

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 at December 31, 2018 and 2019, 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 $936,000 and $1.0 million as of December 31, 2018 and 2019, respectively. The changes in the fair value of the liability resulted in losses of $164,000 and $100,000 for the years ended December 31, 2018 and 2019, respectively, which were included in other income (expense), net in the accompanying statements of operations and comprehensive loss.

8. Convertible Notes

The Company issued unsecured convertible notes with aggregate principal amounts of $1.3 million and $884,000 in 2018 and 2019, 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 $2.2 million and accrued interest of $131,000 converted into 2,333,117 shares of Series B-1 convertible preferred stock. See Note 17.

The carrying value of the convertible notes as of December 31 were as follows (in thousands):

	As of December 31,	
	2018	2019
Convertible note principal and accrued interest	$ 1,268	$ 2,241
Less: unamortized discount for issuance costs	(14)	(18)
Less: unamortized discount related to derivative liability	(532)	(670)
Net carrying value, convertible notes	$ 722	$ 1,553

9. Commitments and Contingencies

Operating Leases

The Company leases office and laboratory space with a one-year lease term. Rent is expensed as incurred. The Company incurred rent expense of approximately $82,000 and $97,000 for the years ended December 31, 2018 and 2019, respectively. The Company will continue to account for its leases under ASC 840, *Leases,* until it adopts ASC 842, *Leases*, as discussed further under *Recent Accounting Pronouncements Not Yet Adopted* in Note 2.

Legal Proceedings

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount.

Indemnifications

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company intends to enter into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' insurance coverage that reduces its exposure and enables the Company to recover a portion of any future amounts paid. The Company believes the estimated fair value of these indemnification agreements in excess of applicable insurance coverage is minimal.

10. Convertible Preferred Stock

Convertible preferred stock as of December 31, 2018 and 2019 consisted of the following (in thousands, except share amounts):

Convertible Preferred Stock	Shares Authorized	Shares Issued and Outstanding	Carrying Value at December 31, 2018	Carrying Value at December 31, 2019	Aggregate Liquidation Preference
Series A	13,600,000	12,172,000	$ 15,163	$ 15,163	$ 15,215
Series A-1	8,584,536	8,584,536	1,888	1,888	1,073
Total	22,184,536	20,756,536	$ 17,051	$ 17,051	$ 16,288

The rights, preferences, and privileges of the Series A and Series A-1 convertible preferred stock (collectively, Preferred Stock) are as follows:

Dividends

The holders of shares of Series A and Series A-1 Preferred Stock are entitled to receive non-cumulative dividends and non-dividend distributions in preference to any dividend or non-dividend distribution on the common stock, when, and if declared by the Company's board of directors. Such dividend and non-dividend distribution preference survives until the holders of the Series A Preferred

Stock and Series A-1 Preferred Stock have received a per share amount equal to: (a) in the case of dividends, 1.32 times the Series A Purchase Price or Series A-1 Purchase Price, as applicable, or (b) in the case of non-dividend distributions, the Series A Purchase Price or Series A-1 Purchase Price, as applicable.

Conversion

Preferred Stock will automatically convert into shares of common stock on a 1:1 basis upon the earlier to occur: (a) after the payment of the distribution preference to the holders of the Series A and Series A-1 Preferred Stock, and (b) upon the closing of a firmly underwritten public offering pursuant to an effective registration statement covering the offer and sale of common stock in which the gross proceeds to the Company are at least $50.0 million. The conversion ratio will be adjusted in the case of specified changes to the Company's capitalization as a result of stock splits, combinations, common stock dividends and distributions, reclassifications, exchanges, substitutions, reorganizations, mergers or consolidations.

In addition to the automatic conversion, the holders of Series A and Series A-1 Preferred Stock have the right to convert such shares, at any time, into shares of common stock. The initial conversion rate shall be 1:1, subject to any adjustments for stock splits, combinations, common stock dividends and distributions, reclassifications, exchanges, substitutions, reorganizations, mergers or consolidations.

Dividends and Distributions After Conversion

After such conversions, the holders of common stock (including the holders of common stock issued upon conversion of the Series A and Series A-1 Preferred Stock) are entitled to participate pro rata in any dividends or non-dividend distributions paid on the Common Stock, when, as and if declared by the board of directors.

Liquidation, Acquisition or Asset Sale

In the event of any liquidation or winding up of the Company, or upon an acquisition of the Company or the sale or other disposition of substantially all of the Company's assets, the proceeds shall be paid first to the holders of the Series A and Series A-1 Preferred Stock equal to their purchase price, less any declared and paid dividends or non-dividend distributions. Any remaining amounts shall be distributed to the holders of the common stock, Series A Preferred Stock and Series A-1 Preferred Stock on a pro rata basis. The liquidation preference is less than the carrying value of the Series A-1 preferred stock as a portion of the carrying value originated from an $815,000 beneficial conversion feature recorded upon issuance of the underlying shares.

Voting

Each holder has one vote for each share of Series A or Series A-1 Preferred Stock.

Classification

Upon the occurrence of certain change in control events that are outside the Company's control, including liquidation, sale or transfer of the Company, holders of the convertible preferred stock can effectively cause redemption for cash. As a result, the Company has classified the convertible preferred stock as mezzanine equity on the balance sheets as the stock is contingently redeemable. The Company has elected not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because it is uncertain whether or when an event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of convertible preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a liquidation event will occur.

11. 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 December 31,	
	2018	2019
Convertible preferred stock	20,756,536	20,756,536
Stock options outstanding	10,022,500	12,012,500
Shares available for future grant	1,750,000	3,170,000
Common stock warrants	26,249	26,249
Total	32,555,285	35,965,285

Common stock warrants are exercisable at a price of $1.00 per share through April 8, 2021.

12. Stock-based Compensation

The Company maintains the 2014 Equity Incentive Plan (“2014 Plan”), as amended in August 2016, which allows for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, and restricted stock unit awards to employees, officers, non-employee directors, consultants and advisors. As of December 31, 2019, the Company has reserved 24,395,000 shares of common stock for issuance under the 2014 Plan.

The Company grants stock options with exercise prices equal to the estimated fair value of common stock on the date of the grant as determined by the board of directors based on the most recent third-party valuation of the common stock. Terms of stock award agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the plan, and typically have a contractual term of ten years from the date of grant. In the case of options granted to holders of more than 10% of the voting power of the Company, the exercise price may not be less than 110% of the fair market value of the common stock on the date the option is granted, and the term of the option may not exceed five years. Stock options granted have multiple vesting schedules ranging from immediate 100% vesting to cliff vesting ratably over four years.

Restricted stock awards are awards of a specific number of shares of the Company’s common stock, and are subject to continued service and vesting conditions.

Stock-based Compensation Expense

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

	Year Ended December 31,	
	2018	2019
Research and development	$ 53	$ 55
General and administrative	143	198
Total stock-based compensation expense	$ 196	$ 253

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 there has been no public market for the Company's common stock, the board of directors exercises reasonable judgment and considers 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 the Company's 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 the Company's security holders, the trends, development and conditions in the life sciences and biotechnology sectors, the economy in general, 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 has been privately held and does 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 mid-point 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 on its common stock. 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:

	Year Ended December 31,	
	2018	2019
Risk-free interest rate	2.6%	1.6%
Expected volatility	76.3%	75.0%
Expected term (in years)	6.6	6.5
Expected dividend yield	—	—

The weighted-average grant-date fair value of options granted to employees and directors during the years ended December 31, 2018 and 2019 were $0.10 and $0.11, respectively. The re-measured weighted-average fair value of options granted to advisors during the years ended December 31, 2018 and 2019 were $0.14 and $0.13, respectively.

Stock Option Activity

A summary of option activity 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, 2018	1,750,000	10,022,500	$ 0.12		
Authorized	4,060,000	—	—		
Granted	(2,790,000)	2,790,000	0.17		
Exercised	—	(650,000)	0.11		
Forfeited/expired	150,000	(150,000)	0.17		
Balance at December 31, 2019	3,170,000	12,012,500	$ 0.13	7.16	$ 500
Expected to vest		4,703,334	$ 0.17	8.79	$ 18
Options exercisable		7,309,166	$ 0.10	6.11	$ 477

The total fair value of options granted to employees, directors, and advisors that vested during the year ended December 31, 2018 was $160,000, which included $115,000 for options granted to employees and directors and $45,000 for options granted to advisors. The total fair value of options that vested during the year ended December 31, 2019 was $183,000, which included $104,000 for options granted to employees and directors and $79,000 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 for all options that were in-the-money at December 31, 2019. The aggregate intrinsic value of options exercised was $297,000 during 2018 and $38,500 during 2019, determined as of the date of option exercise. As of December 31, 2019, there was $374,000 of total unrecognized compensation cost related to unvested stock options. The Company expects to recognize this cost over a remaining weighted-average period of 1.41 years. The Company utilizes newly issued shares to satisfy option exercises.

Stock options outstanding and exercisable consisted of the following at December 31, 2019:

	Employees and Directors		Non-employees	
Exercise Price ($)	Share Options Outstanding	Share Options Exercisable	Share Options Outstanding	Share Options Exercisable
0.02	600,000	600,000	125,000	125,000
0.06	2,287,500	2,287,500	—	—
0.125	—	—	300,000	300,000
0.13	1,912,500	1,539,583	650,000	650,000
0.15	527,500	375,833	275,000	275,000
0.165	500,000	500,000	—	—
0.17	3,285,000	175,000	1,300,000	481,250
0.187	250,000	—	—	—
Total	9,362,500	5,477,916	2,650,000	1,831,250

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. As of December 31, 2019, there were 66,667 shares subject to repurchase, all of which were related to non-employee RSAs and have been excluded from the weighted-average number of shares outstanding for the purposes of calculating earnings per share.

A summary of RSA activity was as follows:

	Share Equivalent	Weighted-Average Grant Date Fair Value
Non-vested at December 31, 2018	100,000	$ 0.17
Granted	—	—
Vested	(33,333)	0.17
Non-vested at December 31, 2019	66,667	$ 0.17

As of December 31, 2019, there was approximately $6,000 of total unrecognized compensation cost related to non-vested restricted stock awards that will be recognized as expense over a weighted-average period of 1.23 years.

13. Income Taxes

Components of Income and Income Tax

All components of net loss before the effects of the income tax provision are related to losses incurred in the United States. The Company did not record a provision (benefit) for income taxes for the years ended December 31, 2018 and 2019.

The provision for income taxes differs from the amount expected by applying the federal statutory rates to the net loss before taxes as follows:

	Year Ended December 31,	
	2018	2019
Federal statutory income tax rate	21.0%	21.0%
Non-deductible expenses and others	0.2	(0.6)
Non-deductible expense related to the convertible notes and derivative liability	—	(1.7)
Non-deductible expense related to the grant liability	—	(0.3)
Tax credits	2.8	2.2
Change in valuation allowance	(24.0)	(20.6)
Effective income tax rate	—%	—%

Significant Components of Deferred Taxes

The components of the Company's deferred tax assets were as follows (in thousands):

	Year Ended December 31,	
	2018	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 3,032	$ 3,911
Research and development tax credit carryforwards	600	716
Accrued liabilities and other	47	93
Stock-based compensation	60	82
Total deferred tax assets	3,739	4,802
Deferred tax liabilities:		
Prepaid expenses and other	(13)	(12)
Total deferred tax liabilities	(13)	(12)
Less valuation allowance	(3,726)	(4,790)
Net deferred tax assets	$ —	$ —

Deferred income taxes reflect temporary differences between the carrying amounts of assets and liabilities for financial reporting and income tax purposes, and operating losses and tax credit carryforwards. The Company considers a number of factors concerning the realizability of its net deferred tax assets, including its history of operating losses, the nature of the deferred tax assets, and the timing, likelihood and amount, if any, of future taxable income during the periods in which those temporary differences and carryforwards become deductible, all of which require significant judgment. As of December 31, 2019, the Company has recorded a full valuation allowance on its net deferred tax assets as the Company has concluded that it is not more likely than not that such losses or credits will be utilized. The valuation allowance increased by $1.2 million and $1.1 million during 2018 and 2019, respectively.

At December 31, 2019, the Company has federal net operating loss and tax credit carryforwards of $9.4 million and $1.0 million, respectively, which expire over a period of 11 to 20 years. Net operating loss carryforwards of $9.2 million were generated after 2017, and therefore do not expire.

Uncertain Tax Positions

The Company files federal income tax returns. With few exceptions, the Company is no longer subject to income tax examinations by tax authorities for years prior to 2016. However, to the extent allowed by law, the tax authorities may have the right to examine prior periods where net operating losses or tax credits were generated and carried forward and may make adjustments to the amount of the net operating loss or credit carryforward amount. The Company is not currently under examination in any jurisdiction.

A reconciliation of the beginning and ending amount of unrecognized tax benefits were as follows (in thousands):

	Year Ended December 31,	
	2018	2019
Beginning balance	$ 152	$ 200
Additions for tax positions taken in the current year	48	39
Ending balance	$ 200	$ 239

If the unrecognized tax benefits for uncertain tax positions as of December 31, 2019 are recognized, there will be no impact to the effective tax rate due to the valuation allowance. The Company recognizes interest and penalties related to unrecognized tax benefits within the income tax expense line in the

accompanying financial statements. At December 31, 2019, there were no material interest and penalties on uncertain tax benefits. The Company does not anticipate any significant changes to its unrecognized tax benefits in the next 12 months.

14. Employee Benefit Plans

The Company has a 401(k) Plan for all of its employees. The 401(k) Plan allows eligible employees to defer, at the employee's discretion, up to 100% of their pretax compensation up to the Internal Revenue Service annual limit. The Company did not make any matching contributions for the years ended December 31, 2018 or 2019.

15. 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:

	Year Ended December 31,	
	2018	2019
Convertible preferred stock on an as-converted basis	20,756,536	20,756,536
Unvested RSAs	100,000	66,667
Stock options to purchase common stock	10,022,500	12,012,500
Common stock warrants	26,249	26,249
Total	30,905,285	32,861,952

16. Unaudited Pro Forma Net Loss Per Share Attributable to Common Stockholders

Pro forma basic and diluted net loss per share has been computed to give effect to the assumed conversion of all outstanding convertible preferred stock into shares of common stock, the exercise of the outstanding warrants for shares of common stock and the repayment of the grant liability upon completion of a qualifying IPO of the Company's common stock.

The following table sets forth the computation of the unaudited pro forma basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share data):

	Year Ended December 31, 2019 (Unaudited)
Numerator:	
Net loss	$ (5,161)
Loss on remeasurement of grant liability	
Net loss used in computing pro forma net loss per share attributable to common stockholders, basic and diluted	
Denominator:	
Weighted-average shares of common stock used in computing net loss per share attributable to common stockholders	
Pro forma adjustment to reflect conversion of convertible preferred stock	
Pro forma adjustment to reflect exercise of common stock warrants	
Weighted-average shares of common stock used in computing pro forma net loss per share attributable to common stockholders, basic and diluted	
Pro forma net loss per share attributable to common stockholders, basic and diluted	$ —

17. Subsequent Events

For the year ended December 31, 2019, management evaluated subsequent events through July 24, 2020, the date these financial statements were available to be issued.

Subsequent to December 31, 2019, the Company granted 355,000 stock options with an exercise price of $0.17 per share.

The Company issued $1.7 million of additional convertible notes during January 2020, including $250,000 of convertible notes to the Company's chief operating officer and affiliates, which the Company has determined to be related parties.

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 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.

Management continues to evaluate the potential impacts of the COVID-19 pandemic on the development of its product candidates, and business. The Company is working closely with its manufacturing vendors to maintain adequate product supply and with healthcare providers as future studies are planned to mitigate risk to patients while adhering to regulatory, institutional and government guidance and policies. The Company remains committed to its development plans and acknowledges the potential risk for delays in the product supply chain and in anticipated timelines for its preclinical studies and clinical trials.

In May and June 2020, the Company issued an aggregate of 74,328,105 shares of Series B convertible preferred stock at a purchase price of $1.15 per share for proceeds of $81.8 million, net of offering costs. The Company issued warrants to purchase 18,582,009 shares of its common stock, of which 5,456,521 shares were exercised concurrently with the Series B convertible preferred stock issuance for net proceeds of $55,000. In addition, the Company issued warrants to purchase 1,010,955 shares of its Series B convertible preferred stock at $1.15 per share. The Series B convertible preferred stock financing triggered the automatic conversion of the Company's then outstanding convertible promissory notes into an aggregate of 4,067,148 shares of Series B-1 convertible preferred stock based on a price of $0.9775 per share (85% of the $1.15 original issuance price of the Series B convertible preferred stock).

In July 2020, the Company established Athira Pharma Australia PTY LTD, a subsidiary, to facilitate clinical trials in Australia. As of the date hereof, research and development operations have not commenced in Australia.

Shares

Athira Pharma, Inc.

Common Stock

Goldman Sachs & Co. LLC **Jefferies** **Stifel**

JMP Securities

Through and including , 2020 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

Estimated expenses, other than underwriting discounts and commissions, payable by the registrant in connection with the sale of the common stock being registered under this registration statement are as follows:

	Amount Paid or To Be Paid
SEC registration fee	$ *
FINRA filing fee	*
Exchange listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous	*
Total	$ *

* To be provided by amendment

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law empowers a corporation to indemnify its directors and officers and to purchase insurance with respect to liability arising out of their capacity or status as directors and officers, provided that the person acted in good faith and in a manner the person reasonably believed to be in its best interests, and, with respect to any criminal action, had no reasonable cause to believe the person's actions were unlawful. The Delaware General Corporation Law further provides that the indemnification permitted thereunder shall not be deemed exclusive of any other rights to which the directors and officers may be entitled under the corporation's bylaws, any agreement, a vote of stockholders or otherwise. The certificate of incorporation of the registrant provides for the indemnification of the registrant's directors and officers to the fullest extent permitted under the Delaware General Corporation Law. In addition, the bylaws of the registrant require the registrant to fully indemnify 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) by reason of the fact that such person is or was a director, or officer of the registrant, or is or was a director or officer of the registrant serving at the registrant's request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, to the fullest extent permitted by applicable law.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except (1) for any breach of the director's duty of loyalty to the corporation or its stockholders, (2) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (3) for payments of unlawful dividends or unlawful stock repurchases, redemptions or other distributions or (4) for any transaction from which the director derived an improper personal benefit. The registrant's certificate of incorporation provides that the registrant's directors shall not be personally liable to it or its stockholders for monetary damages for breach of fiduciary duty as a director and that if the Delaware General Corporation Law is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of the registrant's directors shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

Section 174 of the Delaware General Corporation Law provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption may be held liable for such actions. A director who was either absent when the unlawful actions were approved, or dissented at the time, may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

As permitted by the Delaware General Corporation Law, the registrant has entered into separate indemnification agreements with each of the registrant's directors and certain of the registrant's officers which require the registrant, among other things, to indemnify them against certain liabilities which may arise by reason of their status as directors, officers or certain other employees.

The registrant expects to obtain and maintain insurance policies under which its directors and officers are insured, within the limits and subject to the limitations of those policies, against certain expenses in connection with the defense of, and certain liabilities which might be imposed as a result of, actions, suits or proceedings to which they are parties by reason of being or having been directors or officers. The coverage provided by these policies may apply whether or not the registrant would have the power to indemnify such person against such liability under the provisions of the Delaware General Corporation Law.

These indemnification provisions and the indemnification agreements entered into between the registrant and the registrant's officers and directors may be sufficiently broad to permit indemnification of the registrant's officers and directors for liabilities (including reimbursement of expenses incurred) arising under the Securities Act of 1933.

The underwriting agreement between the registrant and the underwriters filed as Exhibit 1.1 to this registration statement provides for the indemnification by the underwriters of the registrant's directors and officers and certain controlling persons against specified liabilities, including liabilities under the Securities Act with respect to information provided by the underwriters specifically for inclusion in the registration statement.

Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information regarding all unregistered securities sold by us since July 1, 2017:

(a) From July 1, 2017 through June 30, 2020, we granted 6,415,000 options to purchase shares of our common stock to our employees, directors and consultants at a weighted average exercise price of $0.1685 per share under our 2014 Equity Incentive Plan, or 2014 Plan. We also issued and sold an aggregate of 5,542,000 shares of our common stock to our employees, directors and consultants at a weighted average exercise price of $0.08143 per share pursuant to exercises of options granted under our 2014 Plan.

(b) From December 17, 2018 through January 13, 2020, we issued and sold subordinated convertible promissory notes in an aggregate principal amount of $3,816,000.

(c) From October 17, 2017 to March 13, 2018, we issued and sold an aggregate of 3,313,200 shares of our Series A convertible preferred stock at a purchase price of $1.25 per share, for aggregate consideration of approximately $4.14 million.

(d) In November 2018, we issued 100,000 restricted shares of our common stock to an advisory board member as compensation for services provided to us.

(e) On May 29, 2020, we issued and sold an aggregate of 4,067,148 shares of our Series B-1 convertible preferred stock upon conversion of approximately $3.98 million in outstanding convertible notes, at a conversion price of $0.9775 per share.

(f) From May 29, 2020 through June 23, 2020, we issued and sold an aggregate of 74,328,105 shares of our Series B convertible preferred stock at a purchase price of $1.15 per share, for aggregate consideration of approximately $85.48 million. Concurrently with these issuances, we also issued and sold warrants to purchase 18,582,009 shares of our common stock at an exercise price of $0.01 per share to the purchasers of our Series B convertible preferred stock. Each purchaser of our Series B convertible preferred stock received warrants to purchase a number of shares of our common stock equal to 25% of the number of shares of our Series B convertible preferred stock purchased by such purchaser in the transaction.

(g) On May 29, 2020, we issued warrants to purchase up to 1,010,955 shares of our Series B convertible preferred stock to JMP Securities LLC, in partial consideration for their services in connection with the sale and issuance of our Series B convertible preferred stock.

(h) From May 29, 2020 to June 15, 2020, we issued an aggregate of 5,456,521 shares of our common stock upon exercise of warrants to purchase shares of our common stock, at an exercise price of $0.01 per share.

No underwriters were involved in the sales, and the certificates representing the securities sold and issued contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration.

The offers, sales and issuances of the securities described in Items 15(b), (c), (e), (f), (g), and (h) were exempt from registration under the Securities Act under Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor and had adequate access, through employment, business or other relationships, to information about the registrant.

The offers, sales and issuances of the securities described in Item 15(a) and (d) were exempt from registration under the Securities Act under Section 4(a)(2) of the Securities Act in that such sales did not involve a public offering or under Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were the registrant’s employees, consultants or directors and received the securities under the registrant’s 2014 Plan. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

The following exhibits are filed as part of this registration statement.

Exhibit Number	Description
1.1*	Form of Underwriting Agreement
3.1*	Form of Amended and Restated Certificate of Incorporation, to be effective upon completion of the offering
3.2*	Form of Amended and Restated Bylaws, to be effective upon completion of the offering
4.1*	Specimen Common Stock Certificate of the Registrant
4.2*	Investors' Rights Agreement, dated May 29, 2020, as amended, by and among the registrant and the investors and founders named therein
4.3*	Form of Warrant to Purchase Series B Preferred Stock
4.4*	Form of Warrant to Purchase Common Stock
4.5*	Warrant to Purchase Common Stock of the Registrant, dated April 8, 2013
5.1*	Opinion of Wilson Sonsini Goodrich & Rosati, Professional Corporation
10.1+*	Form of Director and Executive Officer Indemnification Agreement
10.2+*	2014 Equity Incentive Plan
10.3+*	Form of Stock Option Agreement under the 2014 Equity Incentive Plan
10.4+*	2020 Equity Incentive Plan
10.5+*	Form of Stock Option Agreement under the 2020 Equity Incentive Plan
10.6+*	2020 Employee Stock Purchase Plan
10.7+*	Form of Subscription Agreement under the 2020 Employee Stock Purchase Plan
21.1*	List of subsidiaries of the Registrant
23.1*	Consent of Ernst and Young, LLP, Independent Registered Public Accounting Firm
23.2*	Consent of Wilson Sonsini Goodrich & Rosati, Professional Corporation (included in Exhibit 5.1)
24.1	Power of Attorney

+ Indicates a management contract or compensatory plan.

* To be filed by amendment

(b) Financial statement schedules.

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser. Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. If a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Seattle, State of Washington, on , 2020.

ATHIRA PHARMA, INC.

By: _____
Leen Kawas
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose individual signature appears below hereby authorizes and appoints Leen Kawas and Mark Litton, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this registration statement on Form S-1, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his or her substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
Leen Kawas	President, Chief Executive Officer and Director *(Principal Executive Officer)*	
	Chief Financial Officer *(Principal Financial and Accounting Officer)*	
Tadataka Yamada	Chairman of the Board of Directors	
Joseph Edelman	Director	
John M. Fluke, Jr.	Director	
Joseph Harding	Director	