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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

OR

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

Commission File Number 001-39503

Athira Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**45-3368487**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

18706 North Creek Parkway, Suite 104
Bothell, Washington 98011
(Address of principal executive officer)
(425) 620-8501
(Registrant's telephone number, including area code)

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

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price of the shares of common stock on June 28, 2024 (the last business day of the registrant's most recently completed second fiscal quarter) as reported by The Nasdaq Stock Market LLC on such date was approximately $86.0 million. Shares of the registrant's common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the registrant have been excluded from this computation. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

The number of shares of Registrant's Common Stock outstanding as of February 24, 2025 was 39,042,445.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement to be delivered to stockholders in connection with the 2025 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K. Such proxy statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the Registrant's fiscal year ended December 31, 2024.

Table of Contents

Summary Risk Factors

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

- We are a clinical-stage biopharmaceutical company with a limited operating history.
- Our development of ATH-1105 may never lead to a marketable product.
- Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives.
- Our approach to targeting neurotrophic factors through the use of small molecules is based on a novel therapeutic approach, which exposes us to unforeseen risks. We have limited data from preclinical studies and clinical trials to date, including for ATH-1105, and we cannot be certain that future trials will yield data in support of the safety, efficacy and tolerability of our drug candidates.
- We may not be successful in identifying and implementing any strategic transaction and any strategic transactions that we may consummate in the future may not be successful.
- We have concentrated our research and development efforts on the treatment of central and peripheral nervous system degenerative disorders, a field that has seen very limited success in product development.
- Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of early, smaller-scale preclinical studies and clinical trials with a single or few clinical trial sites may not be predictive of eventual safety or effectiveness in large-scale potentially pivotal clinical trials across multiple clinical trial sites. We may encounter substantial delays in clinical trials, or may not be able to conduct or complete clinical trials on the expected timelines, if at all.
- We may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- We have been and may in the future be subject to claims, lawsuits, arbitration proceedings, government investigations, securities class action litigation and other legal, regulatory and administrative proceedings and face potential liability and expenses related thereto, which could divert management's attention, and insurance coverage may not be sufficient to cover all costs and damages. This could have a material adverse effect on our business, operating results and financial condition.
- 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.
- Our reporting of topline or final data for our clinical trials may be delayed and our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented.
- 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.
- We will require substantial additional funding to finance our operations, complete the development and commercialization of ATH-1105 and develop and commercialize other current and potential drug candidates. If we are unable to raise this funding and access capital when needed, we may be forced to delay, reduce, or eliminate our drug product development programs, commercialization efforts or other operations.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.

- If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.
- 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 drug candidates we develop, our commercial opportunities will be negatively impacted.
- The loss of any of our key personnel could significantly harm our business, results of operations and competitive position.
- We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.
- The regulatory approval processes of the U.S. Food and Drug Administration, or 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 drug candidates, we will not be able to commercialize, or will be delayed in commercializing, our drug candidates, and our ability to generate revenue will be materially impaired.
- We 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 drug candidates.
- Even if approved, our drug candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.
- We have never commercialized a drug candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any drug products on our own or together with suitable collaborators.
- Intellectual property discovered or developed through government funded programs may be subject to federal regulations such as “march-in” rights, certain reporting requirements and a manufacturing 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, which could adversely affect our ability to successfully develop and commercialize our drug products.
- If we do not regain compliance with or continue to satisfy the Nasdaq continued listing requirements, our common stock could be delisted from the Nasdaq, which may make it more difficult for investors to sell shares of our common stock and consequently may negatively impact the price of our common stock.
- The market price of our common stock has been and may continue to be volatile, which could result in substantial losses for investors.
- We and certain of our directors and executive officers have been, and may in the future be, named as defendants in lawsuits that could result in substantial costs and divert management’s attention.
- Actions by activist stockholders have in the past been, and may in the future be, disruptive and could cause uncertainty about the strategic direction of our business.

Our Risk Factors are not guarantees that no such conditions exist as of the date of this report and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part.

PART I

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. This section should be read in conjunction with our audited consolidated financial statements and related notes included in Part II, Item 8 of this report. The statements contained in this report that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act.

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

- our financial performance;
- the sufficiency of our existing cash, cash equivalents and investments to fund our future operating expenses and capital expenditure requirements;
- our expectations regarding the costs and expected cost savings and related benefits from our workforce reduction initiated in September 2024, or the Restructuring;
- our ability to obtain funding for our operations, including funding necessary to develop and commercialize our drug candidates;
- the ability of our nonclinical studies and clinical trials to demonstrate safety and efficacy of our drug candidates;
- the success, cost and timing of our development activities, nonclinical studies and clinical trials;
- the rate and degree of market acceptance of our drug candidates;
- the timing or likelihood of regulatory filings and approvals;
- the potential learnings from our ACT-AD and SHAPE trials, LIFT-AD independent unblinded interim efficacy and futility analysis, and LIFT-AD trial and their ability to inform and improve future clinical development plans;
- the potential of our Phase 1 ATH-1105 clinical trial and any subsequent clinical trials to show the clinical benefits of ATH-1105;
- the timing and focus of our future clinical trials, and the reporting of data from those trials;
- anticipated milestone timelines, such as the timing of data releases, and our ability to meet such timelines;
- our plans relating to commercializing our drug candidates, if approved;
- our plans and ability to establish sales, marketing and distribution infrastructure to commercialize any drug 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 drug candidates, if approved;
- our reliance on third parties to conduct clinical trials of our drug candidates, and for the manufacture of our drug candidates for nonclinical studies and clinical trials;
- the success of competing therapies that are or may become available;
- the beneficial characteristics, safety and efficacy of our drug candidates;
- regulatory developments in the United States and other jurisdictions;
- our ability to obtain and maintain regulatory approval of our drug candidates in the United States and other jurisdictions, and any related restrictions, limitations or warnings in the label of any approved drug candidate;
- future agreements with third parties in connection with the commercialization of our drug candidates;
- our plans, capacity and capability relating to the further development and manufacturing of our drug 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 drug candidates and technology;
- the outcome of legal proceedings which have been or may in the future be instituted against us and certain of our directors and officers, including the legal proceedings discussed in Part I, Item 3 — "Legal Proceedings," and elsewhere in this report;
- the actions by activist stockholders, which have in the past been, and may in the future be, disruptive and could cause uncertainty about the strategic direction of our business;
- our plans and ability to regain compliance with the Nasdaq listing rules;
- the size and growth potential of the markets for our drug candidates, if approved for commercial use, and our ability to serve those markets;
- the potential benefits of any strategic collaborations, partnerships, or other transactions we may enter into;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act; and
- our plans and expectations regarding our exploration of strategic alternatives focused on maximizing stockholder value, including whether or not such process will result in a strategic transaction on terms satisfactory to us, or other alternatives which increase stockholder value.

These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part I, Item 1A — “Risk Factors,” and elsewhere in this report. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. Our Risk Factors are not guarantees that no such conditions exist as of the date of this report and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part.

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 report,

and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

This report includes our trademarks and registered trademarks, including Athira, Athira Pharma, the Athira logo, and other trademarks, trade names, or service marks of Athira. Each other trademark, trade name or service mark appearing in this report belongs to its holder. Solely for convenience, trademarks, trade names, and service marks referred to in this report are listed without ® or TM symbols, but we will assert, to the fullest extent under applicable law, our or the rights of the applicable licensors to these trademarks, trade names, and service marks.

In this report, "we," "our," "us," "Athira," and "the Company" refer to Athira Pharma, Inc. and its wholly-owned subsidiary.

Item 1. Business.

Overview

Athira is a clinical-stage biopharmaceutical company focused on developing small molecules engineered to restore neuronal health and slow neurodegeneration. Athira's approach is designed to modulate the neurotrophic hepatocyte growth factor, or HGF, system, that is critical to normal brain function and may play a key role in maintaining the health and functioning of neuronal networks. Athira believes that by acting on the neurotrophic HGF system and its multiple downstream signaling pathways, it may be able to enhance the body's natural ability to protect and repair neuronal networks by reducing inflammation, promoting regeneration, and reducing disease-specific protein pathologies, thereby positively impacting the course of disease. Athira aims to achieve these goals by advancing its pipeline of novel small molecule compounds which are designed to and have exhibited properties in enhancing the neurotrophic HGF system in either the central nervous system, or CNS, by crossing the blood brain barrier, or BBB, or the peripheral nervous system, or PNS.

Athira is actively reviewing options for partnerships or arrangements that will allow it to realize the potential of its drug candidates. The company's lead drug candidate is ATH-1105. ATH-1105 is a novel, orally available, brain-penetrant, next-generation small molecule drug candidate designed to positively modulate the neurotrophic HGF system for potential treatment of neurodegenerative diseases, including amyotrophic lateral sclerosis, or ALS, Alzheimer's disease, or AD, and Parkinson's disease, or PD. ATH-1105 is currently in development for the potential treatment of ALS. Athira conducted a first-in-human Phase 1 double-blind, placebo-controlled trial that enrolled 80 healthy volunteers to evaluate single and multiple oral ascending doses of ATH-1105. The study was completed in November 2024 and evaluated the safety and tolerability of ATH-1105 and included measurements of pharmacokinetic outcomes. The results of the Phase 1 trial showed that ATH-1105 demonstrated a favorable safety profile and was well-tolerated in healthy volunteers, supporting continued clinical development.

Athira's previous lead drug candidate, fosgonimeton, is a small molecule drug candidate designed to positively modulate the neurotrophic HGF system for potential treatment of neurodegenerative diseases. In September 2024, Athira announced the topline results for LIFT-AD, a randomized, double-blind, placebo-controlled, parallel-group 26-week Phase 2/3 clinical trial with fosgonimeton in mild-to-moderate AD. The primary and key secondary endpoints of the LIFT-AD trial did not reach statistical significance compared with placebo at 26 weeks. Based on these results, Athira decided to pause further development of fosgonimeton and to shift its focus to the clinical development of ATH-1105.

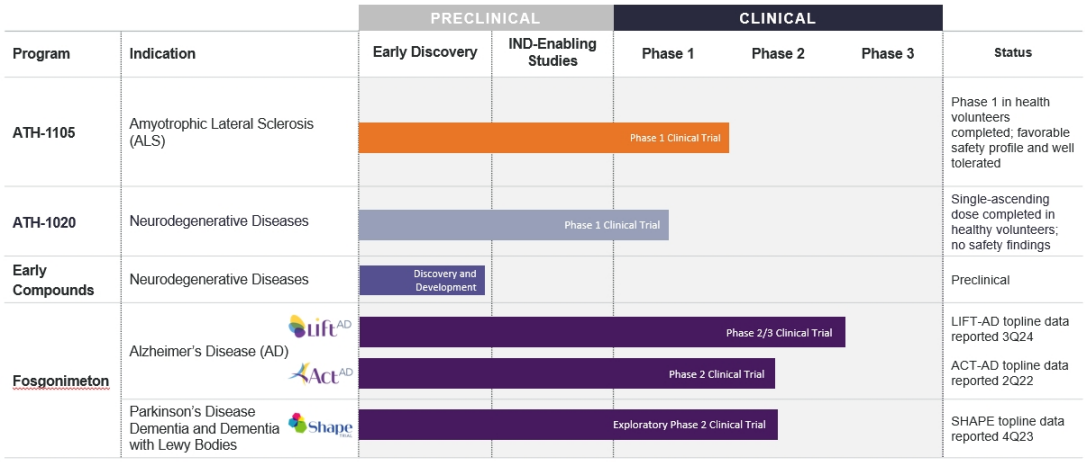
Athira's Strategy

To further its goal of developing small molecules engineered to restore neuronal health and slow neurodegeneration, Athira's strategy is to advance its pipeline of small molecule drug candidates, focusing on drug candidates that show both strong pharmacokinetics and pharmacodynamics, or PK/PD, translation and early predictive clinical data.

Athira's Pipeline

Figure 1 below illustrates the current development stage of Athira's proprietary drug candidates and early discovery and development programs, of which only ATH-1105 is currently in clinical development, for the potential treatment of ALS. Athira has also explored the use of its drug candidates in other indications in the CNS and PNS with the goal of improving neuronal health in multiple neurodegenerative diseases. In addition, Athira's drug discovery efforts have focused on designing and testing new early compounds to enhance the neurotrophic HGF system for a variety of clinical applications.

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



ATH-1105

ATH-1105 is a novel, orally available, brain-penetrant, next generation, small molecule drug candidate designed to positively modulate the neurotrophic HGF system. Athira conducted a first-in-human Phase 1 double-blind, placebo-controlled trial that enrolled 80 healthy volunteers to evaluate single and multiple oral ascending doses of ATH-1105. The study was completed in November 2024 and evaluated the safety and tolerability of ATH-1105 and included measurements of pharmacokinetic outcomes. The results of the Phase 1 trial showed that ATH-1105 demonstrated a favorable safety profile and was well-tolerated in healthy volunteers, supporting continued clinical development.

In preclinical models of ALS, treatment with ATH-1105 resulted in improvements in motor neuron survival and function. In vitro, ATH-1105 treatment protected primary spinal motor neurons from glutamate toxicity and prevented accumulation of toxic protein aggregates. Additionally, ATH-1105 induced target activation in cultures of ALS patient-derived motor neurons. In a preclinical mouse model of ALS, treatment with ATH-1105 significantly prevented loss of body weight, and improved motor function including balance, coordination and muscle strength. Athira additionally reported that treatment with ATH-1105 significantly improved electrophysiological measures of functional nerve signaling and protected against motor neuron axon degeneration and demyelination. ATH-1105 treatment also significantly reduced biomarkers of inflammation and neurodegeneration and prolonged survival. Study results were presented at the Motor Neurone Disease Association International Symposium in December 2022 and 2023 and published in *Frontiers in Neuroscience*, 2024. Weight loss, motor deficits, inflammation, loss of functional nerve signaling, and motor neurondegeneration and demyelination are all hallmarks of ALS disease; treatment with ATH-1105 significantly improved all of these aspects in the preclinical models tested.

ATH-1020

ATH-1020 is a novel, orally available, next generation, small molecule drug candidate designed to positively modulate the neurotrophic HGF system. Athira filed an IND application with the FDA for ATH-1020 at the end of 2021 and received notice of acceptance in January 2022. This compound was originally assessed for neuropsychiatric indications in preclinical models as presented at the American Society for Experimental Therapeutics Annual Conference in February 2022.

In preclinical models of diabetic neuropathic pain, Athira demonstrated significant improvements in two aspects of disease that are prominent symptoms in people suffering from neuropathic pain: increased sensitivity to mechanical and thermal stimulation. The significant improvements in neuropathic pain were partially sustained after seven days of not receiving ATH-1020, suggesting persistent and potentially disease-modifying effects. Data from these studies were presented at the Society for Neuroscience Annual Conference in November 2022 and the American Society for Experimental Neurotherapeutics in March 2023. Athira has completed the SAD escalation portion of the Phase 1 trial, in which ATH-1020 demonstrated a favorable safety profile and was well-tolerated in healthy volunteers.

Early Compounds

In addition to the compounds described above, Athira has evaluated several other compounds in preclinical discovery and development for neurodegenerative diseases and other indications where it believes positive modulation of the neurotrophic HGF system may have therapeutic potential.

Mechanism of Disease

Causes of neurodegenerative diseases are not fully understood as these diseases are complex with several contributing factors including inflammation, oxidative stress, neurotoxicity, excitotoxicity, synaptic dysfunction, and protein pathologies that ultimately lead to neuronal damage, neuronal network degeneration and a decline in function. Intrinsic to these diseases is the disruption of a healthy neuronal network that can be overcome and repaired or maintained when the body's natural repair mechanisms are intact. However, a loss of or reduction in ability of the body to repair itself can lead to dysregulation that then manifests as symptoms and overall functional decline. One such naturally occurring repair mechanism is the neurotrophic HGF system.

Scientific evidence supporting the neurotrophic HGF system as a naturally occurring repair mechanism is backed by over 30 years of research. MET is one of the most stably expressed genes in the adult human brain and is essential to a healthy, functional nervous system. HGF/MET signaling plays a critical role in both the development and maintenance of nervous system tissue. In ALS, studies have highlighted the importance of HGF in key processes affected by the disease. HGF functions as a potent survival factor for motor neurons, and impaired HGF/MET signaling has detrimental effects on neuromuscular junction integrity. Preclinical studies in ALS animal models show that HGF delivery reduces motor neuron degeneration, improves motor function, and prolongs lifespan. Additionally, HGF signaling has been linked to muscle function, the loss of which is a key feature of ALS. And although evidence supports the neurotrophic HGF system as an attractive target for combating neurodegenerative diseases, such as ALS, with its multimodal mechanism of action, it has proven a difficult drug target. There are approved and in-development gene therapy approaches to increase HGF expression beyond normal physiological levels, but these are limited as potentially viable treatment options for neurological disorders due to limited distribution and more invasive delivery requirements, such as intrathecal or intravenous, or locally restricted to the periphery, such as via intramuscular routes of administration.

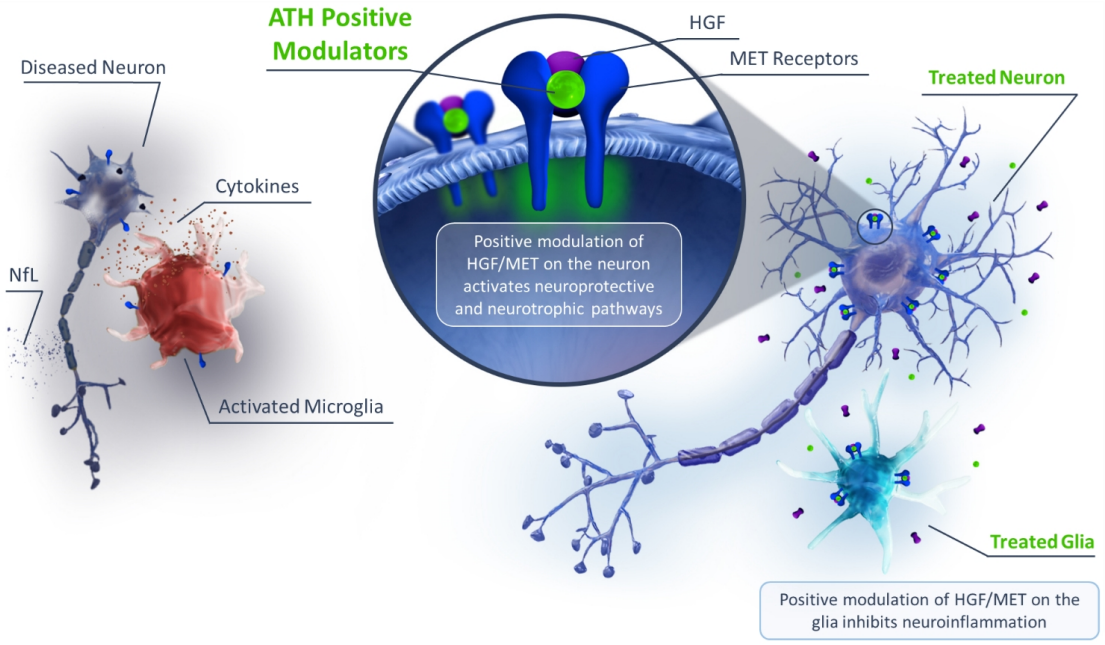
To date, drug developers have been deploying approaches that typically address only a single factor of the cascade of pathologies that lead to neurodegeneration, yet translating early successful results to meaningful clinical benefit has been mixed if not elusive. Athira believes that to address such complex and multifactorial diseases requires a novel multimodal approach, such as targeting the neurotrophic HGF system through non-invasive small molecules that enhance levels of HGF system activation to protect and repair neuronal networks.

Mechanism of Action

Athira has developed a pipeline of proprietary small molecule compounds, or ATH positive modulators, designed to enhance the neurotrophic HGF system and promote its neuroprotective, neurotrophic and anti-inflammatory effects, including protection of neurons from a variety of insults. These novel small molecules are designed to cross the blood-brain barrier for CNS disorders or remain in the periphery for PNS and other indications, and mechanistically produce a series of multimodal effects that support their therapeutic promise to: reduce inflammation, promote regeneration, provide neuroprotection, and, ultimately, slow disease progression.

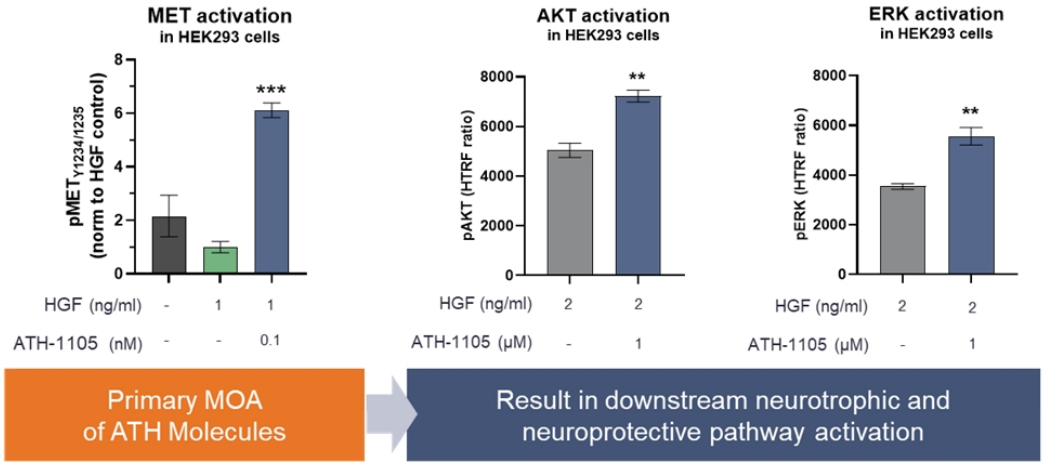
Figure 2 below illustrates the hypothesized mechanism of action of ATH positive modulators and the cellular disease state where diseased neurons generate a biomarker of neurodegeneration, NfL, as well as other signature markers of neuronal damage. Contributing to a diseased neuron are also proinflammatory cytokines produced by activated microglia. In the treated neuron state where ATH positive modulators are designed to enhance HGF/MET signaling to promote neuroprotective and neurotrophic pathways, reduced neuron degeneration and NfL production occur while the treated glia show reduced activation and production of proinflammatory cytokines, illustrating the potential reduction in neurodegeneration and inhibition of neuroinflammation through the enhancement of the neurotrophic HGF system.

Figure 2. Hypothesized Mechanism of Action of ATH Positive Modulators.



As ATH positive modulators interact with the HGF system, neurotrophic and neuroprotective pathways are activated downstream, including the activation of the extracellular-signal regulated kinase, or ERK and protein kinase B, or AKT pathways, which play critical roles in protecting neurons from damage and death, including from oxidative stress, excitotoxicity, and apoptosis. Figure 3 below shows cell culture data demonstrating that one of the key mechanisms of action of ATH positive modulators is through activation of AKT and ERK via MET activation.

Figure 3. ATH-1105 enhances HGF signaling and promotes neurotrophic and neuroprotective pathways.



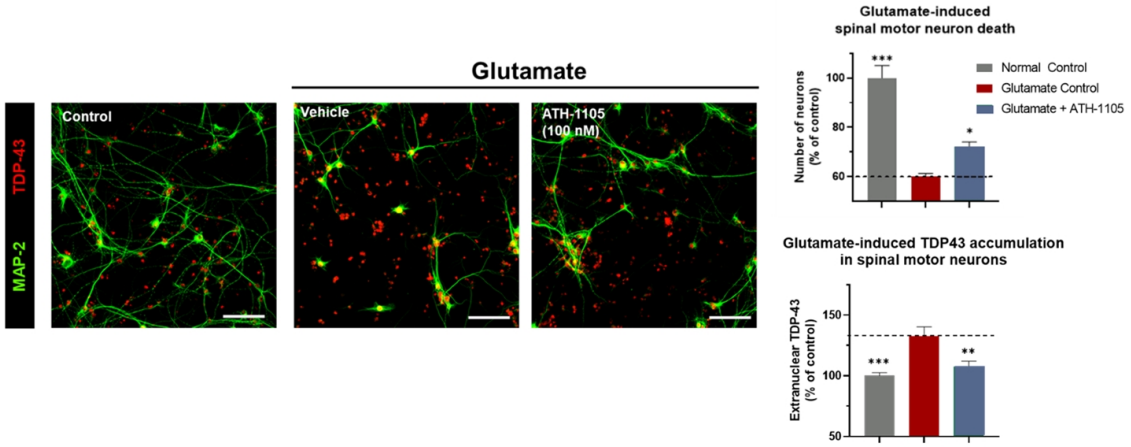
Positively modulating the neurotrophic HGF system promotes its multimodal effects, which Athira believes can potentially address the complex pathology in neurodegenerative diseases. These positive multimodal effects taken together may lead to improvement in function.

ATH-1105

ATH-1105 Preclinical Evidence for ALS

ATH-1105 is a novel oral small molecule drug candidate being assessed as a potential treatment for ALS. In a spinal motor neuron model, ATH-1105 significantly protected against neuron death by glutamate-induced excitotoxicity, while reducing pathological aggregation of TAR DNA-binding protein 43, or TDP-43. Figure 4 summarizes the data with images of microtubule-associated protein-2, or MAP-2-labeled spinal motor neurons in green, and extranuclear TDP-43 in red. In the control image on the left with no excitotoxic insult (glutamate), there is minimal overlap of MAP-2 neurons with extranuclear TDP-43. When glutamate is applied to the motor neuron cultures, there's an overall reduction in the number of neurons and increased extranuclear TDP-43 as shown by overlapping red-green staining in the middle image. When cell cultures were treated with ATH-1105, the effect of glutamate-induced excitotoxicity on the overall number of motor neurons and extranuclear TDP-43 protein aggregation was significantly reduced, as seen in the rightmost image and as quantified in the bar graphs.

Figure 4. ATH-1105 is Neuroprotective Against Excitotoxic Insult and Reduces Extranuclear TDP-43 Levels in Spinal Motor Neurons.



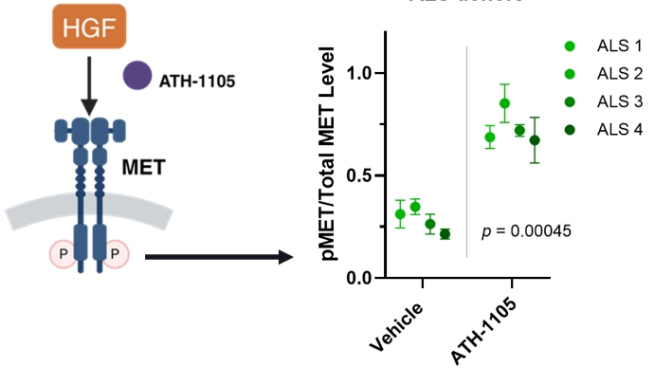
Data presented as mean + SEM. Statistics applied: 1-way ANOVA with Fisher least significant difference test. *p<0.05; **p<0.01; ***p<0.001 versus Glutamate Control. Scale bar: 100 µm. n=5-6 per group.
MAP-2, microtubule-associated protein-2; TDP-43, TAR DNA-binding protein 43.

ATH-1105 has also demonstrated target engagement in ALS patient-derived induced pluripotent stem cells (iPSCs) that were differentiated into motor neurons. In this model, as summarized in Figure 5, ALS patient-derived motor neurons treated with ATH-1105 100 nM exhibited a significant increase in MET activation (pMET) demonstrating engagement of HGF signaling, when compared to motor neurons treated with vehicle. These results were presented at the Motor Neurone Disease Association International Symposium in December 2024.

Figure 5. ATH-1105 increases MET activation in ALS patient-derived motor neurons.

Human iPSC-derived motor neurons sourced from Cedar Sinai via AnswerALS consortium

Donor ID	Indication	Sex	Age
ALS 1	Sporadic ALS	F	67
ALS 2	Sporadic ALS	F	69
ALS 3	Sporadic ALS	M	69
ALS 4	Sporadic ALS	M	67

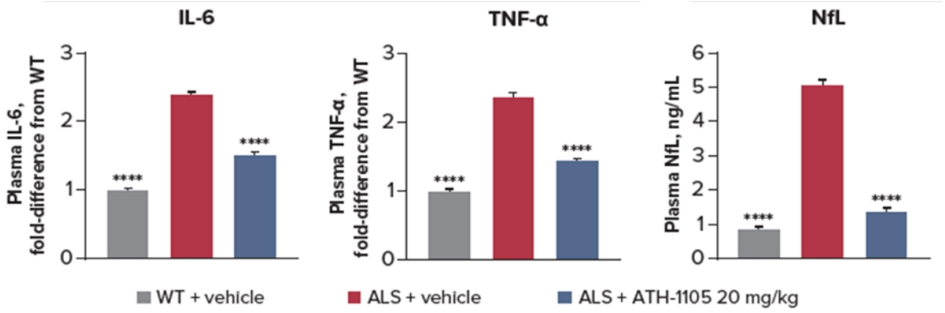


Human iPSC-derived motor neurons sourced from Cedar Sinai via AnswerALS consortium. Motor neurons were cultured in growth factor deprived media and treated with vehicle or ATH-1105 every 48h for 6 days. MET activation was measured 24h post ATH-1105 treatment. Data presented as mean ± SEM. Statistical significance was determined via paired t-test comparing MET activation (pMET/Total MET) in motor neurons treated with vehicle or ATH-1105 100 nM; n = 2 technical replicates from each donor.

Plasma biomarkers of inflammation and neurodegeneration were significantly reduced following treatment with ATH-1105 in a transgenic TDP-43-driven mouse model of ALS (Figure 6). These results support the anti-inflammatory and neuroprotective effects of ATH-1105 through enhancement of neurotrophic HGF system signaling. In the TDP-43-driven ALS model, significant increases in the proinflammatory cytokines tumor necrosis factor alpha, or TNF-alpha, and interleukin 6, or IL-6, were

observed compared to healthy wild-type, or WT, control animals. When ALS-model mice, or ALS mice, were treated with ATH-1105 significant reductions in both TNF-alpha and IL-6 were observed, demonstrating anti-inflammatory activity. Consistent with the neuroprotective effects demonstrated in cell-based models, a significant reduction in plasma levels of the neurodegeneration biomarker, NfL, was observed in ALS mice treated with ATH-1105, which is indicative of neuroprotection.

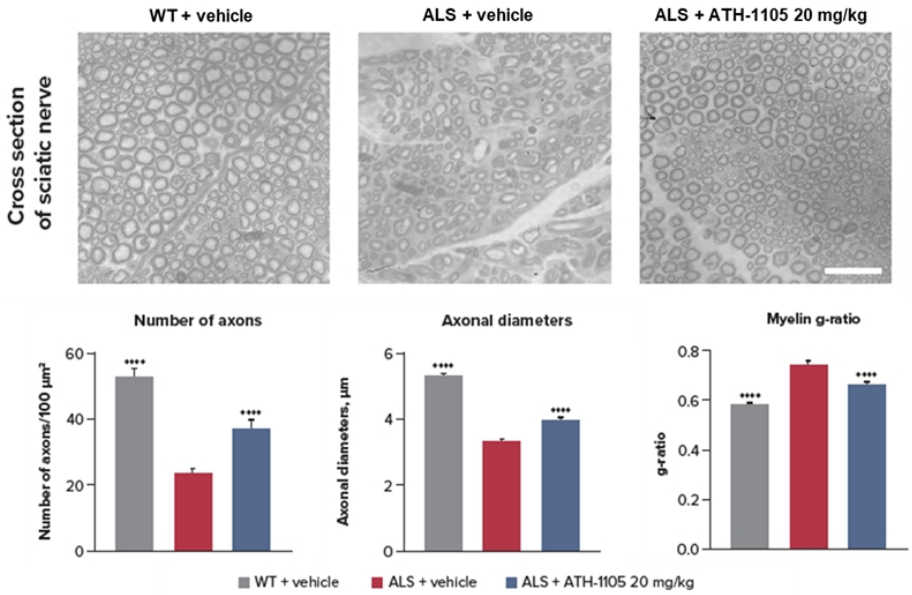
Figure 6. ATH-1105 Improves Biomarkers of Inflammation and Neurodegeneration in a Mouse Model of ALS.



Graphical representation of plasma IL-6, TNF-α in fold-difference over the WT + vehicle group, and NfL levels in ng/ml at two months of treatment. N=10 per group. Data presented as mean ± SEM. Statistical significance was determined by 1-way ANOVA with the Dunnett's test versus ALS + vehicle. ****p<0.0001.
ALS, amyotrophic lateral sclerosis; IL-6, interleukin 6; NfL, neurofilament light chain; TNF-α, tumor necrosis factor alpha; WT, wild-type.

Treatment with ATH-1105 in a mouse model of ALS protected against axon degeneration and demyelination as observed from histological examination of cross-sections of the sciatic nerve. Figure 7 below includes an image of the sciatic nerve from a WT healthy control animal, on the left, featuring a large number of large diameter axons surrounded by a consistent and highly regular coating of myelin sheath. In the middle, a sciatic nerve image from an ALS disease control animal is shown, where a marked reduction in the number of axons, a decrease in average axon diameter, and irregular myelination is observed. On the right, when ALS animals are treated with ATH-1105, sciatic nerve integrity is preserved with a greater population of large diameter axons and preservation of regular myelination. Graphs below the images are quantified data showing these effects of ATH-1105 in a mouse model of ALS.

Figure 7. Treatment with ATH-1105 Protected Against Axon Degeneration and Demyelination in a Mouse Model of ALS.

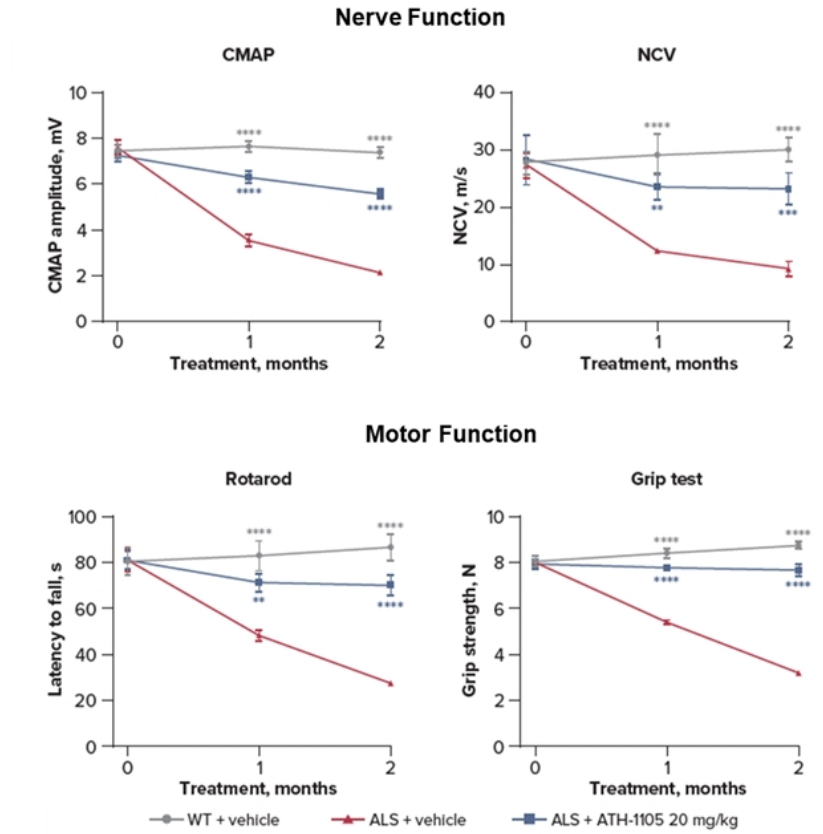


Histology images of sciatic nerve cross-sections stained with toluidine blue to label myelin. Scale is 10 µm (all panels). Graphical representation of the number of axons (per 100 µm2), axonal diameter (in micrometers), and mean of myelin g-ratio, defined as the ratio of the inner axonal diameter to the total axonal diameter, following two months of treatment. Data presented as mean + SEM. Statistical significance was determined by 1-way ANOVA with the Dunnett's test versus ALS + vehicle. ****p<0.0001.
ALS, amyotrophic lateral sclerosis; WT, wild-type.

Further analyses of electrophysiological and behavioral assessments indicated the protection of the motor neurons with ATH-1105 translated to improved nerve and motor function (Figure 8). Compound muscle action potential, or CMAP, and nerve conduction velocity, or NCV, are two electrophysiological measures of functional nerve signaling. Treatment with ATH-1105 in a mouse model of ALS demonstrated consistent and significant improvements of nerve function compared to ALS disease control animals.

Two examples of motor function improvements are shown by the rotarod, an assessment of balance and coordination, and the grip test, an assessment of strength. ALS disease control animals showed significant motor impairments compared to WT healthy control animals. ATH-1105 treatment in this mouse model of ALS led to significant improvements in both the rotarod and grip tests compared to the vehicle treated ALS disease control animals, demonstrating preservation of motor function. Other motor behavior tests assessing balance, coordination and muscle strength were the balance beam and Kondziela screen tests. Across all motor function measures, significant improvements were seen in ALS animals treated with ATH-1105 compared to ALS animals treated with vehicle.

Figure 8. Treatment with ATH-1105 Improves Nerve and Motor Function in a Mouse Model of ALS.

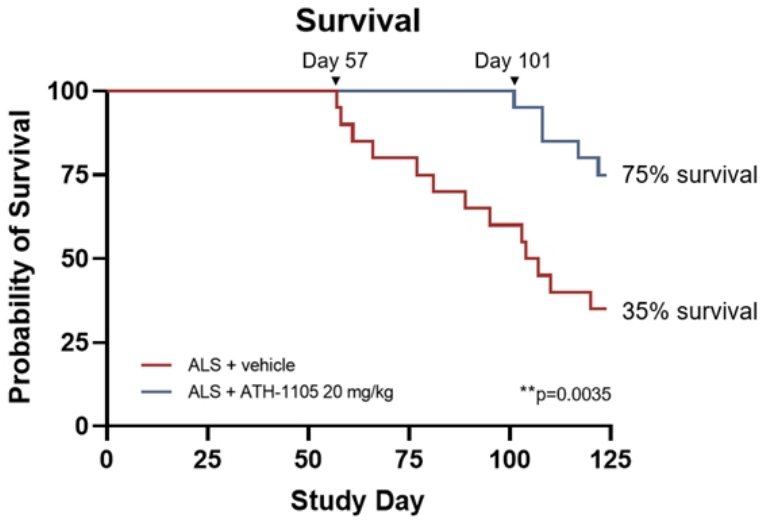


Graphical representation of CMAP amplitude, NCV, rotarod latency, and grip strength at baseline and after one and two months of treatment. Data presented as mean ± SEM. Statistical significance was determined by 2-way ANOVA with the Dunnett's test versus ALS + vehicle. **p<0.01; ***p<0.001; ****p<0.0001. N=10 per group.
ALS, amyotrophic lateral sclerosis; CMAP, compound muscle action potential; NCV, nerve conduction velocity; WT, wild-type.

The above study results, depicted in Figure 8, were presented at the American Academy of Neurology, or AAN, in April 2023, and the ALS Drug Development Summit in May 2023.

Treatment with ATH-1105 in a mouse model of ALS extends survival and improves other disease-related measures. Figure 9 below compares ALS mice treated with oral ATH-1105 20 mg/kg once daily in blue with oral vehicle once daily treated ALS mice in red. Mice were treated from one month of age to a humane endpoint maximum of five months of age, for a total of up to four months of treatment. ATH-1105 increased time to first mortality and significantly prolonged survival compared to ALS disease control animals (p=0.0035). ATH-1105 also significantly protected against body weight reduction (p<0.01). These findings were reported at the AAN 2023 Annual Meeting in April 2023.

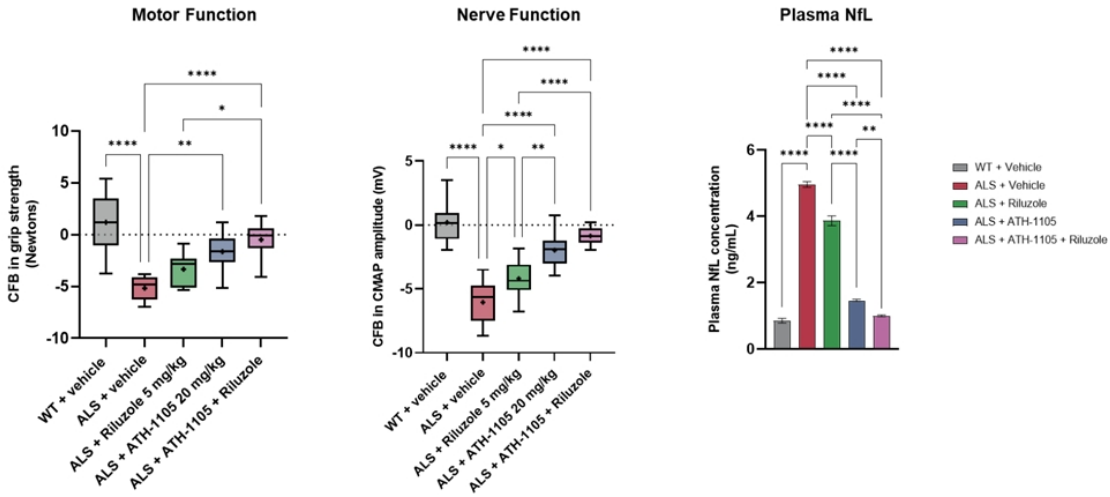
Figure 9. ATH-1105 Significantly Improved Survival in a Mouse Model of ALS.



Data presented as Kaplan-Meier curve
Statistics applied: Log-rank (Mantel-Cox) test for survival curve comparison, **p<0.01. n=20 mice per group at start

Treatment with ATH-1105 in a mouse model of ALS outperforms treatment with riluzole under the conditions tested in assessments of motor function, nerve function, and in reducing disease-related plasma biomarkers. Figure 10 below compares performance in the grip test of WT mice (grey) and transgenic ALS mice treated daily with vehicle (red), intraperitoneal riluzole 5 mg/kg (green), oral ATH-1105 20 mg/kg (blue), or both ATH-1105 and riluzole (purple). Mice treated with ATH-1105 alone and co-administration of riluzole and ATH-1105 consistently outperformed the vehicle-treated ALS disease control group. In both the ATH-1105 and the co-administration of ATH-1105 and riluzole groups, performance on the test approached that of the WT healthy control group. ATH-1105 treatment outperformed riluzole treatment in tests of motor function including the grip, rotarod, Kondziela screen, and balance beam tests. ATH-1105 also outperformed riluzole in tests of nerve function preservation including CMAP amplitude and NCV. ATH-1105 treatment further reduced plasma levels of IL-6 and TNF-alpha compared to riluzole, which are biomarkers of inflammation. ATH-1105 treatment also more greatly reduced plasma levels of NfL compared to riluzole, which is a biomarker of neurodegeneration. These findings were reported at the Northeast ALS Consortium meeting in October 2023, and the Motor Neurone Disease Association conference in December 2023.

Figure 10. ATH-1105 Preserves Motor and Nerve Function and Reduces Plasma NfL Compared with Riluzole in a Mouse Model of ALS.



Graphical representation of change from baseline following two months of treatment in grip test, CMAP amplitude, and Plasma Nfl. Data presented as mean ± SEM, or box-and-whisker plots
Statistics applied: One-way ANOVA with Dunnett's test. *p<0.05; **p<0.01; *** p<0.001; **** p<0.0001. n=10 mice per group; Abbreviations: CFB, change from baseline, CMAP, compound muscle action potential, NfL, neurofilament light chain

Clinical Development Plan for ATH-1105 in ALS

Weight loss, motor deficits, inflammatory effects, loss of muscle integrity, nerve degeneration and demyelination are all classical hallmarks of disease in people with ALS; treatment with ATH-1105 significantly improved all of these deficits preclinically. Athira conducted a first-in-human Phase 1 double-blind, placebo-controlled trial that enrolled 80 healthy volunteers to evaluate single and multiple oral ascending doses of ATH-1105. The study was completed in November 2024 and evaluated the safety and tolerability of ATH-1105 and included measurements of pharmacokinetic outcomes. The results of the Phase 1 trial showed that ATH-1105 demonstrated a favorable safety profile and was well-tolerated in healthy volunteers, supporting continued clinical development.

ATH-1020

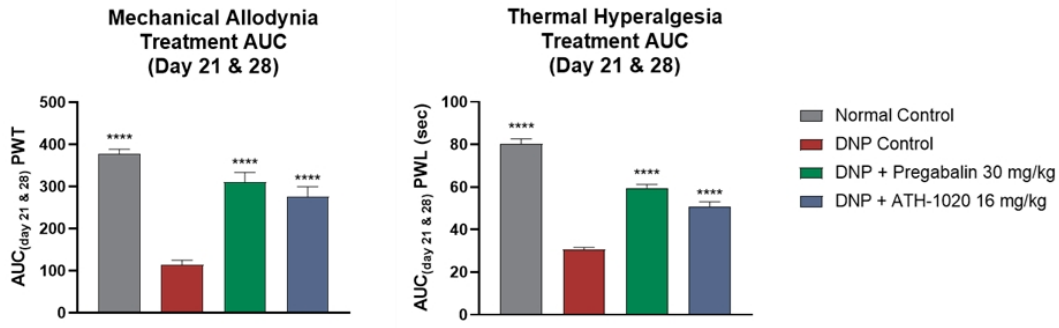
ATH-1020 Preclinical Evidence for Neuropathic Pain

ATH-1020 is a novel, orally available, next generation, small molecule drug candidate designed to positively modulate the neurotrophic HGF system. Enhancing HGF/MET signaling promotes neuroprotective, neurotrophic, and anti-inflammatory effects, and as neuropathic pain disorders, including diabetic neuropathy, or DNP, have components of oxidative stress, nerve damage, and inflammation, positive modulation of the HGF/MET pathway may provide therapeutic benefit in these disease areas. Data below were presented at the Society for Neuroscience Annual Conference in November 2022.

This compound was originally assessed for neuropsychiatric indications in preclinical models as presented at the American Society for Experimental Therapeutics Annual Conference in February 2022.

In animal models of DNP hypersensitivity to mechanical and thermal pain are commonly experienced, which are also representative of symptoms in people with neuropathic pain. Shown in Figure 11 below, treatment with ATH-1020 significantly reduced pain behaviors over the testing period compared to DNP controls alone.

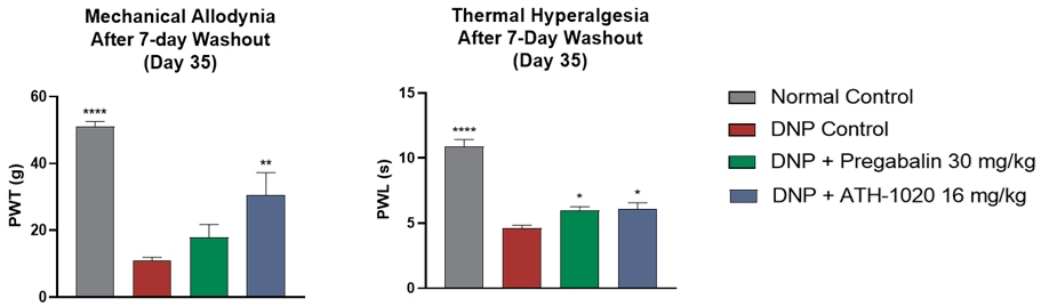
Figure 11. Reduced Mechanical and Thermal Pain-Related Behaviors Following ATH-1020 Treatment in a Rat Model of Diabetic Neuropathic Pain.



Data presented as means + SEM. ****p<0.0001 using one-way ANOVA with Dunnett test vs DNP control.
ANOVA, analysis of variance; AUC, area under the curve; DNP, diabetic neuropathic pain; PWL, paw withdrawal latency; PWT, paw withdrawal threshold.

Persistence of reduced pain behaviors following ATH-1020 treatment were assessed after a short-term (23-hour) or a long-term (7-day) washout period. Study results demonstrated that even after short- and long-term washout periods, where no drug is present, the effects of ATH-1020 reduction of pain behaviors remained persistent, suggesting a potential disease modifying effect (Figure 12).

Figure 12. Persistent Pain Reduction after 7-day Washout Following ATH-1020 Treatment.



Data presented as means + SEM. *p<0.05; **p<0.01; ****p<0.0001 using one-way ANOVA with Dunnett test vs DNP control.
ANOVA, analysis of variance; AUC, area under the curve; DNP, diabetic neuropathic pain; PWL, paw withdrawal latency; PWT, paw withdrawal threshold.

ATH-1020 Clinical – Phase 1 Trial in Healthy Volunteers

Athira filed an IND application with the FDA for ATH-1020 at the end of 2021 and received notice of acceptance in January 2022. In September 2022, it completed the single-ascending dose escalation portion of the Phase 1 trial. ATH-1020 demonstrated a favorable safety profile and was well-tolerated in healthy volunteers.

Fosgonimeton

Athira's previous lead drug candidate, fosgonimeton, is a small molecule drug candidate designed to positively modulate the neurotrophic HGF system for potential treatment of neurodegenerative diseases. In September 2024, Athira announced the topline results for LIFT-AD, a randomized, double-blind, placebo-controlled, parallel-group 26-week Phase 2/3 clinical trial with fosgonimeton in mild-to-moderate AD. The primary and key secondary endpoints did not reach statistical significance compared with placebo at 26 weeks. However, both components of the Global Statistical Test (GST), cognition (ADAS-Cog11) and function (ADCS-ADL23), directionally favored fosgonimeton treatment, and in pre-specified subgroups characterized by more rapid disease progression (moderate AD and APOE4 carriers), cognition and function improved or stabilized in the fosgonimeton treated group. In addition, data across biomarkers of protein pathology (Aβ42/40, p-Tau181, and p-Tau217), inflammation (GFAP) and neurodegeneration (NfL) showed directional improvements with fosgonimeton treatment that are consistent with the broad neuroprotective mechanism of HGF modulation.

Based on these results, Athira decided to pause further development of fosgonimeton and to shift its focus to the clinical development of ATH-1105.

Market Opportunity

The potential target indications for Athira's small molecule positive modulators include ALS and other neurodegenerative diseases. A recent study estimated that approximately 33,000 persons in the United States are affected with ALS. This number was projected to increase to approximately 36,000 by 2030. Prevalence at the global level varies geographically. Cases worldwide have been projected to increase from approximately 223,000 in 2015 to approximately 377,000 in 2040.

Currently, there are only four approved drugs that are specifically indicated for the treatment of ALS, of which none targets neurotrophic factor systems with a multimodal mechanism of action with the potential to offer neuroprotective, anti-inflammatory and potentially disease modifying effects.

Potential Commercialization Plan

ATH-1105 is currently in development for the potential treatment of ALS. The potential commercialization strategy is expected to consider the following key elements:

- potential first-line therapy;
- an add-on therapy for patients on existing therapies; and
- a therapy for patients who have stopped existing therapies.

Athira aims to demonstrate the therapeutic potential of ATH-1105 in ALS as an initial indication. Given the unique potential of ATH-1105 to provide broad protection against neurodegeneration, there may be therapeutic application in additional neurodegenerative indications including but not limited to frontal temporal dementia, Parkinson's, polyneuropathies, and others. Athira expects its commercialization strategies, including distribution plans, will evolve as clinical development progresses

Athira is actively reviewing options for partnerships or other arrangements that will allow it to realize the commercial potential of its drug candidates.

Manufacturing

Athira's focus on small molecule therapeutics enables it to use well-established and widely available manufacturing processes and infrastructure, formulation compositions, and drug administration technologies or devices. Athira does not operate its own facilities for manufacturing, storing, or distributing drug candidates. It utilizes third-party contract development and manufacturing organizations, or CDMOs, to manufacture and supply preclinical and clinical materials during the development of drug candidates. Athira and various regulatory bodies have audited the CDMOs it contracts with, and such CDMOs have a proven track record of GMP-compliant manufacturing.

ATH-1105 is purified as a stable solid and then released to other CDMOs for formulation and packaging into the final drug product for use in clinical testing. Athira believes the synthesis of ATH-1105 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.

For the potential commercialization of any drug candidates that receive regulatory approval, Athira expects to rely on partners' manufacturing capabilities or use similar third-party CDMO contract resources.

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 slow neurodegeneration, with its principal drug candidate focused on the treatment of ALS, Athira faces, 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 drug candidates that Athira successfully develops and commercializes will compete with current treatments and new treatments that may become available in the future. With the advancement of ATH-1105 as a novel small molecule therapeutic that positively modulates the neurotrophic HGF system, Athira must consider companies as competitors who are developing other novel approaches, including those that target other neurotrophic systems to address ALS and other neurological diseases. Additionally, because ATH-1105 is orally administered, Athira must also consider as competitors companies developing ALS therapies as oral therapeutics or with other routes of administration.

Because of the range of potential competitors, many of Athira's 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, or marketing and sales than Athira does. In addition, these same competitors, who may be in a clinical development stage, could also be competing with Athira for patient recruitment, clinical research organization, and operational resources. These entities also compete with Athira in the recruitment and retaining of qualified scientific and management personnel, as well as the acquisition of enabling or complementary technologies for advancing Athira's product candidates 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 Athira's competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Athira's commercial opportunity could be substantially limited if its competitors develop and commercialize products that are more effective, safer, more convenient or less expensive than Athira's comparable drug products. In geographies that are critical to Athira's commercial success, competitors may also obtain regulatory approvals first, resulting in these competitors building a strong market position in advance of the entry of Athira's drug candidates. In addition, Athira's ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of other treatments.

Specific to targeting HGF/MET, however, Athira is not aware of any direct competitors currently developing small molecules targeting the neurotrophic HGF system for ALS. Athira is aware of two companies developing HGF/MET-directed therapies for ALS, including VM202, a plasmid DNA encoding human HGF developed by Helixmith, and KP-100, a recombinant HGF protein developed by Kringle Pharma. Both assets have been investigated in Phase 2 clinical trials for ALS, where they were shown to be safe and well-tolerated but failed to reach statistical significance on efficacy endpoints.

ATH-1105 has the potential to offer neuroprotective and anti-inflammatory effects by targeting the HGF/MET system. Athira's preclinical data have demonstrated this multimodal approach may have positive benefits across several biological and clinical measures. While several potential direct competitors may exist, Athira has not yet identified any competitive asset that has demonstrated consistent and congruent positive effects offering neuroprotection, anti-inflammation, reduction in disease-specific protein pathologies, and neurotrophic and functional benefits.

Intellectual Property

Athira owns or has in-licensed numerous patents and patent applications and possesses substantial know-how and trade secrets relating to the development and commercialization of its drug candidates, including related manufacturing processes and technologies.

As of December 31, 2024, the company's patent portfolio includes its exclusively owned intellectual property, including issued patents and pending patent applications in the United States, issued patents and pending patent applications in jurisdictions outside of the United States, and a pending international patent application filed under the Patent Cooperation Treaty. The patents and patent applications issued and pending outside of the United States are counterparts to the foregoing United States patents and patent applications and are generally held in Argentina, Australia, Brazil, Canada, Chile, China, Eurasia, Europe, Hong Kong, India, Indonesia, Israel, Japan, Mexico, Malaysia, New Zealand, Philippines, Singapore, South Africa, South Korea, Taiwan, and Thailand. Athira's owned patents and patent applications have claims directed to ATH-1105 and its other small molecule drug candidates, including ATH-1020 and fosgonimeton, as compositions of matter and methods of use thereof.

Individual patents are in force 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 in force 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 United States Patent and Trademark Office, or USPTO, delay or the FDA regulatory review period (a patent term adjustment or patent

term extension, respectively). 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. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent. Athira's owned issued patents will expire on dates ranging from 2037 to 2042, exclusive of any patent term adjustment or patent term extension. If patents are issued on Athira's owned pending non-provisional patent applications, the resulting patents are projected to expire on dates ranging from 2037 to 2043, exclusive of any patent term adjustment or patent term extension.

When appropriate, Athira seeks to protect aspects of its technology and business not amenable to, or that it does not consider appropriate for, patent protection as trade secrets. Athira seeks to protect this intellectual property, in part, as trade secrets, by entering into confidentiality agreements with those who have access to its confidential information, including employees, contractors, consultants, collaborators, and advisors. The company also seeks to preserve the integrity and confidentiality of its proprietary technology and processes by maintaining physical security of its premises and physical and electronic security of its information technology systems.

Athira seeks trademark protection in the United States and in certain other jurisdictions where available and when it deems appropriate. Athira's trademark portfolio includes issued trademark registrations for Athira Pharma and other pending trademark applications in the United States and internationally.

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, or GLP, 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 institutional review board, or 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 good clinical practice, or GCP, requirements to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of a New Drug Application, or 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 current good manufacturing practice, or 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, pharmacology, and PK/PD 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 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, or 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 risk evaluation and mitigation strategy, or 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.

In addition, the FDA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, any of which could delay Athira's ability to obtain approvals, increase the costs of compliance or restrict the company's ability to maintain any regulatory approvals it may have obtained. In June 2024, the U.S. Supreme Court overruled the Chevron doctrine, which gives deference to federal agencies' statutory interpretations in litigation against the agencies where the law is ambiguous. This Supreme Court decision may invite various stakeholders to bring lawsuits against the FDA or other federal agencies to challenge longstanding decisions and policies, including FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the agency's normal operations. Athira cannot predict the full impact of this decision on the company or the pharmaceutical industry in general. Further, changes in the leadership of the FDA and other federal agencies under the new Trump administration can result in further changes in the funding, operations, and policies of the federal agencies, which may impact Athira's clinical development plans and timelines.

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 drug product candidates as appropriate. On December 29, 2022, the Consolidated Appropriations Act, 2023, including the Food and Drug Omnibus Reform Act, or FDORA, was signed into law. FDORA made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements.

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;
- drug 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.

Orange Book Listing

In seeking approval of an NDA or a supplement thereto, NDA applicants are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Upon FDA approval, each of the patents listed by the NDA applicant is published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Upon submission of an ANDA or 505(b)(2) NDA, an applicant is required to certify to the FDA concerning any patents listed for the RLD in the Orange Book that:

- no patent information on the drug product that is the subject of the application has been submitted to the FDA;
- such patent has expired;
- the date on which such patent expires; or
- such patent is invalid, unenforceable or will not be infringed upon by the manufacture, use, or sale of the drug product for which the application is submitted.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired. If the ANDA or 505(b)(2) NDA applicant has provided a paragraph IV certification, the applicant must send notice of the paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder, or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time, depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

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, or 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 the Health Insurance Portability and Accountability Act of 1996, or 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.

U.S. 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 and was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, in June 2021 the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and healthcare measures promulgated by the new Trump administration will impact the ACA, Athira's business, financial condition and results of operations.

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 2032 with the exception of a temporary suspension implemented under various novel coronavirus disease, or COVID-19, relief legislation. 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, effective January 1, 2024, the American Rescue Plan Act of 2021 eliminated the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on Athira's business. In August 2022, Congress passed the Inflation Reduction Act of 2022, or IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. CMS has published the negotiated maximum fair prices for the first ten drugs covered under Medicare Part D, which will go into effect on January 1, 2026. The second cycle of negotiations will occur in 2025, with the negotiated prices going into effect in 2027. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the new Trump administration on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drug candidates if approved.

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. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our drug products. FDA has authorized the state of Florida to develop Section 804 Importation Programs to import certain prescription drugs from Canada for a limited period of time to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. We expect that additional state and federal healthcare reform measures will be adopted in the future. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drug candidates. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

Employees and Human Capital Resources

As of December 31, 2024, we had 26 employees, all of whom were full-time and 15 of whom were engaged in research and development activities. Twelve of our employees hold Ph.D. or M.D. degrees. None of our employees is represented by a labor union or covered under a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

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 18706 North Creek Parkway, Suite 104, Bothell Washington 98011. Our telephone number is (425) 620-8501. 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 report, and the inclusion of our website address in this report is an inactive textual reference only.

We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the Securities and Exchange Commission, or SEC, in accordance with the Exchange Act. These include our annual reports on Form 10-K, our quarterly reports on Form 10-Q, and our current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC.

Item 1A. Risk Factors.

You should carefully consider the *following risk factors, in addition to* the other information *contained in this report*, *including the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and our consolidated financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed. This report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report. Our Risk Factors are not guarantees that no such conditions exist as of the date of this report and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part.*

Risks Related to Our Business and the Development of Our Drug Candidates

We are a clinical-stage biopharmaceutical company with a limited operating history.

We are a clinical-stage biopharmaceutical company focused on developing small molecules engineered to restore neuronal health and slow 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. To date, we have not completed a pivotal clinical trial, obtained marketing approval for any drug candidate, manufactured a commercial scale drug candidate, or conducted sales and marketing activities necessary for successful drug 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 are currently focusing our efforts primarily on the development of ATH-1105 and we may fail to or be unable to design and execute clinical trials to support marketing approval of ATH-1105 or any other drug candidates we seek to develop. 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 FDA or foreign regulatory authorities will agree with our study design, protocol or protocol amendments, or statistical plan, or that they 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 drug 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 drug candidates. Even if regulatory

approval is secured for any of our drug candidates, the terms of such approval may limit the scope and use of our drug candidate, which may also limit its commercial potential.

Our approach to targeting neurotrophic factors through the use of small molecules is based on a novel therapeutic approach, which exposes us to unforeseen risks. We have limited data from preclinical studies and clinical trials to date, including for ATH-1105, and we cannot be certain that future trials will yield data in support of the safety, efficacy and tolerability of our drug candidates.

We have discovered and are developing a pipeline of small molecule drug candidates to treat neurodegenerative diseases. Our drug candidates target an endogenous neurotrophic factor which is expected to protect and repair neuronal networks, which we believe could ultimately result in improvements in clinical outcomes and disease-relevant biomarkers. The therapeutic promise of neurotrophic factors in neurodegenerative diseases had been hampered in earlier therapies by the lack of efficient and non-invasive delivery to the CNS. Our small molecule drug candidates are designed to penetrate the BBB and enhance the activity of a neurotrophic factor, but we cannot be certain of the safety and efficacy of our drug candidates in applicable patients or that our clinical trials will provide sufficient evidence that our design approach results in the intended therapeutic effect.

The primary and all secondary endpoints of our Phase 2 ACT-AD clinical trial of fosgonimeton in AD were not met by protocoled analysis. A subsequent post hoc analysis of the data in a pre-specified subgroup from patients on fosgonimeton without background AChEIs showed a meaningful, but not statistically significant, improvement in both ERP P300 latency and cognitive performance compared to placebo at 26 weeks. Although post hoc analyses cannot be used to establish efficacy, these analyses can be helpful in informing the design of current and future clinical studies. In addition, the primary endpoint of our Phase 2 SHAPE clinical trial in PDD and DLB was not met by protocoled analysis. Directionally positive results were observed for the 40 mg fosgonimeton dose group with improvements in cognitive, functional and biomarker measurements. In particular, the five patients in the modified intent to treat, or mITT, population treated with fosgonimeton 40 mg once daily saw improvement in ADAS-Cog13 individually, and collectively improved compared with placebo (n=7 mITT, one-sided p=0.0321). Results for patients in the 70 mg dose group were inconsistent.

The topline data from our Phase 2/3 LIFT-AD clinical trial of fosgonimeton in AD showed that neither the trial's primary endpoint (the Global Statistical Test, or GST, a combination of results from measures of cognition (ADAS-Cog11) and function (ADCS-ADL23)) nor its key secondary endpoints of ADAS-Cog11 and ADCS-ADL23 reached statistical significance compared with placebo at 26 weeks. However, both components of GST, cognition (ADAS-Cog11) and function (ADCS-ADL23), directionally favored fosgonimeton treatment, and in pre-specified subgroups characterized by more rapid disease progression (moderate AD and APOE4 carriers), cognition and function improved or stabilized in the fosgonimeton treated group. In addition, data across biomarkers of protein pathology (Aβ42/40, p-Tau181, and p-Tau217), inflammation (GFAP) and neurodegeneration (NfL) showed directional improvements with fosgonimeton treatment that are consistent with the broad neuroprotective mechanism of HGF modulation. Based on these results, we decided to pause further development of fosgonimeton.

Following the readout of topline data from LIFT-AD, in September 2024 we announced our intention to focus on advancing the clinical development program for ATH-1105 as a potential treatment for ALS. We completed our first-in-human Phase 1 clinical trial in healthy volunteers evaluating the safety and tolerability of ATH-1105, in November 2024. The results of the Phase 1 clinical trial showed that ATH-1105 demonstrated a favorable safety profile and was well-tolerated in healthy volunteers, supporting continued clinical development.

We have limited evidence regarding the efficacy, safety and tolerability of ATH-1105 and other small molecules in our drug product pipeline. We or a future partner may ultimately determine that ATH-1105, or any of our other small molecules, does not possess certain properties required for therapeutic effectiveness.

We or a future partner may spend substantial funds attempting to develop these drug candidates and never succeed in doing so.

Our development of ATH-1105 may never lead to a marketable product.

We are developing ATH-1105 as a small molecule aimed at restoring neuronal health. We have not received regulatory approval for ATH-1105 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.

Advancing ATH-1105 as a small molecule aimed at restoring neuronal health creates significant challenges for us or a future partner, including:

- obtaining marketing approval;
- if ATH-1105 is approved, educating medical personnel regarding the potential efficacy and safety benefits, as well as the challenges, of incorporating ATH-1105 into existing treatment regimens, including in combination with other treatments for ALS or as a monotherapy; and
- establishing the sales and marketing capabilities upon obtaining any marketing approvals to gain market acceptance.

Our prospects as a standalone business are highly dependent on the successful development of ATH-1105. Following the September 2024 announcement of topline results from the Phase 2/3 LIFT-AD clinical trial of fosgonimeton showing that neither the trial's primary endpoint nor its key secondary endpoints were met, we announced our intention to focus on advancing the clinical development program for ATH-1105 as a potential treatment for ALS and other neurodegenerative diseases. Like fosgonimeton, ATH-1105 is a small molecule designed to positively modulate the HGF system. Although we are encouraged about the potential for ATH-1105 based on preclinical data, we or a future partner may decide to discontinue development of some or all of our product candidates, including if we or a future partner do not demonstrate the safety and efficacy of ATH-1105 in current and future clinical trials. We may pursue strategic alternatives to maximize stockholder value, which could involve, without limitation, exploring the potential for a possible merger, business combination, investment, a purchase, license or other acquisition of assets or return of capital to stockholders.

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 drug candidates. We have no drug products approved for commercial sale and do not anticipate generating any revenue from drug product sales for the next several years, if ever. Our ability to generate drug product revenue will depend heavily on the successful clinical development and eventual commercialization of ATH-1105 or any other drug candidates we may seek to develop. 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 drug candidates and any future drug candidates, as well as the associated costs, including any unforeseen costs;
- 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 drug candidates and any future drug candidates;
- timely submission of application for and receipt of marketing approvals from applicable regulatory authorities for any drug 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 drug 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 drug 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 drug candidates;
- commercial acceptance of our drug candidates by patients, the medical community and third-party payors;
- identifying, assessing and developing new drug 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 patent challenges, derivation proceedings, or interference or infringement claims, if any;
- negotiating favorable terms in any collaboration, licensing or other arrangement that may be necessary or desirable to develop, manufacture or commercialize our drug candidates;
- obtaining coverage and adequate reimbursement by hospitals, government and third-party payors for drug 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 are, 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 drug 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 drug candidate development, and could require additional clinical trials, including bridging studies and potential confirmatory or Phase 3 registrational trials, 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 drug candidate. An NDA or other relevant regulatory filing must include extensive nonclinical and clinical data and supporting information to establish that the drug 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 drug product. We cannot be certain that our current or future drug candidates will be successful in clinical trials. Further, even if they are successful in clinical trials, our drug candidates or any future drug candidates may not receive regulatory approval. If we do not receive regulatory approvals for current or future drug candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a drug 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.

We have concentrated our research and development efforts on the treatment of central and peripheral nervous system 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 PNS degenerative disorders. Collectively, efforts by pharmaceutical companies in the field of CNS and PNS 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 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, ALS and other CNS or PNS disorders. Our future success is highly dependent on the successful development of our technology and our drug candidates for treating CNS and PNS disorders. Developing and, if approved, commercializing our drug candidates for treatment of CNS and PNS disorders subjects us to a number of challenges, including ensuring that we have selected the optimal doses, executing an appropriate clinical trial to test for efficacy and obtaining regulatory approval from the FDA and other regulatory authorities.

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

Our lead drug candidate, ATH-1105, is currently in clinical development for the potential treatment of ALS. It is impossible to predict when or if any of our drug 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 drug candidates, we or a future partner must demonstrate through lengthy, complex and expensive nonclinical studies and clinical trials that our drug 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 drug 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 drug 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. For example, in our fosgonimeton Phase 1a/b clinical trial, which enrolled 88 patients, including only 11 patients with mild-to-moderate AD, of whom seven patients were treated with fosgonimeton and the other four patients were randomized to the control, suggested improvements in brain network activity including potentially positive effects on brain function. However, our subsequent Phase 2 ACT-AD clinical trial in AD did not meet its primary endpoint of a change in ERP P300 latency for the full study population nor did it meet the secondary endpoints, and our Phase 2/3 LIFT-AD clinical trial in AD did not meet its primary endpoint (the GST, a combination of results from measures of cognition (ADAS-Cog11) and function (ADCS-ADL23)) nor its key secondary endpoints of

ADAS-Cog11 and ADCS-ADL23. Based on these results, we decided to pause further development of fosgonimeton and to shift our focus to the clinical development of ATH-1105.

Early, smaller-scale studies, biomarker analyses, and clinical trials with a single or relatively few clinical trial sites may not be predictive of eventual safety and effectiveness in large-scale pivotal clinical trials across multiple clinical trial sites. Even if data from a pivotal clinical trial are positive, regulators may not agree that such data are sufficient for approval and may require that we conduct additional clinical trials, which could materially delay our anticipated development timelines, require additional funding for such additional clinical trials, and adversely impact our business. 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 addition, 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.

In the future, we may initiate an open-label trial for one or more of our product candidates. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards, or IRBs, of the institutions in which such clinical trials are being conducted, by a data safety monitoring board for such clinical trial or by the FDA or comparable foreign regulatory authorities. Clinical trials can be delayed or terminated or fail to meet endpoints 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 clinical development strategy or statistical plan;
- 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 on a timely basis;
- the number of patients required for clinical trials of our drug 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;
- protocol deviations or non-compliance with GCP requirements, or other data integrity reasons, that cause us or the FDA or other regulatory authorities to exclude data from non-compliant sites or investigators, which may cause the trial to be underpowered to meet the endpoints;
- delays by us or our CROs in qualifying or analyzing patient data at the completion of clinical trials;
- failure to demonstrate a benefit from using a drug 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 supply of drug candidate for use in nonclinical studies or clinical trials from third-party suppliers.

Further, conducting clinical trials in foreign countries, as we may do for our drug 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 drug candidates. If we experience delays in the completion of, or termination of, any clinical trial of our drug candidates, the commercial prospects of our drug candidates will be harmed, and our ability to generate product revenues from any of these drug candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

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

- incur unplanned costs;
- determine to limit or terminate clinical trials, including our open-label extension trial;
- be delayed in or prevented from obtaining marketing approval for our drug 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 drug candidate 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 drug product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

We may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug 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 and drug candidates that we identify for specific indications. As a result, we may forgo or delay pursuit of opportunities with other drug 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 and drug 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 drug candidate, we may relinquish valuable rights to that drug 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.

Our long-term prospects depend in part upon discovering, developing and commercializing additional drug 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 drug candidates beyond those we currently have in clinical and nonclinical development. A drug candidate can unexpectedly fail at any stage of nonclinical and clinical development. The historical failure rate for drug 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 drug candidate may not be predictive of the results that will be obtained in later stage clinical trials of the drug candidate.

The success of other future drug 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 drug candidate for use in clinical trials; and
- adverse events in the clinical trials.

Even if we successfully advance any other future drug 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 drug candidates.

We have been and may in the future be subject to claims, lawsuits, arbitration proceedings, government investigations, securities class action litigation and other legal, regulatory and

administrative proceedings and face potential liability and expenses related thereto, which could divert management's attention, and insurance coverage may not be sufficient to cover all costs and damages. This could have a material adverse effect on our business, operating results and financial condition.

We have been and may in the future be subject to claims, lawsuits, arbitration proceedings, government investigations, securities class action litigation and other legal, regulatory and administrative proceedings. For example, in November 2022, we received a Civil Investigative Demand from the Civil Division of the Department of Justice, or the Demand. The Demand sought documents and information relating to our relationship with WSU, certain of our grant applications in 2016 and 2019 with the NIH, and our receipt of a NIH grant in 2020. We cooperated with the Department of Justice with respect to the Demand and in December 2024 reached a settlement with respect thereto. In February 2023, the Securities and Exchange Commission, or SEC, sent us a subpoena seeking documents and information relating to, among other things, our former chief executive officer's alteration of images in certain research papers. We cooperated with the SEC with respect to the subpoena. On March 29, 2024, we received a letter from the SEC stating that the SEC had concluded its investigation without any enforcement action against us.

In the ordinary course of business we have been and may in the future be the subject of various legal claims. Any such claims, investigations or proceedings against us, whether meritorious or not, could be time-consuming, result in costly litigation, be harmful to our reputation, require significant management attention and divert significant resources, and the resolution of any such claims, investigations or proceedings could result in substantial damages, settlement costs, fines or penalties that could adversely affect our business, financial condition or operating results or result in harm to our reputation and brand, sanctions, consent decrees, injunctions or other remedies requiring a change in our business practices.

In the past, securities class action litigation has often followed announcement of significant business transactions, such as the sale of a company or other strategic transaction, or of negative events, such as negative results from clinical trials. We may be exposed to such litigation or government or regulatory investigations even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

Further, under certain circumstances we may have contractual or other legal obligations to indemnify and to incur legal expenses on behalf of investors, directors, officers employees, customers, vendors or other third-parties. For example, our amended and restated bylaws provide that we will indemnify our directors and officers, and may indemnify our employees, agents and other persons, to the fullest extent permitted by the Delaware General Corporation Law. We have also entered into indemnification agreements with directors and officers that require us, among other things, to indemnify them against claims that may arise due to their service in those capacities. These indemnification agreements also require us to advance expenses reasonably and actually incurred by them in investigating or defending any such claims, and it may be difficult or impossible to recover any advanced expenses if it turns out the person was not entitled to indemnification. If we are required or agree to defend or indemnify, or advance expenses to, any of our investors, directors, officers, employees, customers, vendors or other third-parties, we could incur material costs and expenses that could adversely affect our business, results of operations or financial condition.

Washington State University, or WSU, has undertaken a review of claims of potential research misconduct involving our former chief executive officer's doctoral research at WSU. We cannot predict what conclusions WSU will reach, whether or when WSU will share its conclusions with us or the public, and what effect, if any, this investigation may have on our business and reputation.

In addition to the previously disclosed investigation of the independent special committee of our board of directors, WSU has also announced that it has undertaken a review of claims of potential research misconduct involving research conducted by Dr. Leen Kawas, our former chief executive officer, during her doctoral studies at WSU. We cannot predict what, if any, effect this investigation may have on our business

and reputation. It is possible that the investigation by WSU could come to different conclusions, or uncover additional or different information, than the investigation of the independent special committee of our board of directors, the primary finding of which was that Dr. Kawas altered images in her 2011 doctoral dissertation and at least four research papers that she co-authored while a graduate student at WSU, and published from 2011 to 2014. The conclusions from WSU's investigation could have a material adverse impact on our business, reputation, scientific credibility, and prospects, as well as our in-licensed patents and pending patent applications, current grants and pending grant applications, and our relationship with WSU, from whom we in-license patents and patent applications underlying certain of our drug candidates.

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 topline 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 topline 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. Topline 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, topline data should be viewed with caution until the final data are available.

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

Additionally, we rely on data received from clinical trials, whether preliminary or final, to inform decisions on future clinical trials, including trial design, trial size, and whether or not to initiate additional clinical trials. However, this does not guarantee that our expectations based on earlier data will be realized in future clinical trials. For example, in November 2020, we initiated ACT-AD, an exploratory Phase 2 clinical trial, to better understand the overall effects of fosgonimeton on working memory processing speed and cognitive measures. Topline results of ACT-AD were announced in June 2022. We used these data to help inform strategic decisions around LIFT-AD. In September 2024, we announced the topline results for LIFT-AD, showing that the trial did not meet its primary or key secondary endpoints. Moreover, preliminary or topline results are 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.

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 drug candidate or drug 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, topline, 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 drug candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our reporting of topline or final data for our clinical trials may be delayed and our regulatory submissions or receipt of necessary marketing approvals could be delayed or prevented.

Our projected timeline for announcing our topline data for ATH-1105 or any other drug candidates we may seek to develop may be delayed, including, among other reasons, due to possible delays in data cleaning, processing or analysis, either on our part and/or on the part of any of our third-party vendors, which could harm our business, operating results, prospects or financial condition.

We also may not be able to initiate or continue clinical trials for our drug 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 drug candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' programs. Additionally, publicly reported results of our completed clinical trials may impact enrollment of our trials in progress. If we are unable to locate a sufficient number of such patients, our clinical trial and development plans could be delayed.

If we are delayed or unsuccessful in enrolling the desired number of subjects in our trials, whether as a result of the outcomes of prior trials conducted by us, competing clinical trials, overly stringent eligibility requirements, or other factors, our clinical trial results could be delayed, the costs of our clinical trials could materially increase, and the overall development timeline for ATH-1105 or any other drug candidates we may seek to develop could be negatively impacted. Even if we are successful in enrolling the targeted number of subjects in our trials, the FDA and other regulators may request additional clinical trials with larger numbers of subjects as a condition to any regulatory approval.

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. Further, to the extent any of our clinical trial sites fail to comply with the approved study protocol, good clinical practices, or FDA regulations, we may be required to exclude such sites, participants such sites may have enrolled, as well as the data collected by such sites. If any of these events were to occur, or if we are required to exclude any data for any reason, we may be required to recruit more sites or more participants than we initially thought. Enrollment delays or other delays in our clinical trials may result in increased development costs for our drug candidates and jeopardize our ability to obtain marketing approval for the sale of our drug 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 drug 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, 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, or marketing and sales than we do. Our competitors may compete with us in patient recruitment, use of clinical research organizations, and procurement of operational resources. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

Drug 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 drug products. Our competitors may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our drug candidates. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our drug products. Current and future CMS coverage restrictions on classes of drugs that encompass our drug candidates could have a material adverse impact on our ability to commercialize our drug candidates, if approved, generate revenue and attain profitability. It is unclear how future CMS coverage decisions and policies will impact our business. 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 titled "Part I, Item 1 – Business – Competition."

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

We may develop drug candidates in combination with one or more other approved or unapproved therapies. Even if any drug 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 drug 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 drug candidates are replaced as the standard of care for the indications we choose for any of our drug 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 drug products, if approved, being removed from the market or being less successful commercially.

We also may choose to evaluate drug 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 drug 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 drug product. In addition, unapproved therapies face the same risks described with respect to our drug candidate ATH-1105, 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 drug candidate we develop, we may be unable to obtain approval of or market such combination therapy.

Risks Related to Our Financial Position and Capital Needs

We will require substantial additional funding to finance our operations, complete the development and commercialization of ATH-1105, and develop and commercialize other current and potential drug candidates. If we are unable to raise this funding and access capital when needed, we may be forced to delay, reduce, or eliminate our drug product development programs, commercialization efforts or other operations.

Since our inception, we have used substantial amounts of cash to fund our operations, and we will continue to incur expenses for 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-1105. Developing ATH-1105 and conducting clinical trials for the potential treatment of ALS, and any other indications that we may pursue in the future will require substantial amounts of capital and we are actively seeking a partner to assist with the development of ATH-1105 through a joint collaboration agreement, provision of non-dilutive funding, or a combination of these and other structures. In addition, if we or a future partner obtain marketing approval for ATH-1105 or any future drug candidates, we expect

this would result in significant commercialization expenses related to sales, marketing, manufacturing, and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company.

Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. As of December 31, 2024, we had cash, cash equivalents and investments of $51.3 million. Based upon our current operating plan, we estimate that our existing cash, cash equivalents and investments will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months following the date of this report.

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 ATH-1105 and other clinical trials, including for potential additional indications that we may pursue beyond ALS, such as AD;
- the willingness of the FDA and EMA to accept ATH-1105 clinical trial data, as well as data from any completed and planned clinical and nonclinical studies and other work, as the basis for review and approval of ATH-1105 for ALS and the potential need for additional clinical trials;
- the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;
- the number and characteristics of drug candidates that we pursue;
- our ability to manufacture sufficient quantities of our drug 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, drug candidates and technologies;
- the cost, timing and outcomes of any litigation involving our company, including securities class actions and government investigations which we may be or may in the future become involved in;
- 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 drug 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.

Because we have undertaken a process to assess strategic alternatives, the timing of which is uncertain, our future capital requirements may vary significantly from what we expect. If a strategic transaction is not consummated, we will require substantial additional funding to support our continuing operations and development. In addition, even if we are successful in completing a strategic transaction, we may still need to raise additional funds for any research and development or clinical programs we choose to pursue. Because the time and efforts required for successful research and development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities for any product candidates that ultimately may be approved for sale.

In January 2023, we entered into a sales agreement with Cantor Fitzgerald & Co., or Cantor Fitzgerald, and BTIG, LLC, or BTIG, to sell shares of our common stock having aggregate sales proceeds of up to $75.0 million, from time to time, through an at-the-market, or ATM, equity offering program under which Cantor Fitzgerald and BTIG are acting as sales agents. We have not sold any securities pursuant to this ATM offering. However, 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 or abandon 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 drug candidates or otherwise agree to terms unfavorable to us.

We expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. In addition, we may seek additional capital to take advantage of favorable market conditions or strategic opportunities even if we believe we have sufficient funds for our current or future operating plans.

Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. For example, the current inflationary economic environment and health epidemics have resulted in a disruption of global financial markets. If the disruption persists or deepens, we could be unable to access additional capital, which could negatively affect our ability to consummate certain corporate development transactions or other important, beneficial or opportunistic investments. If additional funds are not available to us when we need them, on terms that are acceptable to us, or at all, we may be required to take steps that could adversely impact our business, including delaying, limiting, reducing or terminating nonclinical studies, clinical trials or other research and development activities or eliminating one or more of our development programs altogether, or delaying, limiting or reducing or terminating efforts to prepare for commercialization of any future approved drug products. We currently have a shelf registration statement effective and an existing ATM equity offering program, however, our ability to raise capital under this registration statement and through our ATM equity offering program may be limited in the future by, among other things, SEC rules and regulations impacting the eligibility of smaller companies to use Form S-3 for primary offerings of securities.

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 drug product sales and our drug candidates will require substantial additional investment before they may provide us with any revenue. We had net losses of $96.9 million and $117.7 million for the year ended December 31, 2024 and 2023, respectively, and an accumulated deficit of $406.1 million as of December 31, 2024.

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

We expect to incur significant expenses and operating losses for the foreseeable future, including as a result of the following actions that we may take to:

- continue our research and nonclinical and clinical development of our drug candidates;
- expand the scope of our clinical studies for our current and prospective drug candidates;
- initiate additional nonclinical, clinical or other studies for our drug candidates;
- 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 drug candidates that successfully complete clinical trials;
- attract, hire and retain additional personnel;
- operate as a public company;
- maintain our facilities and lab space;
- seek to identify and validate additional drug candidates;
- acquire or in-license other drug candidates and technologies or engage in other strategic transactions;
- make milestone or other payments under our in-license or other agreements;
- maintain, protect and expand our intellectual property portfolio;
- create additional infrastructure to support our operations and our drug product development efforts; and
- incur expenses in connection with legal proceedings, and addressing potential stockholder activism.

Our expenses could increase beyond expectations for a variety of reasons, including if we experience any delays or encounter issues with any of the above, 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.

Adverse events or perceptions affecting the financial services industry could adversely affect our operating results, liquidity, financial condition and prospects.

Limited liquidity, defaults, non-performance or other adverse developments affecting financial institutions or parties with which we do business, or perceptions regarding these or similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, in March 2023, Silicon Valley Bank, or SVB, was closed and placed in receivership and subsequently, additional financial institutions have been placed into receivership. We did not hold cash deposits or other accounts with SVB and did not, and as of the date of this report do not, otherwise have a direct business relationship with SVB or similarly situated financial institutions. However, companies that did have a business relationship with SVB faced:

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- loss of access to revolving existing credit facilities or other working capital sources or the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- potential or actual breach of obligations, including U.S. federal and state wage laws and contracts that required them to maintain letters or credit or other credit support arrangements; and
- termination of cash management arrangements or delays in accessing or actual loss of funds subject to cash management arrangements.

As a result of U.S. government intervention, account holders subsequently regained access to their accounts, including the uninsured portion of deposit accounts; however, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB and similarly situated financial institutions were unable to access to such sources of liquidity. There is no guarantee that the U.S. government will intervene to provide access to uninsured funds in the future in the event of the failure of

other financial institutions, or that they would do so in a timely fashion. In such an event, parties with which we have commercial agreements may be unable to satisfy their obligations to, or enter into new commercial arrangements with, us.

Concerns regarding the U.S. or international financial systems could impact the availability and cost of financing, thereby making it more difficult for us to acquire financing on acceptable terms or at all.

Any of these risks could materially impact our operating results, liquidity, financial condition and prospects.

The value of our investments is subject to significant capital markets risk related to changes in interest rates and credit spreads as well as other investment risks, which may adversely affect our operating results, liquidity, financial condition and prospects.

Our results of operations are affected by the performance of our investment portfolio. Our excess cash is invested by an external investment management service provider, under the direction of our management in accordance with our investment policy. The investment policy defines constraints and guidelines that restrict the asset classes that we may invest in by type, duration, quality and value. Our investments are subject to market-wide risks, and fluctuations, as well as to risks inherent in particular securities. The failure of any of the investment risk strategies that we employ could have a material adverse effect on our operating results, liquidity, financial condition and prospects.

The value of our investments is exposed to capital market risks, and our results of operations, liquidity, financial condition or cash flows could be adversely affected by realized losses, impairments and changes in unrealized positions as a result of: significant market volatility, changes in interest rates, changes in credit spreads and defaults, a lack of pricing transparency, a reduction in market liquidity, declines in equity prices, changes in national, state/provincial or local laws and the strengthening or weakening of foreign currencies against the U.S. dollar. Levels of write-down or impairment are impacted by our assessment of the intent to sell securities that have declined in value as well as actual losses as a result of defaults or deterioration in estimates of cash flows. If we reposition or realign portions of the investment portfolio and sell securities in an unrealized loss position, we will incur realized losses. Any such charge may have a material adverse effect on our results of operations and business.

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

As of December 31, 2024, we had federal net operating loss carryforwards, or NOLs, to offset future taxable income of approximately $9.5 million and federal tax credit carryforwards of approximately $16.5 million, which expire over a period of 7 to 13 years. Federal NOLs of $196.0 million generated after the 2017 tax year will carry forward indefinitely and will be subject to the 80% of taxable income limitation. At December 31, 2024, we also had state NOLs of $3.9 million, which expire over a period of 17 to 20 years. A lack of future taxable income would adversely affect our ability to utilize these NOLs.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in ownership by “5 percent shareholders” over a rolling three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and tax credit carryforwards to offset post-change taxable income or taxes. We may have already experienced one or more ownership changes through our equity offerings and other changes in our stock ownership.

Depending on the timing of any future utilization of our pre-change 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. In addition, future changes in our stock ownership as well as other changes that may be outside of our control, could result in additional ownership changes under Section 382 of the Code. Our NOLs may also be impaired under similar provisions of state law or limited pursuant to provisions of the Tax Cuts and Jobs Act amendments to the Code, as modified by the Coronavirus Aid, Relief, and Economic Security Act.

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.

Changes in tax laws could have a material adverse effect on our business, cash flows, results of operations or financial condition.

We are subject to the tax laws, regulations, and policies of several taxing jurisdictions. Changes in tax laws, as well as other factors, could cause us to experience fluctuations in our tax obligations and effective tax rates and otherwise adversely affect our tax positions or our tax liabilities. For example, in August 2022, as part of the Inflation Reduction Act of 2022, the United States enacted a 1% excise tax on stock buybacks and a 15% alternative minimum tax on adjusted financial statement income. Additionally, beginning in 2022, the Code eliminated the right to deduct research and development expenditures and instead requires taxpayers to capitalize and amortize U.S. and foreign research and development expenditures over five and 15 tax years, respectively. Additionally, many countries and local jurisdictions and organizations such as the Organization for Economic Cooperation and Development have proposed or implemented new tax laws or changes to existing tax laws, including additional taxes on payroll or employees. Any new or changes to tax laws could adversely affect our effective tax rate, operating results, tax credits or incentives or tax payments, which could have a material adverse effect on our business, cash flows, results of operations or financial condition.

Risks Related to Strategic Process and Potential Strategic Transaction

We may not be successful in identifying and implementing any strategic transaction and any strategic transactions that we may consummate in the future may not be successful.

Following our receipt of the topline results of LIFT-AD, we made the determination to explore strategic alternatives focused on maximizing stockholder value. As part of this process, we are exploring potential strategic alternatives that may include, but are not limited to, an acquisition, merger or reverse merger, business combination, equity or debt financing, sale of the Company, sale, exclusive license or other disposition of all or a portion of our assets, a return of capital to stockholders, or other transaction. However, there can be no assurance that we will be able to successfully consummate any particular strategic transaction. The process of continuing to evaluate these strategic options is costly, time-consuming and complex and we have incurred and may continue to incur significant costs related to this continued evaluation. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented, or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business and may diminish or delay any potential cash distributions to our stockholders. In addition, we may not be able to adequately limit or avoid future liabilities, including future costs relating to the lease on our headquarters, which may impair the value of any potential transaction or present additional challenges to completing a strategic transaction.

There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly reduce or delay any future distributions to our stockholders.

We may not realize any additional value in a strategic transaction.

The market capitalization of our company is currently below the value of our current cash, cash equivalents and short-term investments. Potential counterparties in a strategic transaction involving our company may place minimal or no value on our assets, including ATH-1105. Further, the development and any potential commercialization of our product candidates would require substantial additional cash to fund the costs associated with conducting the necessary preclinical and clinical testing and obtaining regulatory approval. Consequently, any potential counterparty in a strategic transaction involving our company may

choose not to spend the additional resources necessary to continue developing our product candidates and may attribute little or no value, in such a transaction, to those product candidates.

If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.

Although there can be no assurance that a strategic transaction will result from the process we have undertaken to assess strategic alternatives, the negotiation and consummation of any such transaction will require significant time on the part of our management, and the diversion of management's attention may disrupt the orderly operation of our company. The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected acquisition, disposition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or incurrence of non-recurring, impairment or other charges;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain key employees of our company or any acquired business; and
- possibility of future litigation.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

Our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that a strategic transaction will be pursued or completed, and, whether or not such strategic transaction is completed, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, with the passage of time, the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

Risks Related 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 drug candidates, we will

not be able to commercialize, or will be delayed in commercializing, our drug candidates, and our ability to generate revenue will be materially impaired.

Our drug 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 drug 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 drug candidates, the FDA and other comparable foreign regulatory authorities may approve our drug 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 drug product's commercial potential. We have not submitted for, or obtained, regulatory approval for any drug candidate, and it is possible that none of our drug candidates will ever obtain regulatory approval. Further, development of our drug candidates or regulatory approval may be delayed for reasons beyond our control.

Applications for our drug 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 drug 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 drug 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 or resulting in delays in our regulatory approval, including, for example, legislation or agency policies that aim to reform the accelerated approval process and FDA's increased scrutiny of post-approval confirmatory studies, which can result in withdrawal of accelerated approval if such studies fail to confirm a clinical benefit.

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 drug candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we obtain approval of our drug candidates, regulatory authorities may approve any of our drug 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 drug products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug 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 drug candidates, which would significantly harm our business, results of operations and prospects.

Our current or future drug 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 drug 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 drug 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 drug 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 drug 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 drug 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 drug candidates are used in combination with other therapies, our drug candidates may exacerbate adverse events associated with the therapy. Patients treated with our drug candidates may also be undergoing separate treatments which can cause side effects or adverse events that are unrelated to our drug candidates, but may still impact the success of our clinical trials, including, for example, by interfering with the effects of our drug candidates.

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 drug candidate altogether. We, the FDA other comparable regulatory authorities or an IRB may suspend clinical trials of a drug 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 drug 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 drug candidates obtains marketing approval, toxicities associated with such drug 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 drug product or the withdrawal of the drug product from the market. We cannot predict whether our drug 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 drug candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our drug candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our drug 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 drug candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the drug 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 drug 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 drug 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 drug 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 drug 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 drug candidates will be harmed.

Even if we receive regulatory approval of our drug 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 drug candidates.

Any regulatory approvals that we receive for our drug candidates will require surveillance to monitor the safety and efficacy of the drug candidate. The FDA may also require a REMS in order to approve our drug 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 drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our drug 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 cGMP regulations, GLP regulations and GCP regulations for any clinical trials that we conduct

post-approval. Later discovery of previously unknown problems with our drug 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 drug candidates, withdrawal of the drug 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 drug 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 drug 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 drug 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. It is difficult to predict how current and future legislation, executive actions, and litigation, including the executive orders, will be implemented, and the extent to which they will impact our business, our clinical development, and the FDA's and other agencies' ability to exercise their regulatory authority, including FDA's pre-approval inspections and timely review of any regulatory filings or applications we submit to the FDA. To the extent any 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. Recently, the U.S. Supreme Court overruled the Chevron doctrine, which gave deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite more companies and other stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could impact the FDA's review of our regulatory submissions. Further, changes in the leadership of the FDA and other federal agencies under the new Trump administration may lead to new policies and changes in the regulations that could increase our compliance costs or delay our clinical development and timelines. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action.

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 drug candidates and generate

revenue and could require us to expend significant time and resources in response and could generate negative publicity.

Disruptions at the FDA, the SEC and other government agencies caused by the outcome of the 2024 federal elections, funding shortages, global health concerns, or other events 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 the outcome of the 2024 federal elections, changes in the administration, 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 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.

To the extent the FDA's normal operations are disrupted or delayed, for example due to the outcome of the 2024 federal elections, changes in the administration, travel restrictions, public health or geopolitical issues, staffing shortages, or lack of funding, the FDA may not be able to complete the necessary inspections or provide feedback in a timely manner during our clinical development or review period. If any such delays or disruptions were to occur, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

We may seek an accelerated approval for one or more of our drug 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 drug 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 drug 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 drug candidate would result in a longer time period to commercialization of such drug candidate, could increase the cost of development of such drug candidate and could harm our competitive position in the marketplace.

Further, to the extent the FDA materially changes its policies or regulatory requirements with respect to the accelerated approval program or its internal review process for such program, our clinical development plans and regulatory approval under such program could be materially impacted or delayed. On December 29, 2022, the Consolidated Appropriations Act, 2023, including the Food and Drug Omnibus Reform Act, or FDORA, was signed into law. FDORA made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements. In January 2025, the Office of Inspector, or OIG, raised concerns with FDA's accelerated approval of three of the 24 drugs review by OIG. It is unclear how this OIG report, future policy changes, changes in the leadership of FDA, and new FDA regulations, including those that may be implemented under the new Trump administration, will impact new drug applications and our clinical development programs.

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 drug candidates or any future drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a drug 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 drug product labeling;
- the recall or discontinuation of our drug products; or
- additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA contained provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health

care programs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the U.S. Department of Health and Human Services Secretary, or HHS Secretary, as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extending the rebate program to individuals enrolled in Medicaid managed care organizations. The ACA also established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. In December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs will be eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business.

As discussed above, since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. On January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how additional challenges and healthcare reform measures of the Biden administration will impact the ACA. Complying with any new legislation and regulatory requirements could be time-intensive and expensive, resulting in a material adverse effect on our business.

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 2032 with the exception of a temporary suspension implemented under various COVID-19 relief legislation.

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. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at increasing competition for prescription drugs. In August 2022, Congress passed the IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Further, the Biden administration released an additional executive order on October 14, 2022, directing the U.S. Department of Health and Human Services, or HHS, to submit a report within ninety (90) days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. Various industry stakeholders, including pharmaceutical companies, the U.S. Chamber of Commerce, the National Infusion Center Association, the Global Colon Cancer Association, and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of IRA are unconstitutional. The impact of these judicial challenges as well as other judicial challenges in view of the Supreme Court's overruling of the *Chevron* doctrine, other legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the new Trump administration on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drug candidates if approved.

Current and future CMS coverage restrictions on classes of drugs that encompass our drug candidates could have a material adverse impact on our ability to commercialize our drug candidates, if approved, generate revenue and attain profitability. It is unclear how future CMS coverage decisions and policies will impact our business.

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 drug products, once approved, or put pressure on our drug product pricing. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our drug products. Further, FDA recently authorized the state of Florida to develop Section 804 Importation Programs to import certain prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. 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 drug 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 or impose price controls may adversely affect:

- the demand for our drug candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our drug products;
- our ability to obtain coverage and reimbursement approval for a drug 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 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 drug product. 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 drug candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure to what extent the trajectory of these legislative and regulatory proposals will be implemented by the federal and state governments, whether additional legislative changes will be enacted, whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug 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, and our participation in the federal health care programs and acceptance of federal grant funding, such as funding from the NIH, 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 drug 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 drug products for which we obtain marketing approval. Similarly, our participation in the federal health care programs and acceptance of federal grant funding from the NIH may subject us to federal false claims laws, civil penalties and assessments, criminal prosecution, and other administrative, civil, and criminal remedies.

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. Under the FCA, a "claim" also includes any request (including grant request) or demand for money or property made to the United States or to a contractor, recipient, if the Federal government provides or will reimburse any portion of the funds claimed. "Funds" include money that the NIH awards as part of research grants. Even if a federal grant is not awarded, the grant applicant may be subject to FCA liability if the information contained in or submitted as part of a grant application, including its certifications and assurances, is found to be false, fictitious, or fraudulent.
- 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 and their subcontractors 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 CMS information related to payments or other transfers of value made to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members.
- 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 drug 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, disgorgement, 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.

In addition to the risks relating to the outcome of the independent special committee's investigation noted above, we are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in

the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

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

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

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

Risks Related to Our Reliance on Third Parties

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 or in-license worldwide intellectual property rights to 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. For example, we are actively seeking a partner to assist with the development of ATH-1105 through a joint collaboration agreement, provision of non-dilutive funding, or a combination of these and other structures. 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.

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 drug 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 drug 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 drug 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 drug candidates or bring them to market and generate product revenue.

Even if we are successful in entering into collaborations involving our drug 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 drug candidates or may elect not to continue or renew development or commercialization of our drug 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 drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our drug candidates;
- a collaborator with marketing and distribution rights to one or more drug 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 drug 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 drug candidates; and
- collaborators may own or co-own intellectual property covering our drug 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 drug candidates could delay the development and commercialization of our drug 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 transactions and 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 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.

We 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 drug candidates.

We 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 drug 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. In particular, protocol deviations or non-compliance with GCP requirements, or other data integrity reasons, can cause us or the FDA or other regulatory authorities to exclude data from non-compliant sites or investigators, which may cause the trial to be underpowered to meet the endpoints. 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 drug 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 drug 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 drug candidates. As a result, our financial results and the commercial prospects for our drug 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 drug 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 drug 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 drug candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our drug 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 drug candidates are sourced, in some cases, from a single-source supplier and sometimes involve long lead times from order to receipt of the materials. If we were to experience an unexpected loss of supply of any of our drug candidates or any of our future drug 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. We expect to continue to rely on third-party manufacturers for the commercial supply of any of our drug 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 drug 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 drug 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 drug 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 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 drug 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 drug 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 drug candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our drug candidates or drugs and harm our business and results of operations. Our current and anticipated future dependence upon others for the manufacture of our drug candidates or drugs may adversely affect our future profit margins and our ability to commercialize any drug candidates that receive marketing approval on a timely and competitive basis.

In addition, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. For example, in 2024, legislative proposals were passed in the House of Representatives and referred to the Senate that would have limited the extension of certain specific types of government contracts or renewals, loans, or grants, to companies that may do business with select Chinese biotechnology equipment or service providers. Others in Congress have advocated for the use of existing executive branch authorities to limit certain Chinese service providers' ability to engage in business in the U.S. Although we do not currently use equipment or services produced or provided by such Chinese biotechnology companies, such changes in applicable trade policy may result in us being unable to obtain or use necessary equipment or services, may limit our ability to seek foreign regulatory approvals for our drug candidates, or may cause significant industry-wide supply delays or capacity limitations that could materially disrupt our operations, supply chain, and ability to produce, sell and distribute our drug candidates.

In a recent example of a change in policy that may impact our reliance on foreign third parties, the U.S. government instituted a new set of rules, effective April 8, 2025, that will prohibit or restrict transactions involving certain types and amounts of sensitive data – including, e.g., certain genomic data, human biosamples, personal health data, etc., even when de-identified – between U.S. persons and foreign persons associated with specific countries of concern, including China. These new rules will require U.S. businesses to seek assurances from all foreign parties with which they share sensitive data (under certain types of agreements) that those parties will not further share that data with parties in countries of concern. This change in trade policy may impact our collection of data for non-clinical and clinical trials and sharing of that data and other data with foreign third parties, and may lead to the potential impacts on our operations, supply chain, and ability to produce, sell and distribute our drug candidates mentioned above.

Furthermore, the U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. We cannot predict whether any proposed legislation will be enacted, what executive actions may implicate these kinds of service relationships, or what other actions may ultimately be taken with respect to trade relations between the United States and China or other countries, including countries which the U.S. government has identified as a foreign adversary that poses national security risks to the United States.

Relatedly, the United States has recently enacted and proposed to enact significant new tariffs. President Trump has directed various federal agencies to further evaluate key aspects of U.S. trade policy and there has been ongoing discussion and commentary regarding potential significant changes to U.S. trade policies, treaties and tariffs. There continues to exist significant uncertainty about the future

relationship between the U.S. and other countries with respect to such trade policies, treaties and tariffs. These developments, or the perception that any of them could occur, may have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global trade and, in particular, trade between the impacted nations and the U.S. Any of these factors could depress economic activity and restrict our access to third party services.

We cannot predict what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation, any of which may materially and adversely affect our business, financial condition, results of operations, and cash flows.

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 drug 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 drug 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 drug 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 drug 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.

Risks Related to Our Ability to Commercialize our Drug Products

Even if approved, our drug 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 drug 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 or reimbursement of any of our approved drug 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 drug candidate as well as competitive products;
- the clinical indications for which the drug candidate is approved;
- the extent of physician acceptance of FDA-approved therapies for target indications;
- restrictions on the use of our drug 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 our drug 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 drug 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 drug products or drug 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 drug candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from such drug candidates and our financial results could be negatively impacted.

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

We have never commercialized a drug candidate. We may license certain rights with respect to our drug candidates to collaborators, and, if so, we will rely on the assistance and guidance of those collaborators. For drug 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 drug 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 drug 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 drug 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 drug candidates, we may not generate revenues from them or be able to reach or sustain profitability.

If the market opportunity for any drug 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 drug candidate development on treatments for various CNS and PNS disorder indications. The addressable patient populations that may benefit from treatment with our drug 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 PNS disorders. Any regulatory approval of our drug 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 drug products for any other therapeutic indications not expressly approved by the FDA. Additionally, the potentially addressable patient population for our drug candidates may not ultimately be amenable to treatment with our drug candidates. Even if we receive regulatory approval for any of our drug 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 drug candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business.

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

We face an inherent risk of product liability as a result of the planned clinical testing of our drug candidates and will face an even greater risk if we commercialize any drug products. For example, we may be sued if our drug 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 drug 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 drug candidates or drug 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;
- drug 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 drug 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 drug 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 drug 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 drug products could limit our ability to market those drug 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 drug product in a particular country, but then be subject to price regulations that delay our commercial launch of the drug product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the drug product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if any drug 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 drug candidates will depend in part on the extent to which coverage and adequate reimbursement for these drug 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 drug candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our drug 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 drug 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 drug 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 CMS, an agency within 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 drug 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 drug products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drug 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 drug products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drug 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 drug candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any drug 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 drug 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 drug candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative

changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

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

We plan to eventually seek regulatory approval of our drug 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 health epidemics on our ability to produce our drug candidates and conduct clinical trials in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with legal requirements applicable to privacy, data protection, information security and other matters;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes and government payors in foreign countries;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

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

Risks Related 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 drug 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 drug 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 current or 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, found unenforceable 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 or the patent owner before various patent offices or in courts. Thus, the degree of future protection for our and any current or 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 or limitations in our ability to properly protect the intellectual property rights relating to our drug candidates could have a material adverse effect on our financial condition and results of operations.

We cannot be certain that the claims in our pending patent applications or those of any current or 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 drug 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 and patent applications may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- changes to patent laws in the United States or in other countries may limit the ability to obtain, defend or enforce patents, or may apply retroactively to affect the term or scope of patents;
- 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 drug candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope or term 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 current or 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 current or 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. Certain of these parties may also be subject to public information disclosure statutes and could determine to disclose patentable aspects of our research and development output pursuant to a request thereunder, notwithstanding the existence of a non-disclosure and confidentiality agreement. Any of these actions could jeopardize our ability to seek patent protection.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates or their use 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 the term is not sufficiently long, 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, term, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of any current or future licensors may not result in patents being issued which protect our drug candidates or their use 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 issues 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, invalidated or rendered unenforceable as a result of challenges by third parties. Consequently, we do not know whether our drug 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 current or 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, term, validity, or enforceability, and our patents or the patents of any current or 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 or term

of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our drug 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 current or 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, scope, validity or patentability with respect to our patents and patent applications and those of any current or future licensors.

For example, in view of the lawsuits disclosed elsewhere in this report including in this "Risk Factors" section under the heading "-*We and certain of our directors and executive officers have been, and may in the future be, named as defendants in lawsuits that could result in substantial costs and divert management's attention*," and in "Part I, Item 3 – Legal Proceedings," third parties may challenge the validity or enforceability of our in-licensed patents and patent applications. The outcome following legal assertions of invalidity and unenforceability is unpredictable. 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 technology and drug products not covered by our issued patents. 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 in-licensed patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future drug candidates. Further, these proceedings could have a material adverse effect on our business, results of operations and financial condition.

Even though we own patents and patent applications covering our small molecule drug candidates, our patents and any future patents we obtain may not effectively prevent others from developing or commercializing products similar to our drug candidates. While the fosgonimeton patent family is distinct from, and not part of the same patent family as, the dihexa patent licensed from WSU, and therefore is not implicated in the allegations that Dr. Kawas altered images in connection with her doctoral studies, third parties may use these allegations to cast doubt on the validity and enforceability of our owned patents or patent applications. Such events may result in substantial cost and require significant time from our scientists and management, and could dissuade companies from collaborating with us to license, develop, or commercialize current or future drug candidates, even if the eventual outcome is favorable to us.

We or WSU may in the future file one or more requests for supplemental examination of certain patents for the USPTO to reconsider the enforceability and validity of the patents (including any patents relating to dihexa) in view of the allegations that Dr. Kawas altered images in connection with her doctoral studies. The outcome of any supplemental examination procedure is unpredictable. If a substantial new question of patentability is found, the USPTO Director will order supplemental examination of the patent. An adverse determination in such a proceeding could reduce the scope of, or invalidate or render unenforceable, the affected patent rights. While supplemental examination proceedings that result in our favor would bolster the presumption of validity and enforceability of the examined patents, third parties may still challenge the patents and patent applications in litigation or other legal proceedings.

ATH-1105, our small molecule drug candidate currently in development for the potential treatment of ALS, was independently developed by us and is not covered by nor subject to the WSU license agreement.

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 drug candidates but that are not covered by the claims of the patents that we own or license;

- we or any current or 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 current or future licensors or collaborators might not have been the first to file patent applications covering certain of our or their 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 application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application 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 drug candidates and drug products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation and other legal actions, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, reexaminations, IPR proceedings and PGR proceedings and oppositions 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 drug candidates. There may be third-party patents or patent applications with claims to compositions, materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our drug 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 or patent applications that may be infringed by commercialization of any of our drug candidates, and we cannot be certain that we were the first to file a patent application related to a drug candidate, its use, or our 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 drug candidates or their use 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 drug candidates 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 defense to 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 drug candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of the date of this report, others may hold proprietary rights that could prevent our drug candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our drug candidates, 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 drug candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion for management and other personnel. 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 drug 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 drug 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 drug 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 drug 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 drug 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, or if we are unable to maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or drug 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 current or future licensors' patents, which could be expensive, time consuming and unsuccessful. Further, our issued patents or any current or 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, 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 drug candidates or their method of use, the defendant could counterclaim that our patent or the patent of any current or future licensors is invalid or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including allegations of a lack of novelty, obviousness, lack of sufficient 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 application misrepresented or fraudulently 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 current or future licensors' patents in such a way that they no longer cover our technology or any drug candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to a validity claim, 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 any drug 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 or unenforceability is unpredictable, and prior art could render our patents or any current or future licensors' patents invalid. There is no assurance that all potentially relevant prior art relating to our patents and patents applications or the patents and patent applications of any current or 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 patents and patent applications or the patents and patent applications of any current or future licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Additionally, a finding that issued claims lack sufficient written description or are not enabled could render our patent or any current or future licensors' patent invalid. A finding that issued claims are obvious under the standard for obviousness-type double patenting could result in a shortened term for our patent or any current or future licensors' patent, or render our patent or any current or future licensors' patent invalid.

If a third party were to prevail on a legal assertion of invalidity or unenforceability, we may lose at least part, and perhaps all, of the patent protection on such drug candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of any current or future licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug 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 management and other 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 drug product and practicing our own patented technology.

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

During the course of any intellectual property litigation or legal proceeding, there could be public announcements of the initiation of the litigation or legal proceeding as well as results of hearings, rulings on motions, and other interim proceedings. If securities analysts or investors regard these announcements as negative, the perceived value of our existing drug candidates, 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 drug 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 current or future licensors or of third parties. 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 personnel. 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 drug candidates to market.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of any current or future licensors and the enforcement or defense of our issued patents or those of any current or 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 are 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 filed a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours or our current or future licensors even if we or our current or future licensors had made the invention before it was made by such third party. This requires 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 current or future licensors are the first to either (1) file any patent application related to our drug candidates, their use, or our technology or (2) invent any of the inventions claimed in the patents or patent applications.

The Leahy-Smith Act also included a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of printed publications to the USPTO during patent prosecution and additional procedures to attack the validity or enforceability 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 or those of our current or future licensors that would not have been invalidated if first challenged by the third party 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 current or future licensors and the enforcement or defense of our issued patents or those of any current or 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 drug 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. As an example, European patent applications now provide the option, upon grant of a patent, of becoming a Unitary Patent, which is subject to the jurisdiction of the Unitary Patent Court, or UPC, in member states that have acceded to and ratified the EU Patent Package. The option of a Unitary Patent is a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC. European patents granted on applications we file may be subject to loss or revocation via the UPC, which could have a material adverse effect on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time and may adversely affect our ability to enforce or defend the validity of any European patents obtained. We have opted out of the UPC with respect to our European patents to date, and we may decide to opt out of the UPC with respect to any pending or future published European patent applications or patents. If certain formalities and requirements are not met, however, such European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that future European patents and patent applications will avoid falling under the jurisdiction of the UPC, even if we decide to opt out of the UPC.

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 drug 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 drug candidates or their use are obtained, once the patent life has expired, we may be open to competition from competitive products, including generic versions of our drug products. Given the amount of time required for the development, testing and regulatory review of new drug 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 drug products similar or identical to ours.

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

Depending upon the timing, duration and specifics of FDA marketing approval of our drug candidates, one or more of our U.S. patents or those of any current or 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 clinical trials and 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 drug candidates, although the requirements and terms of such extensions vary country-by-country. 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 or launch generic versions of our drug 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 drug product earlier than might otherwise be the case.

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

We own and in-license patents and pending patent applications in the United States and 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 drug products made using our inventions in and into the United States or other jurisdictions. Competitors may use our inventions in jurisdictions where we have not obtained patent protection to develop their own drug products and, further, may export otherwise infringing drug products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These drug products may compete with our drug candidates, and our patents, the patents of any current or 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 current or future licensors' patents or marketing of competing drug 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 current or future licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of any current or 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 patents. 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.

Geopolitical actions could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were

to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have a predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, 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 or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents or applications and those of any current or 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 drug 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, and it may be difficult and costly to register, maintain or protect our rights to these trademarks and trade names in jurisdictions in and outside of the United States. 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 names, 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 our 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 improperly 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 of third parties.

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 their 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 drug candidates. 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 drug 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 drug 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 and development or allow commercialization of drug candidates. These and other licenses may not provide exclusive rights to use such intellectual property and other rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our drug candidates in the future. Further, these and other licenses may also include certain restrictions or obligations that limit our ability to engage with third parties, including potential restrictions on sublicensing or outsourcing certain activities.

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 our drug candidates 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 current or 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 drug candidates 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 it is later determined that third parties own the rights to our in-licensed patents, or if other third parties have ownership rights to our in-licensed patents, such third parties may be able to license such patents to our competitors, and our competitors could market drug products similar or identical to our drug candidates. This could have a material adverse effect on our competitive position, business, financial condition, 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 rights licensed to us. In that event, we may be required to expend significant time and resources to redesign our drug 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 drug 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 manufacturing methods, drug candidates, methods of use, or future methods or drug candidates 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 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 or other 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 and other rights 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 drug candidates infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense 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 other rights 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 other rights, 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 or other rights 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 drug candidates, which could have a material adverse effect on our business, financial condition, 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 drug candidates 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, drug products identical to ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

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

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patent applications and patents relating to our drug candidates and their use, there may be times when the filing and prosecution activities for patent applications and patents relating to our drug 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 patent applications and patents covering our drug 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 drug candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling drug products similar or identical to our drug candidates. 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 or developed through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a manufacturing 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, which could adversely affect our ability to successfully develop and commercialize our drug products.

Pursuant to the Bayh-Dole Act of 1980, or the Bayh-Dole Act, the U.S. government may have certain rights in any invention developed or reduced to practice with government funding. We have in the past, and we may in the future, discovered, developed, acquired, or licensed new intellectual property that has been generated through the use of U.S. government funding or grants in which the U.S. government may have certain rights pursuant to the Bayh-Dole Act. These U.S. government rights include a non-exclusive,

non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as “march-in rights”). Such “march-in” rights would apply to new subject matter arising from the use of such government funding or grants and would not extend to pre-existing subject matter or subject matter arising from funds unrelated to the government funding or grants. If the U.S. government exercises its march-in rights in our intellectual property rights that are generated through the use of U.S. government funding or grants, we could be required to license or sublicense intellectual property discovered or 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. Should any of these events occur, it could significantly harm our business, results of operations and prospects. In addition, the Bayh-Dole Act requires that, in certain circumstances, any products embodying intellectual property generated with the use of U.S. government funds or produced through the use of any such intellectual property 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, which could adversely affect our ability to successfully develop and commercialize our drug products and have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Cybersecurity

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

As discussed in the section of this report titled "Part 1, Item 1.C—Cybersecurity," we have implemented various processes and policies for identifying, assessing, and managing material risks from cybersecurity threats. However, despite the implementation of such safeguards and security measures, our internal computer systems and those of our CROs and other contractors and consultants may nevertheless 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, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our personal, sensitive, confidential or proprietary information and information technology systems, and those of the third parties upon which we rely. For example, in April 2023, CRO Evotec SE faced a cybersecurity attack that temporarily disrupted its systems and operations. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks,

that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Increases in remote work impacting how our employees work and access our systems could lead to additional opportunities for bad actors to launch cyberattacks or for employees to cause inadvertent security risks or incidents and may amplify the impacts of any security breach or incident. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

We may rely on third-party service providers and technologies to operate critical business systems to process sensitive information and other company data in a variety of contexts. We may also rely on third-party service providers to provide certain products or services, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. Security incidents or other interruptions suffered by our third-party service providers could cause us to experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy- or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Our business partners face similar risks, and any security breach of, or security incident impacting, their systems or that they otherwise suffer could adversely affect our security posture. A security breach or incident or privacy violation that leads to loss of or unauthorized use, disclosure or modification of, or access to trade secrets, company resources, personal, sensitive, confidential or proprietary information, including 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 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, any of which could disrupt our business or result in increased costs or loss of revenue or company resources. Moreover, the prevalent use of mobile devices that access confidential information, increase the risk of security breaches and incidents.

Despite efforts to create security barriers to the above-described threats, it is impossible for us to entirely mitigate these risks. To date, we have not experienced any material impact to our business, financial position or results of operations resulting from cyberattacks or other information security incidents such as phishing, social engineering, ransomware or malware attacks; however, because of the frequently changing attack techniques, along with the increased volume and sophistication of such attacks, our business, financial position or results of operations could be adversely impacted in the future. 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 breach or incident were to occur and cause the loss or corruption of data or interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss, unavailability, or corruption 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. Any disruption or security breach or incident resulting in loss or unavailability of, or damage to, our data or systems, or inappropriate use,

disclosure or modification of personal, sensitive, confidential or proprietary information, could result in us incurring liability and in delays to further development and commercialization of our drug 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 security breaches or incidents, that could adversely affect our business and operations or result in the loss, unavailability, or corruption of, or inappropriate access to or use of, critical or sensitive information or company resources. Any such interruptions, breaches or incidents, 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 privacy and security breaches or incidents.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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

As we conduct our clinical trials and continue to enroll patients in our current and 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, including personal health data, regarding individuals in the European Economic Area, or EEA, 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 EEA, 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 subject to uncertainty, including as the result of legal proceedings in the EU. For example, in 2020, the Court of Justice for the EU invalidated the EU-U.S. Privacy Shield and imposed additional obligations in connection with the use of standard contractual clauses approved by the EU Commission. These and other developments with respect to cross-border data transfers may increase the complexity of transferring personal data across borders and may require us to review and amend our mechanisms relating to cross-border data transfer.

Further, the exit of the United Kingdom, or UK, from the EU has created uncertainty regarding data protection regulation in the UK. The UK has implemented legislation similar to the GDPR, referred to as the UK GDPR, which provides for fines of up to the greater of up to the greater of £17.5 million or 4% of global turnover. The GDPR and UK GDPR increased our responsibility and liability in relation to personal data that we process where subject to these regimes, and we may be required to put in place or modify policies and measures to ensure compliance with the GDPR, including as implemented by individual countries, and the UK GDPR, each of which may require us to modify our policies and procedures and engage in additional contractual negotiations, and which may cause us to incur liabilities, expenses, costs, and operational losses. Compliance with the GDPR and UK 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 our efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our activities in the EEA and the UK.

In addition, in the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). California has 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 California Privacy Rights Act of 2020 (CPRA), which became operative January 1, 2023, expands the CCPA's requirements, including applying to personal information of business representatives and employees and establishing a new regulatory agency to implement and enforce the law. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA and CPRA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. Additionally, numerous other states have proposed or enacted laws addressing privacy and security, including Washington's My Health, My Data Act, and several laws imposing obligations similar to those of the CCPA. The U.S. federal government also is contemplating federal privacy legislation. The CCPA, CPRA, and other evolving legislation relating to privacy, data protection, and information security may impact our business activities and exemplify the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

We may also be bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA/CPRA, require us to impose specific contractual restrictions on our service providers, and we may also be subject to use and disclosure limitations in our contracts with providers who share information with us for clinical trials. Additionally, we may publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources. These obligations may necessitate changes to our business model, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations.

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 information security could result in governmental investigations, proceedings and enforcement actions (which could result in 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 laws relating to privacy, data protection, or information security, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

Risks Related to Ownership of Our Common Stock

If we do not regain compliance with or continue to satisfy the Nasdaq continued listing requirements, our common stock could be delisted from the Nasdaq, which may make it more difficult for investors to sell shares of our common stock and consequently may negatively impact the price of our common stock.

We have in the past and we may in the future fail to comply with the Nasdaq listing rules, including, the minimum $1.00 per share closing bid price requirement, the minimum $50.0 million market value of listed securities requirement, and the minimum $15.0 million market value of publicly held shares requirement. From September 4, 2024 to February 26, 2025, our common stock has had a closing bid price below the minimum $1.00 requirement and the market value of our listed securities has been below the minimum $50 million requirement. We received a deficiency notice from Nasdaq with respect to the closing bid price requirement on October 16, 2024. If our common stock ceases to be listed for trading on the Nasdaq for failure to comply with the minimum $1.00 per share closing bid price requirement, the $50 million market value of listed securities requirement, or for any other reason, it may harm our stock price, increase the volatility of our stock price, decrease the level of trading activity and make it more difficult for investors to buy or sell shares of our common stock. If we are not listed on the Nasdaq, our ability to raise capital will be adversely impacted. Trading in our common stock may also be halted or suspended in the future on the Nasdaq due to market or trading conditions at the discretion of the Nasdaq. Any halt or suspension in the trading in our common stock may negatively impact the market price of our common stock.

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

If an active market for our common stock 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 drug 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 has been and may continue to be volatile, which could result in substantial losses for investors.

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

- results of nonclinical studies and clinical trials;
- the success of existing or new competitive products or technologies;
- the timing and results of clinical trials for our current drug candidates and any future drug candidates that we may develop;
- commencement or termination of collaborations for our drug candidates;
- failure or discontinuation of any of our drug candidates;
- results of nonclinical studies, clinical trials or regulatory approvals of drug candidates of our competitors, or announcements about new research programs or drug candidates of our competitors;
- investor reactions to other companies' drug development results, including product failures or negative responses from regulatory authorities;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;

- the recruitment or departure of key personnel, including in connection with our workforce reduction announced in September 2024;
- negative press coverage;
- the status of any litigation and/or government investigations, including the potential commencement of additional litigation or investigations;
- the results of an investigation into our former CEO, Leen Kawas, by WSU;
- the level of expenses related to any of our research programs, drug candidates that we may develop;
- the results of our efforts to develop additional drug candidates or drug 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, including, but not limited to, under our ATM offering;
- sales of our common stock by us, our insiders, or other stockholders;
- 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;
- volatility with the banking system;
- the potential impact of health epidemics on our business;
- direct or indirect impacts on our business, our suppliers and other third parties and our clinical sites as a result of geopolitical events, including the Russia-Ukraine war;
- general economic, industry, and market conditions; and
- the other factors described in this “Part I, Item 1A – Risk Factors” section.

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

We and certain of our directors and executive officers have been, and may in the future be, named as defendants in lawsuits that could result in substantial costs and divert management’s attention.

As described elsewhere in this report in “Part I, Item 3 – Legal Proceedings,” we and certain of our executive officers and directors were named as defendants in a class action lawsuit that generally alleged that we and certain of our officers and directors violated Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder and Sections 11, 12, and 15 of the Securities Act by making allegedly false or misleading statements and omitting material adverse facts regarding our business. Certain of our executive officers and directors were also named as defendants in derivative actions, which were based on similar allegations, and generally alleged that defendants breached their fiduciary duties to us, among other

things. We were named as a nominal defendant in these derivative proceedings. These complaints sought unspecified compensatory and punitive damages, and reasonable costs and expenses, including attorneys' fees, and other relief. Although we have insurance, it provides for a substantial retention of liability and is subject to limitations and may not cover a significant portion, or any, of the expenses or liabilities we may incur or be subject to in connection with any class action lawsuit or other litigation to which we become party. Moreover, any conclusion of such matters in a manner adverse to us and for which we incur substantial costs or damages not covered by our directors' and officers' liability insurance would have a material adverse effect on our financial condition and business. In addition, such litigation would cause our management and board of directors to divert time and attention to the litigation and could adversely impact our reputation and further divert management and our board of directors' attention and resources from other priorities, including the execution of our operating plan and strategies that are important to our ability to grow our business and advance our drug candidates, any of which could have a material adverse effect on our business. In addition, additional lawsuits may be filed, the conclusion of which in a manner adverse to us and for which we incur substantial costs or damages not covered by our directors' and officers' liability insurance would have a material adverse effect on our financial condition and business.

Actions by activist stockholders have in the past been, and may in the future be, disruptive and could cause uncertainty about the strategic direction of our business.

Our business could be negatively affected as a result of stockholder activism, which could be disruptive and cause uncertainty about the strategic direction of our business. For example, in February 2022, an activist stockholder announced his intention to nominate himself and one other candidate for election to our board of directors at our 2022 annual meeting of stockholders. While this proxy contest was unsuccessful, stockholder activism could recur and have an adverse effect on our business, results of operations, and financial condition. For example, at times our market capitalization has been less than the aggregate value of our cash, cash equivalents and investments. Other biotechnology companies in this situation have received proposals from shareholder activists to liquidate and return capital to investors.

We strive to maintain constructive communications with our stockholders and welcome their views and opinions with the goal of enhancing value for all stockholders. However, a proxy contest or other activist behaviors could have an adverse effect on us because:

- responding to actions by activist stockholders can disrupt our operations, is costly and time-consuming, and diverts the attention of our board of directors and senior management team from the pursuit of business strategies, each of which could adversely affect our results of operations and financial condition;
- perceived uncertainties as to our future direction as a result of changes to the composition of our board of directors may lead to the perception of a change in the direction of our business, as well as instability or lack of continuity, all of which may be exploited by our competitors, may result in the loss of potential business opportunities, may cause concern for those enrolling in our clinical trials, and make it more difficult to attract and retain qualified personnel and business partners;
- actions by activist stockholders may interfere with any efforts that we undertake in the future to raise capital;
- actions by activist stockholders could cause significant fluctuations in our stock price based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business; and
- if individuals are elected to our board of directors with a specific agenda as a result of a proxy contest, it may adversely affect our ability to effectively implement our business strategy and to create additional value for our stockholders.

Even if a proxy contest or other activist efforts are not successful, the increased costs that we would bear and the distraction of our board of directors and senior management could negatively impact our business, although we cannot predict with certainty the extent of such negative impacts.

A significant portion of our total outstanding shares 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, 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. In addition, 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.

We also register shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

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

Our directors, executive officers, significant holders of our outstanding common stock and their respective affiliates beneficially own a substantial amount of our outstanding common stock as of December 31, 2024. 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 Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

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

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act, the regulations of The Nasdaq Global Select Market, the rules and regulations of the SEC, 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. 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, as required by Section 404 of the Sarbanes-Oxley Act. We may experience difficulty in meeting these reporting requirements in the future.

The process of building and maintaining our accounting and financial functions and infrastructure has required and will continue to require significant additional professional fees, internal costs and management efforts. 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.

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 amended and restated certificate of incorporation and amended and restated 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, the amended and restated certificate of incorporation and amended and restated bylaws:

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

- prevent cumulative voting rights (therefore allowing the holders of a plurality of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chairman of the board, our chief executive officer or by the board of directors; and
- provide that stockholders are permitted to amend the bylaws only upon receiving at least two-thirds of the total votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

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

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

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court in Delaware or the federal district court for the District of Delaware) 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 amended and restated bylaws; any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our amended and restated 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 amended and restated bylaws further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The enforceability of similar exclusive federal forum provisions in other companies' organizational documents has been challenged in legal proceedings, and while the Delaware Supreme Court has ruled that this type of exclusive federal forum provision is facially valid under Delaware law, there is uncertainty as to whether other courts would enforce such provisions and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

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

General Risk Factors

The loss of any of our key personnel could significantly harm our business, results of operations and competitive position.

In order to compete, we must attract, retain, and motivate executives and other key employees. Hiring and retaining qualified executives, scientists, technical and legal and accounting staff are critical to our business, and competition for experienced employees in our industry can be high. The loss of one or more of these key employees, or our inability to hire additional key personnel when needed, could have a material adverse effect on our business and prospects.

In addition, the organizational restructuring we undertook in September 2024 that significantly reduced our workforce, including the departure of our chief business officer and chief financial officer and our chief operating officer and chief development officer, may negatively impact employee morale for those who are not directly impacted, which may increase employee attrition and hurt future recruiting efforts, hindering our ability to achieve our key priorities. Any failure to achieve the expected benefits from the reduction in workforce could adversely affect our stock price, financial condition and ability to achieve our key priorities, as well as lead to litigation.

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

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

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

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

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

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Select Market, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We have hired, and expect that we will continue to need to hire, additional accounting, finance, and other personnel in connection with 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 continue to evaluate and monitor these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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

As a public company, we are subject to reporting and other obligations under the Exchange Act, including the requirements of Section 404 of the Sarbanes-Oxley Act, 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 our 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. 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.

The potential effects of health epidemics could adversely impact our business, including our nonclinical studies and clinical trials.

Our business could in the future be adversely impacted by the effects of possible health epidemics and other outbreaks which could cause disruptions that could severely impact our business, nonclinical studies and clinical trials. Such disruptions may include:

- delays or difficulties in enrolling and retaining patients in our clinical trials;
- difficulties interpreting data from our clinical trials due to the possible effects of such diseases on cognition of the subjects enrolled in our clinical trials;

- 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 drug 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;
- interruptions, difficulties or delays arising in our existing operations and company culture as a result of some or all of our employees working remotely;
- 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.

The trading prices for shares of biopharmaceutical companies have in the past been and could in the future be highly volatile as a result of health epidemics, including the COVID-19 pandemic, and the trading prices for shares of our common stock could also experience high volatility. In the event of an emergence of new disease outbreaks or a resurgence of COVID-19, we could 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 a health epidemic, including a resurgence of COVID-19, could materially and adversely affect our business and the value of our common stock.

The ultimate impact of a possible health epidemic or other outbreak, including a resurgence of COVID-19, on our business operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted. 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 drug candidates. Our ability to obtain clinical supplies of our drug candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Attention to ESG (environmental, social and governance) matters may cause us to incur additional costs or expose us to additional risks.

A variety of stakeholder groups, including investors, governmental and nongovernmental organizations, are focused on corporate environmental, social and governance, or ESG, practices. Our ESG practices may not meet the standards of our investors or other stakeholders, and they as well as advocacy groups may campaign for us to change our business, operations or practices to better address ESG-related concerns. A failure, or perceived failure, of us to respond to any such campaigns could harm our business and reputation and have a negative impact on the market price of our common stock. Moreover, if ESG best practices, reporting standards and disclosure requirements continue to develop, we may incur increasing costs related to ESG monitoring and reporting.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management Strategy

We have implemented various processes and policies for identifying, assessing, and managing material risks from cybersecurity threats. Our cybersecurity risk management strategy is designed following the Cybersecurity Framework set by the National Institute of Standard and Technology, or NIST.

We assess our information technology, or IT, environment against the NIST Cybersecurity Framework, as well as various cyber-attack vectors, working to identify and remediate risks. We implement reasonable administrative, technical and procedural safeguards to manage cybersecurity risks, for example, by enforcing single sign-on or multi-factor authentication where supported, and the use of mobile device management to secure company resources on employee personal devices. Additionally, we engage third-party cybersecurity experts to assess the security of our network and perform continuous system monitoring, and we engage a third party to perform internal audits of our IT General Controls, or ITGCs. We have implemented certain processes to oversee and identify risks from cybersecurity threats associated with our use of third-party service providers, for example, by evaluating such service providers' own cybersecurity processes and reviewing available certification and audit reports, including International Organization for Standardization, or ISO, certifications for information security management systems, and System and Organization Controls, or SOC, reports.

At this time, we have not experienced cybersecurity incidents, or are aware of any risks from cybersecurity threats, that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition.

Cybersecurity Governance

Board of Directors

Our board of directors is responsible for general oversight and regular review of information regarding our risks, including cybersecurity risks. Members of management communicate an overview of our current cybersecurity environment to our board of directors at least annually and provide updates to our board of directors regarding cybersecurity matters periodically throughout the year. Additionally, our third-party auditors inform the audit committee of our board of directors of our ITGC framework and control testing results, which include controls related to cybersecurity risks. Further, management has established cybersecurity incident response processes for escalating the communication of cybersecurity incidents up to the board of directors, as appropriate.

Management

Material risks from cybersecurity threats are assessed and managed by a dedicated team comprised of internal and external IT professionals experienced in cybersecurity threat risk management, who ultimately report to our senior vice president, finance and accounting. Our senior vice president, finance and accounting has extensive operational and leadership experience overseeing accounting and finance functions at various organizations, including oversight of critical accounting and finance IT systems. Our senior IT consultant has over 20 years of experience with IT and cybersecurity risk management, having served in senior executive-level IT positions at multiple Fortune 500 companies and companies within the life sciences industry.

Our team of IT professionals, which continuously monitors our IT environment for cybersecurity threats and incidents, routinely reports on cybersecurity incident prevention, detection, mitigation, and remediation efforts to our senior vice president, finance and accounting and chief compliance officer. Additionally, we have established policies addressing processes for responding to potential cybersecurity

incidents, including assessment, communication, and remediation protocols. Our incident response processes further provide for the escalation of cybersecurity incidents to our executive management team and board of directors, as appropriate.

Item 2. Properties.

Our corporate headquarters is located in Bothell, Washington, where we currently lease approximately 19,326 square feet of laboratory and office space, which leases expire in August 2027. 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.

Item 3. Legal Proceedings.

From time to time, we are subject to various legal proceedings or claims that arise in the ordinary course of business. The following is a brief description of the more significant legal proceedings in which we have been involved.

Securities Class Actions

Starting in June 2021, putative securities class action lawsuits were filed in the U.S. District Court for the Western District of Washington against us and certain of our current and former members of management and the board of directors. After these lawsuits were consolidated and lead plaintiffs were appointed to represent the putative class, lead plaintiffs filed a consolidated amended complaint on January 7, 2022, which asserted violations of Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 and Sections 11, 12, and 15 of the Securities Act. The consolidated amended complaint alleged that our initial public offering, or IPO, and secondary public offering, or SPO, registration statements and/or other public statements were materially false and misleading because they omitted to state that certain of our former CEO's published doctoral research papers at Washington State University, or WSU, contained allegedly improperly altered images. Lead plaintiffs sought unspecified compensatory damages, as well as equitable and injunctive relief on behalf of themselves and the purported class. On July 29, 2022, the court issued an order granting in part and denying in part the defendant's motion to dismiss. The order dismissed the Section 10(b) and Section 20(a) claims arising under the Exchange Act, dismissed the Section 11 claim arising under the Securities Act as to all defendants other than the Company and our former CEO, dismissed the Section 12(a)(2) claim arising under the Securities Act as to the lead plaintiffs, and dismissed the Section 15 claim arising under the Securities Act against all defendants other than our former CEO. On November 4, 2022, we and our former CEO filed our individual answers to the consolidated amended complaint. In mid-November 2022, the parties began conducting fact discovery.

On March 29, 2024, following a mediation and the parties' agreement in the fourth quarter of 2022 to settle the securities class action for $10 million subject to the court's approval, the court entered an order preliminarily approving a settlement of the securities class action.

On November 1, 2024, following class notice and a final approval hearing, the court entered a final written judgment and order granting final approval of the settlement and closed the case.

As a result of the foregoing, we recorded a legal settlement expense of $10.0 million in operating expenses in the fourth quarter of 2022. An accrued liability of $10.0 million was recorded on the accompanying condensed consolidated balance sheets as of December 31, 2023. Additionally, we recorded an insurance recovery of $1.6 million in operating expenses in the fourth quarter of 2023 and an insurance recovery receivable of $1.6 million on the accompanying condensed consolidated balance sheets as of December 31, 2023. This insurance recovery represents the amount of the settlement covered by our insurers. We and our insurance providers paid the settlement fee during 2024 and no further liability exists following the court granting final approval of the settlement and closing the case in November 2024.

Shareholder Derivative Actions

Starting in April 2022, shareholder derivative actions were filed in the U.S. District Court for the Western District of Washington against certain current and former members of our board of directors. The derivative complaints alleged that our board of directors breached its fiduciary duties by failing to prevent alleged misstatements in our public filings, failing to discover altered images in certain research papers, and failing to take appropriate action. The derivative complaints asserted claims for violations of Section 14(a) of the Exchange Act as well as claims for breach of fiduciary duty, contribution and indemnification, aiding and abetting, and waste of corporate assets.

On May 26, 2022, the court issued an order consolidating the derivative cases and staying them until further order of the court. On March 18, 2024, following a mediation and the parties entering into a stipulation of settlement to settle the consolidated derivative action for certain corporate governance reforms and the payment of a fee and expense award to plaintiffs' counsel, plaintiffs filed an unopposed motion for preliminary approval of a settlement of the derivative action. On July 18, 2024, the court entered an order and judgment granting plaintiffs' motion for final approval of derivative settlement, finding the settlement to be fair, reasonable, and adequate to the settling parties and our shareholders, and dismissing the derivative action with prejudice.

We paid the fee and expense award related to this shareholder derivative action settlement during the third quarter of 2024.

Government Investigation

In November 2022, we received a Civil Investigative Demand from the Civil Division of the Department of Justice, or the Demand. The Demand sought documents and information relating to our relationship with WSU, certain of our grant applications in 2016 and 2019 with the NIH and our receipt of a NIH grant in 2020. We cooperated with the Department of Justice with respect to the Demand.

In September 2024, we reached an agreement in principle (subject to approvals within the Department of Justice and the Office of Inspector General of the U.S. Department of Health and Humans Service) to settle the Department of Justice's claims, including alleged violations of the False Claims Act in connection with the NIH grant applications and our receipt of an NIH grant in connection with one of those applications. This agreement also included the same claims alleged in a confidential, sealed *qui tam* complaint. On December 31, 2024, we entered into a settlement agreement with the Department of Justice, OIG-HHS, and the *qui tam* lawsuit relator in which we agreed to pay approximately $4.1 million.

We recorded a legal expense of $4.1 million based on developments in the third quarter of 2024 and a corresponding accrued liability on the accompanying consolidated balance sheets as of December 31, 2024. We paid the $4.1 million settlement in January 2025.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information for Common Stock

Our common stock began trading on The Nasdaq Global Select Market under the symbol "ATHA" on September 18, 2020. Prior to that date, there was no public trading market for our common stock.

Holders of Record

As of February 20, 2025, there were approximately 41 holders of record of our common stock. Because many of our shares are held by brokers and other institutions on behalf of shareholders, we are unable to estimate the total number of shareholders represented by these record holders.

Dividend Policy

We currently intend to retain all available funds and future earnings to fund the development and growth of our business and we do not anticipate paying any cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities

None.

Stock Performance Graph

As a smaller reporting company, we are not required to provide the information requested by this item pursuant to Item 201(e) of Regulation S-K.

Issuer Repurchases of Equity Securities

None.

Item 6. [Reserved].

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following management's discussion and analysis of financial condition and results of operations in conjunction with our consolidated financial statements and notes thereto included in Part II, Item 8 of this Annual Report on Form 10-K. This discussion and analysis and other parts of this report 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 Annual Report on Form 10-K titled "Risk Factors" and elsewhere in this report. 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 report titled "Special Note Regarding Forward-Looking Statements."

Overview

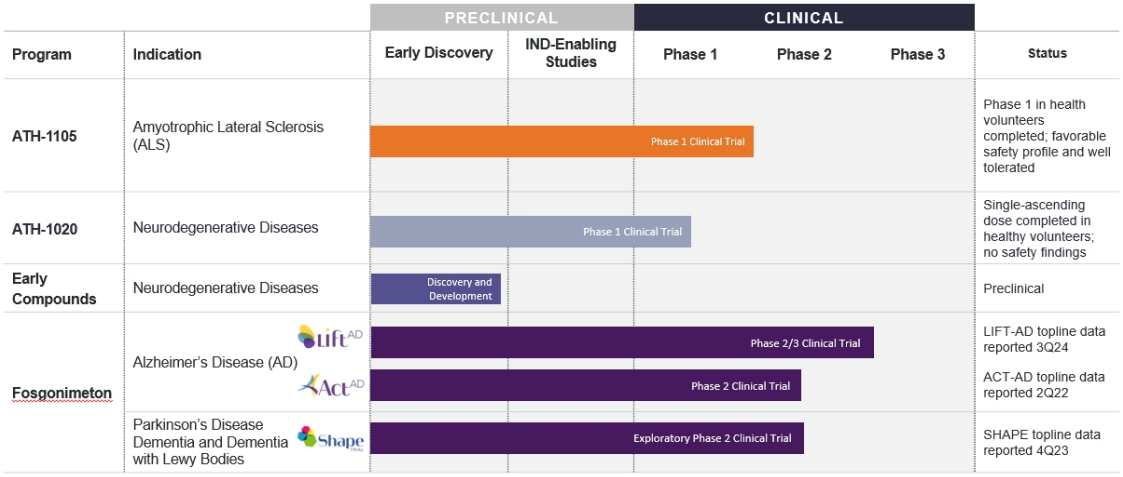
We are a clinical-stage biopharmaceutical company focused on developing small molecules engineered to restore neuronal health and slow neurodegeneration. Our approach is designed to modulate the neurotrophic HGF system, that is critical to normal brain function and may play a key role in maintaining the health and functioning of neuronal networks. We believe that by acting on the neurotrophic HGF system and its multiple downstream signaling pathways, we may be able to enhance the body's natural ability to protect and repair neuronal networks by reducing inflammation, promoting regeneration, and reducing disease-specific protein pathologies, thereby positively impacting the course of disease. We aim to achieve these goals by advancing our pipeline of novel small molecule compounds which are designed to and have exhibited properties in enhancing the neurotrophic HGF system in either the CNS, by crossing the BBB, or the PNS.

Athira is actively reviewing options for partnerships or arrangements that will allow it to realize the potential of its drug candidates. Our lead drug candidate is ATH-1105. ATH-1105 is a novel, orally available, brain-penetrant, next-generation small molecule drug candidate designed to positively modulate the neurotrophic HGF system for potential treatment of neurodegenerative diseases, including amyotrophic lateral sclerosis, or ALS, and Alzheimer's disease, or AD, and Parkinson's disease, or PD. ATH-1105 is currently in development for the potential treatment of ALS. We conducted a first-in-human Phase 1 double-blind, placebo-controlled trial that enrolled 80 healthy volunteers to evaluate single and multiple oral ascending doses of ATH-1105. The study was completed in November 2024 and evaluated the safety and tolerability of ATH-1105 and included measurements of pharmacokinetic outcomes. The results of the Phase 1 trial showed that ATH-1105 demonstrated a favorable safety profile and was well-tolerated in healthy volunteers, supporting continued clinical development.

Our previous lead drug candidate, fosgonimeton, is a small molecule drug candidate designed to positively modulate the neurotrophic HGF system for potential treatment of neurodegenerative diseases. In September 2024, we announced the topline results for LIFT-AD, a randomized, double-blind, placebo-controlled, parallel-group 26-week Phase 2/3 clinical trial with fosgonimeton in mild-to-moderate AD. The primary and key secondary endpoints of the LIFT-AD trial did not reach statistical significance compared with placebo at 26 weeks. Based on these results, we decided to pause further development of fosgonimeton and to shift our focus to the clinical development of ATH-1105.

The following figure illustrates the current development stage of our proprietary drug candidates and early discovery and development programs, of which only ATH-1105 is currently in clinical development, for the potential treatment of ALS. We have also explored the use of our drug candidates in other indications in the CNS and PNS with the goal of improving neuronal health in multiple neurodegenerative diseases. In

addition, our drug discovery efforts have focused on designing and testing new early compounds to enhance the neurotrophic HGF system for a variety of clinical applications.



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 drug products approved for commercial sale, and we have not generated any revenues related to our drug products since inception. Our ability to generate drug product revenue sufficient to achieve profitability, if ever, will depend on the successful development of one or more of our drug 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 processes and drug administration technologies or devices. We do not currently operate our own facilities for manufacturing, storing, or distributing our drug candidates. We utilize third-party contract manufacturing organizations, or CMOs, to manufacture and supply our preclinical and clinical materials during the development of our drug candidates. We believe the synthesis of ATH-1105 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 that may be needed. Our goal is to identify and develop small molecule drug 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 drug products, at least until our resources and operations are at a scale that justifies investment in internal manufacturing capabilities.

Following our receipt of the topline results of LIFT-AD, we made the determination to explore strategic alternatives focused on maximizing stockholder value. As part of that effort, we have paused further development of fosgonimeton while continuing our ongoing development of ATH-1105 and are exploring partnering options. Despite devoting significant effort to identifying and evaluating potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value.

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

To date, we have funded our operations primarily through proceeds from the sale of equity securities, including proceeds from the sale and issuance of common stock in our IPO and in a subsequent follow-on public offering, the sale and issuance of convertible preferred stock, common stock warrants, and convertible notes, and to a lesser extent from grant income and stock option exercises. From inception to December 31, 2024, we have raised aggregate net cash proceeds of approximately $407.4 million primarily from the issuance of our common stock (excluding option exercises), convertible preferred stock, common stock warrants, and convertible notes. We have incurred significant operating losses to date. Our net losses were $96.9 million and $117.7 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $406.1 million and cash, cash equivalents and investments of $51.3 million.

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

- continue to advance ATH-1105 and any other drug candidates through preclinical studies and clinical trials;
- advance our pipeline of drug candidates;
- continue to invest in our drug development programs;
- continue manufacturing activities;
- attract, hire and retain personnel;
- obtain, maintain, expand and protect our intellectual property portfolio;
- operate as a public company;
- maintain our laboratory and office facilities;
- implement and maintain operational, financial and management information systems; and
- seek regulatory approval for any drug candidates that successfully complete clinical trials.

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 drug candidates. Until such time as we can generate significant revenue from drug 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 drug candidates or other operations. Our ability to raise additional funds may be negatively impacted by potential adverse global economic conditions and disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. 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 drug product development programs, commercialization efforts or other operations. Insufficient liquidity may also require us to relinquish rights to drug 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, cash equivalents and investments will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months following the date of this report.

National Institutes of Health Grant

In December 2020, we accepted a grant from the National Institutes of Health, or NIH, to support our ACT-AD Phase 2 clinical trial for fosgonimeton. Under the terms of the agreement and approval received from the NIH, we were awarded an aggregate of $15.2 million, all of which had been received as of December 31, 2024. Grant income recognized during the year ended December 31, 2023 of $0.2 million represented the remaining balance of the total $15.2 million approved grant amount available at the beginning of that year. During the year ended December 31, 2023, we received cash of $1.4 million in connection with the NIH grant. There was no grant income recognized or cash received in connection with the NIH grant during the year ended December 31, 2024. We will not recognize any additional grant income in connection with the NIH grant in the future.

Recent Developments

Process to Evaluate Strategic Alternatives

Following our receipt of the topline results of LIFT-AD, we made the determination to explore strategic alternatives focused on maximizing stockholder value. As part of that effort, we have paused further development of fosgonimeton and concluded our related open label extension clinical trial while continuing our ongoing development of ATH-1105 and are exploring partnering options.

We have engaged Cantor Fitzgerald & Co. to act as an advisor in exploring potential strategic alternatives that may include, but are not limited to, an acquisition, merger or reverse merger, business combination, equity or debt financing, sale of the Company, sale, exclusive license or other disposition of all or a portion of our assets, a return of capital to stockholders, or other transaction. There can be no assurance that these efforts will result in the pursuit of a transaction or that any transaction, if pursued, will be completed on attractive terms, if at all. We have not set a timetable for completion of this evaluation process and do not intend to disclose further developments unless and until it is determined that further disclosure is appropriate or necessary.

Workforce Reduction

On September 15, 2024, we committed to a workforce reduction that resulted in the termination of approximately 70% of our workforce. We took this step to decrease our costs, extend our cash runway, and create a more streamlined organization to support our strategic priorities, including the continued development of ATH-1105. We substantially completed the Restructuring by December 31, 2024. See Note 13 to our consolidated financial statements included elsewhere in this report for additional information.

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 our drug discovery efforts and the development of our drug 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 and other expenses consisting of direct and allocated expenses for rent and depreciation, and lab consumables.

We expense research and development costs as incurred. Non-refundable advance payments for goods and services that will be used over time for research and development are capitalized and recognized as goods are delivered or as the related services are performed. In-licensing fees and other costs to acquire technologies used in research and development that have not yet received regulatory approval and that are not expected to have an alternative future use are expensed when incurred. We track direct costs by

stage of program, clinical or preclinical. However, we do not track indirect costs on a program specific basis because these costs are deployed across multiple programs and, as such, are not separately classified.

As of the date of this report, we cannot reasonably determine the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our drug candidates. Drug candidates in later stages of development generally have higher development costs than those in earlier stages. We expect to continue to incur research and development expenses for the foreseeable future as we continue to engage in research and development activities related to developing our drug candidates, our drug candidates advance into later stages of development, we conduct larger clinical trials, we seek regulatory approvals for any drug candidates that successfully complete clinical trials, we expand or advance our drug product pipeline, we maintain, expand, protect and enforce our intellectual property portfolio, and we incur expenses associated with hiring or retaining personnel to support our research and development efforts. We also expect our research and development expenses to decrease in the near term as a result of our decision to pause further development of fosgonimeton and to shift our focus to the clinical development of ATH-1105.

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

- the impact of our strategic alternative review process and the consummation of any resulting strategic transaction or partnership;
- the number and scope of preclinical and IND-enabling studies;
- the phases of development of our drug candidates;
- the progress and results of our research and development activities;
- per subject trial costs;
- the number of trials required for regulatory approval;
- 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 drug candidates;
- the receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- the hiring and retention of research and development personnel;
- the degree to which we obtain, maintain, defend and enforce our intellectual property rights;
- the impact of health epidemics on timelines and clinical operations, which may lead to increased costs; and
- the extent to which we establish collaborations, 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 drug candidates could significantly change the costs and timing associated with the development of that drug 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, business development 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 to continue to incur general and administrative expenses for the foreseeable future as we maintain our headcount to support our continued research activities and development of our programs. We also anticipate that we will continue to incur 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 expect to incur additional costs in connection with our strategic alternative review process and in the event we consummate any strategic transaction or partnership as a result. We also expect these additional general and administrative expenses to be offset, at least in part, in the near term as a result of the Restructuring and related cost savings.

Insurance Recovery Related to Legal Settlement

Insurance recovery related to legal settlement consists of the settlement of the securities class action litigation and the amount covered by our insurers. For more information see Part I, Item 3 “Legal Proceedings—Securities Class Actions".

Grant Income

Grant income consists of income related to the NIH grant and is recognized as qualifying expenses under the grant agreement are incurred. As of December 31, 2024, we had recognized aggregate grant income of $15.2 million in connection with the NIH grant, equal to the total grant amount approved. We will not recognize additional grant income in connection with the NIH grant in the future.

Other Income, Net

Other income, net consists primarily of interest earned on our cash, cash equivalents and investments and the amortization of premiums and accretion of discounts on our available-for-sale securities. Absent further fundraising, we expect interest earned on our cash, cash equivalents and investments to decrease as we continue to expend our cash balances to fund our ongoing operations.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

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

	Year Ended December 31,			
	2024	2023	Dollar Change	% Change
		(in thousands)		
Operating expenses:				
Research and development	$ 70,682	$ 93,790	$ (23,108)	(25)%
General and administrative	26,093	33,304	(7,211)	(22)
Legal expense	4,127	—	4,127	100
Insurance recovery related to legal settlement	—	(1,628)	1,628	(100)
Total operating expenses	100,902	125,466	(24,564)	(20)
Loss from operations	(100,902)	(125,466)	24,564	(20)
Grant income	—	157	(157)	(100)
Other income, net	3,962	7,637	(3,675)	(48)
Net loss	$ (96,940)	$ (117,672)	$ 20,732	(18)

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,			
	2024	2023	Dollar Change	% Change
		(in thousands)		
Direct costs:				
Fosgonimeton (ATH-1017)	$ 41,510	$ 66,524	$ (25,014)	-37 %
ATH-1105	8,567	—	8,567	100
ATH-1020	495	704	(209)	(30)
Preclinical programs and other direct costs	1,580	6,619	(5,039)	(76)
Total direct costs	52,152	73,847	(21,695)	(28)
Indirect costs:				
Personnel-related costs, including stock-based compensation	16,332	17,955	(1,623)	(9)
Facilities and other costs	2,198	1,988	210	11
Total research and development expenses	$ 70,682	$ 93,790	$ (23,108)	(24)

Research and development expenses decreased by $23.1 million, from $93.8 million for the year ended December 31, 2023 to $70.7 million for the year ended December 31, 2024. The decrease was driven primarily by decreases in fosgonimeton program costs of $25.0 million, preclinical and other direct costs of $5.0 million, personnel-related expenses of $1.6 million, and ATH-1020 program costs of $0.2 million. The decrease in fosgonimeton program costs of $25.0 million was driven by decreases in contract research organization and clinical site visit costs for our Phase 2/3 LIFT-AD clinical trial and the corresponding open-label extension for our Phase 2 ACT-AD and Phase 2/3 LIFT-AD clinical trials of $16.4 million and a decrease in contract manufacturing costs of $9.8 million, partially offset by an increase in program consulting costs of $1.5 million. These decreases were partially offset by an increase in ATH-1105 program costs of $8.6 million associated with the ATH-1105 Phase 1 clinical trial, which commenced in the second quarter of 2024, and to a lesser extent, an increase in facilities and other indirect costs.

General and Administrative Expenses

General and administrative expenses decreased by $7.2 million, from $33.3 million for the year ended December 31, 2023 to $26.1 million for the year ended December 31, 2024. The decrease was primarily due to a decrease in business development expenses of $2.2 million, a decrease in general corporate expenses of $1.4 million, a decrease in professional services expenses of $0.9 million, and a decrease in personnel-related expenses of $0.6 million. Additionally, legal expenses, excluding expenses recognized in connection with the Department of Justice investigation, decreased by $2.4 million.

Legal Expense

In connection with the Department of Justice investigation, we recorded a legal expense of $4.1 million during the year ended December 31, 2024. For more information, see the section of this report titled "Legal Proceedings—Government Investigation".

Insurance Recovery Related to Legal Settlement

In connection with the settlement of the securities class action litigation, we recorded an insurance recovery of $1.6 million for the year ended December 31, 2023, representing the amount of the settlement covered by our insurers. For more information see the section of this report titled “Legal Proceedings—Securities Class Actions".

Grant Income

Grant income recognized during the year ended December 31, 2023 of $0.2 million represented the remaining balance of the total $15.2 million approved grant amount available at the beginning of the year. There was no grant income recognized during the year ended December 31, 2024.

Other Income, Net

Other income, net, decreased by $3.6 million, from $7.6 million for the year ended December 31, 2023 to $4.0 million for the year ended December 31, 2024 due to lower income from accretion of discounts on debt securities purchased below par value and held to maturity and lower interest income earned on our available-for-sale securities. These decreases resulted from lower balances of available-for-sale securities held during the year ended December 31, 2024 compared to the year ended December 31, 2023.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have funded our operations primarily with proceeds from the sale and issuance of common stock, convertible preferred stock, common stock warrants, and convertible notes, and to a lesser extent from grant income and stock option exercises. From our inception through December 31, 2024, we have raised aggregate net cash proceeds of $407.4 million primarily from the issuance of our common stock (excluding option exercises), convertible preferred stock, common stock warrants, and convertible notes.

As of December 31, 2024, we had $51.3 million in cash, cash equivalents and investments and have not generated positive cash flows from operations. 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.

Material Cash and Future Funding Requirements

Our material cash requirements include our operating leases for laboratory and office facilities. As of December 31, 2024, we had lease payment obligations of $1.3 million, with $0.5 million payable within 12 months. For additional information regarding our lease commitments, see Note 7 to our consolidated financial statements included elsewhere in this report. Additionally, we have purchase obligations and open purchase orders that support normal operations and are primarily due in the next 12 months. These purchase obligations and open purchase orders are generally cancellable in full or in part through the contractual provisions. We anticipate that our research and development expenses and our general and administrative expenses will decrease in the near-term as a result of our decision to pause further development of fosgonimeton and to shift our focus to the clinical development of ATH-1105, and our decrease in headcount as a result of the Restructuring.

Based upon our current operating plan, we estimate that our $51.3 million of cash, cash equivalents and investments at December 31, 2024 will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months following the date of this report. However, our resource requirements could materially change depending on the outcome of our ongoing strategic alternative review process, including to the extent we identify and enter into any potential strategic transaction. We will need to raise substantial additional capital to fund the development of our drug candidates. Until such time as we can generate significant revenue from drug 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. For example, in January 2023, we entered into a sales agreement with Cantor Fitzgerald and BTIG to sell shares of our common stock having aggregate sales proceeds of up to $75.0 million, from time to time, through an ATM equity offering program under which Cantor Fitzgerald and BTIG are acting as sales agents. As of the date of this report, we have not sold any securities pursuant to this ATM offering. 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 drug candidates or grant licenses on terms that may not be favorable to us 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 negatively impacted by potential adverse global economic conditions and disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. 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 drug product development

programs, commercialization efforts or other operations. Insufficient liquidity may also require us to relinquish rights to drug 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 drug candidates;
- the number of trials required for regulatory approval;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of other drug candidates that we may pursue;
- our ability to establish and maintain collaborations, 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 drug candidates;
- the costs and timing of future commercialization activities, including drug product manufacturing, marketing, sales and distribution, for any of our drug candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our drug 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;
- the costs related to legal proceedings;
- any expenses needed to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- the costs associated with any expansion of our laboratory and office facilities; and
- the extent to which we acquire or in-license other companies' product candidates and technologies or engage in other strategic transactions.

A change in the outcome of any of these or other factors with respect to the development of any of our drug candidates could significantly change the costs and timing associated with the development of that drug 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,	
	2024	2023
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (97,170)	$ (100,753)
Investing activities	54,830	95,089
Financing activities	194	493
Net decrease in cash, cash equivalents and restricted cash	$ (42,146)	$ (5,171)

Operating Activities

During the year ended December 31, 2024, net cash used in operating activities was $97.2 million. This consisted primarily of a net loss of $96.9 million, partially offset by non-cash charges of $11.7 million and an increase in our net operating assets of $12.0 million. The non-cash charges primarily consisted of stock-based compensation expense, depreciation expense, and amortization of premiums and accretion of discounts on our available-for-sale securities. The increase in our net operating assets was primarily due to a decrease in the accrual for legal settlement expenses related to the securities class action litigation and a net decrease in accounts payable and accrued expenses, partially offset by decreases in prepaid expenses and other current and long-term assets, and the insurance recovery receivable related to the securities class action litigation.

During the year ended December 31, 2023, net cash used in operating activities was $100.8 million. This consisted primarily of a net loss of $117.7 million, partially offset by non-cash charges of $10.4 million and a decrease in our net operating assets of $6.5 million. The non-cash charges primarily consisted of stock-based compensation expense, depreciation expense, and amortization of premiums and accretion of discounts on our available-for-sale securities. The decrease in our net operating assets was primarily due to a decrease in unbilled grant receivable and an increase in accounts payable and accrued expenses, partially offset by the recognition of an insurance recovery receivable related to the securities class action litigation.

Investing Activities

During the year ended December 31, 2024, net cash provided by investing was $54.8 million. This consisted of maturities of available-for-sale securities of $69.0 million, partially offset by purchases of available-for-sale securities of $14.1 million and property and equipment of less than $0.1 million.

During the year ended December 31, 2023, net cash provided by investing was $95.1 million. This consisted of maturities of available-for-sale securities of $123.1 million, partially offset by purchases of available-for-sale securities of $27.7 million and property and equipment of $0.3 million.

Financing Activities

During the year ended December 31, 2024, net cash provided by financing activities was $0.2 million, consisting of proceeds received from participation in the Company's employee stock purchase plan and exercises of stock options.

During the year ended December 31, 2023, net cash provided by financing activities was $0.5 million, consisting of proceeds received from participation in the Company's employee stock purchase plan and exercises of stock options.

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.

Research and Development Costs

Research and development costs, including costs associated with our clinical trials, 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 for stock options 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*. The fair value of each share of common stock is based on the closing price of the Company's common stock on the date of grant, or other relevant determination date, as reported on The Nasdaq Global Select Market.
- *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 were privately held prior to September 2020 and do not yet have sufficient 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 9 to our consolidated financial statements included elsewhere in this report 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 $11.0 million and $10.6 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, there was $9.8 million of total unrecognized stock-based compensation expense related to non-vested stock options which we expect to recognize over a remaining weighted-average period of 1.99 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.

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, 2024, we had $9.5 million of federal NOL carryforwards and $16.5 million of tax credit carryforwards which expire over a period of 7 to 13 years. As of December 31, 2024, we had $196.0 million of such NOLs that do not expire. As of December 31, 2024, we also had state net operating loss carryforwards of $3.9 million, which expire over a period of 17 to 20 years.

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 consolidated financial statements included elsewhere in this report for additional information.

Emerging Growth Company Status

We are an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (1) are no longer an emerging growth company and (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 $1.235 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 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 in which the fifth anniversary of our initial public offering occurred.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide the information requested by this item pursuant to Item 305 of Regulation S-K.

Item 8. Financial Statements and Supplementary Data.

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 consolidated balance sheets of Athira Pharma, Inc. (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, 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. 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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
February 27, 2025

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

	December 31,	
	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	$ 48,438	$ 90,584
Short-term investments	2,837	56,835
Prepaid expenses and other current assets	3,566	5,682
Insurance recovery receivable related to legal settlement (Note 7)	—	1,628
Total current assets	54,841	154,729
Restricted cash	631	631
Property and equipment, net	2,444	3,388
Operating lease right-of-use asset	808	1,049
Other long-term assets	55	448
Total assets	$ 58,779	$ 160,245
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 319	$ 129
Accrued liabilities	12,402	18,343
Accrued legal settlement (Note 7)	—	10,000
Current operating lease liability	414	368
Total current liabilities	13,135	28,840
Operating lease liability, less current portion	803	1,217
Total liabilities	13,938	30,057
Stockholders' equity:		
Common stock, $0.0001 par value; 900,000,000 shares authorized at December 31, 2024 and December 31, 2023, respectively; 39,040,945 and 38,172,603 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	4	4
Additional paid-in capital	450,982	439,739
Accumulated other comprehensive income (loss)	1	(349)
Accumulated deficit	(406,146)	(309,206)
Total stockholders' equity	44,841	130,188
Total liabilities and stockholders' equity	$ 58,779	$ 160,245

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

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

	Year Ended December 31,	
	2024	2023
Operating expenses:		
Research and development	$ 70,682	$ 93,790
General and administrative	26,093	33,304
Legal expense	4,127	—
Insurance recovery related to legal settlement	—	(1,628)
Total operating expenses	100,902	125,466
Loss from operations	(100,902)	(125,466)
Grant income	—	157
Other income, net	3,962	7,637
Net loss	$ (96,940)	$ (117,672)
Unrealized gain on available-for-sale securities	350	1,607
Comprehensive loss attributable to common stockholders	$ (96,590)	$ (116,065)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.52)	$ (3.09)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	38,480,875	38,020,182

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

Athira Pharma, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of January 1, 2023	37,877,387	$ 4	$ 428,623	$ (1,956)	$ (191,534)	$ 235,137
Issuance of common stock upon exercise of common stock options	128,534	—	167	—	—	167
Issuance of common stock under employee stock purchase plan	166,682	—	326	—	—	326
Stock-based compensation	—	—	10,623	—	—	10,623
Unrealized gain on available-for-sale securities	—	—	—	1,607	—	1,607
Net loss	—	—	—	—	(117,672)	(117,672)
Balance as of December 31, 2023	38,172,603	$ 4	$ 439,739	$ (349)	$ (309,206)	$ 130,188
Issuance of common stock upon exercise of common stock options	75,660	—	12	—	—	12
Issuance of common stock upon vesting of restricted stock units	620,668	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	172,014	—	182	—	—	182
Stock-based compensation	—	—	11,049	—	—	11,049
Unrealized gain on available-for-sale securities	—	—	—	350	—	350
Net loss	—	—	—	—	(96,940)	(96,940)
Balance as of December 31, 2024	39,040,945	$ 4	$ 450,982	$ 1	$ (406,146)	$ 44,841

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

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

	Year Ended December 31,	
	2024	2023
Operating activities		
Net loss	$ (96,940)	$ (117,672)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	11,049	10,623
Depreciation expense	970	969
Non-cash lease expense	241	214
Amortization of premiums and accretion of discounts on available-for-sale securities, net	(515)	(1,414)
Loss on disposal of equipment	7	—
Changes in operating assets and liabilities:		
Unbilled grant receivable	—	1,227
Prepaid expenses and other current and long-term assets, net	2,509	(113)
Insurance recovery receivable related to legal settlement	1,628	(1,628)
Accounts payable and accrued liabilities	(5,751)	7,367
Accrued legal settlement	(10,000)	—
Operating lease liability	(368)	(326)
Net cash used in operating activities	(97,170)	(100,753)
Investing activities		
Purchases of available-for-sale securities	(14,134)	(27,671)
Maturities of available-for-sale securities	68,997	123,064
Purchases of property and equipment	(33)	(304)
Net cash provided by investing activities	54,830	95,089
Financing activities		
Proceeds from exercise of common stock options and issuance of common stock under employee stock purchase plan	194	493
Net cash provided by financing activities	194	493
Net decrease in cash, cash equivalents and restricted cash	(42,146)	(5,171)
Cash, cash equivalents and restricted cash, beginning of period	91,215	96,386
Cash, cash equivalents and restricted cash, end of period	$ 49,069	$ 91,215

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

ATHIRA PHARMA, INC.
Notes to Consolidated Financial Statements

1. Description of Business

Organization

Athira Pharma, Inc., or 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 Bothell, Washington. The Company is a clinical-stage biopharmaceutical company focused on developing small molecules to restore neuronal health and slow neurodegeneration.

Liquidity and Capital Resources

Since the Company's inception, it has funded its operations primarily with proceeds from the sale and issuance of common stock, convertible preferred stock, common stock warrants, and convertible notes, and to a lesser extent from grant income and stock option exercises. From the Company's inception through December 31, 2024, it has raised aggregate net cash proceeds of $407.4 million primarily from the issuance of its common stock (excluding option exercises), convertible preferred stock, common stock warrants, and convertible notes.

As of December 31, 2024, the Company had cash, cash equivalents and investments of $51.3 million. The Company's net loss for the year ended December 31, 2024 was $96.9 million and cash used in operations for the year ended December 31, 2024 was $97.2 million. Since the Company's inception, it has devoted substantially all of its resources to its research and development efforts such as small molecule compound discovery, nonclinical studies and clinical trials, as well as manufacturing activities, establishing and maintaining the Company's intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations.

Based upon the Company's current operating plan, it estimates that its $51.3 million of cash, cash equivalents and investments at December 31, 2024 will be sufficient to fund its operating expenses and capital expenditure requirements through at least the next 12 months following the date of the Company's Annual Report on Form 10-K. Historically, the Company has incurred net losses from continuing operations and negative operating cash flows. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs; therefore, the Company expects it will need to continue to raise additional capital to accomplish its operating plan. The Company has a sales agreement in place with Cantor Fitzgerald & Co., or Cantor Fitzgerald, and BTIG, LLC, or BTIG, for an "at the market" equity offering facility through which it may offer and sell shares of its common stock equaling an aggregate amount up to $75.0 million, subject to applicable limitations on sales pursuant to SEC rules and regulations pertaining to the Company's Registration Statement on Form S-3. The Company has not sold any securities pursuant to this ATM offering. Should it be determined to be strategically advantageous, the Company could pursue public and private offerings of its equity securities similar to those the Company has previously completed, debt financings, or other strategic transactions, which could include income from collaboration, licensing or similar arrangements with third parties, or receiving research contributions, or grants.

2. Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles, or U.S. GAAP. The consolidated financial statements include the operations of Athira Pharma, Inc., and its wholly owned Australian subsidiary. All intercompany balances and transactions have been eliminated upon consolidation.

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.

Restricted Cash

Restricted cash consists of collateral pledged in connection with the Company's corporate credit cards. The table below reconciles the balances of cash and cash equivalents and restricted cash reported on the consolidated balance sheets to the balances of cash, cash equivalents and restricted cash reported on the consolidated statements of cash flows.

	December 31,	
	2024	2023
Cash and cash equivalents	$ 48,438	$ 90,584
Restricted cash	631	631
Cash, cash equivalents and restricted cash	$ 49,069	$ 91,215

Short-term Investments

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

The Company periodically evaluates whether declines in fair values of its investments below their book value are due to expected credit losses, as well as the Company's ability and intent to hold the investment until a forecasted recovery occurs. Expected credit losses are recorded as an allowance through other income, 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.

Property and Equipment

Property and equipment consist of computer equipment, computer software, laboratory equipment, leasehold improvements and furniture and office equipment. Property and equipment, excluding leasehold improvements, are recorded at cost and depreciation is recognized using the straight-line method based on estimated useful life, generally three to five years. Leasehold improvements are amortized over the

shorter of their useful life or the remaining lease term. Maintenance and repairs are charged to expense as incurred, and costs of improvements are capitalized.

The Company reviews long-lived assets for impairment whenever events or circumstances indicate the carrying amount of an asset group may not be recoverable. Should an impairment exist, the impairment loss would be measured based on the excess of the asset's carrying amount over its fair value. Gains and losses from asset disposals and impairment losses are classified within the consolidated statements of operations and comprehensive loss in accordance with the use of the asset. There were no impairment losses in the years ended December 31, 2024 and 2023 as there have been no events warranting an impairment analysis.

Fair Value Measurements

The carrying amounts of certain financial instruments, including cash, cash equivalents, restricted cash, investments, accounts payable and accrued expenses approximate their fair values due to the short-term nature of those amounts.

Grant Income

In December 2020, the Company accepted a grant from the National Institute on Aging, or the NIA, of the National Institutes of Health, or the NIH, to support its ACT-AD Phase 2 clinical trial for fosgonimeton (then-named ATH-1017), the Company's lead therapeutic candidate being developed for the treatment of individuals with mild-to-moderate Alzheimer's disease. The Company recognizes income related to the NIH grant in the accompanying consolidated statements of operations and comprehensive loss as qualifying expenses under the grant agreement are incurred. As of December 31, 2024, the Company has recognized aggregate grant income of $15.2 million in connection with the NIH grant, equal to the total grant amount approved. The Company will not recognize any additional grant income in connection with the NIH grant in the future.

During the year ended December 31, 2023, the Company recognized grant income of $0.2 million, and received cash of $1.4 million, in connection with the NIH grant. There was no grant income recognized or cash received in connection with the NIH grant during the year ended December 31, 2024.

Research and Development Expenses

Research and development expenses consist primarily of direct and indirect costs incurred for research activities, including development of the pipeline from the Company's drug discovery efforts and the development of its drug 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 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. The Company estimates the period over which such services will be performed and the level of effort to be expended in each period. If actual timing of performance or the level of effort varies from the estimate, the Company adjusts the amounts recorded accordingly. The Company has not experienced any material differences between accrued or prepaid costs and actual costs since inception.

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.

Leases

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

The Company's leases contain options to extend the leases; lease terms are adjusted for these options only when it is reasonably certain the Company will exercise these options. The Company's lease agreements do not contain residual value guarantees or covenants.

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

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

Stock-based Compensation

The Company measures compensation expense for all stock-based payments to employees, officers and directors based on the estimated fair value of the award at the grant date. For stock options, the Company estimates the grant date fair value of each option award using the Black-Scholes option-pricing model. The grant date fair value of restricted stock units is based upon the fair market value of the Company's common stock based on its closing price as reported on the date of grant on the Nasdaq Global Select Market. 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 and restricted stock unit grants subject to performance-based milestone vesting over the remaining implicit 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.

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 Attributable to Common Stockholders

Comprehensive loss attributable to common stockholders consists of net loss and other gains and losses affecting stockholders' equity that, under U.S. GAAP, are excluded from net loss. The Company's comprehensive loss attributable to common stockholders is comprised of net loss and unrealized gains and losses on available-for-sale securities.

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.

Foreign Currency Transaction Remeasurement Adjustments

Monetary assets and liabilities denominated in foreign currencies were translated into U.S. dollars, the reporting currency, at the exchange rate prevailing at the balance sheet date. Income and expenses denominated in foreign currencies were translated into U.S. dollars at the average exchange rate for the period and the transaction remeasurement adjustments are reported within other income, net in the consolidated statement of operations and comprehensive loss. The functional currency of the Company's Australian subsidiary is the U.S. dollar.

Corporate Restructuring

On September 15, 2024, the Company committed to a workforce reduction that resulted in the termination of approximately 70% of the Company's workforce, or the Restructuring. In connection with the Restructuring, the Company incurred costs of $2.9 million, consisting primarily of cash severance costs and

termination benefits, which the Company recognized during the year ended December 31, 2024. The Company substantially completed the Restructuring by December 31, 2024.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or 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 (1) no longer an emerging growth company and (2) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act, unless early adoption is permitted. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2023-07, Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures to improve reportable segment disclosure requirements through enhanced disclosures about significant segment expenses on an interim and annual basis. All disclosure requirements of ASU 2023-07 are required for entities with a single reportable segment. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods for the fiscal years beginning after December 15, 2024, and should be applied on a retrospective basis to all periods presented. Early adoption is permitted. The Company adopted the guidance in the fiscal year beginning January 1, 2024, including the additional required disclosures in Note 6.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740) - Improvements to Income Tax Disclosures. The ASU requires that an entity disclose specific categories in the effective tax rate reconciliation as well as provide additional information for reconciling items that meet a quantitative threshold. Further, the ASU requires certain disclosures of state versus federal income tax expense and taxes paid. The amendments in this ASU are required to be adopted for fiscal years beginning after December 15, 2024. Early adoption is permitted and the amendments should be applied on a prospective basis. The Company does not expect the adoption of this new guidance to have a material impact on its consolidated financial statements and is currently evaluating the effect of adopting the ASU on its disclosures.

3. Fair Value

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

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

Level 2—Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly.

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

The determination of a financial instrument's level within the fair value hierarchy is based on an assessment of the lowest level of any input that is significant to the fair value measurement. The Company considers observable data to be market data, which is readily available, regularly distributed or updated,

reliable and verifiable, not proprietary, and provided by independent sources that are actively involved in the relevant market.

The following tables reflect the Company's financial asset balances measured at fair value on a recurring basis (in thousands):

	December 31, 2024				
	Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:					
Money market fund	1	$ 30	$ —	$ —	$ 30
U.S. government debt and agency securities	2	$ 10,297	$ 2	$ —	$ 10,299
Commercial paper	2	19,394	—	(1)	19,393
Total cash equivalents		$ 29,721	$ 2	$ (1)	$ 29,722
Short-term investments:					
Commercial paper	2	1,445	—	—	1,445
U.S. government debt and agency securities	2	1,392	—	—	1,392
Total short-term investments		$ 2,837	$ —	$ —	$ 2,837

	December 31, 2023				
	Level	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:					
Money market fund	1	$ 63	$ —	$ —	$ 63
Commercial paper	2	59,227	—	(30)	59,197
Total cash equivalents		$ 59,290	$ —	$ (30)	$ 59,260
Short-term investments:					
Commercial paper	2	6,431	—	(4)	6,427
U.S. government debt and agency securities	2	50,723	—	(315)	50,408
Total short-term investments		$ 57,154	$ —	$ (319)	$ 56,835

All the commercial paper and U.S. government debt and agency securities designated as short-term investments have an effective maturity date that is equal to or less than one year from the respective balance sheet date.

4. Property and Equipment, Net

Property and equipment consisted of the following (in thousands):

	December 31,	
	2024	2023
Lab equipment	$ 705	$ 688
Office furniture, fixtures, and computer equipment	712	712
Leasehold improvement	4,322	4,322
Property and equipment, at cost	5,739	5,722
Less: accumulated depreciation	(3,295)	(2,334)
Property and equipment, net	$ 2,444	$ 3,388

Depreciation expense was $970,000 and $969,000 for the years ended December 31, 2024 and 2023, respectively.

5. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2024	2023
Research and development	$ 3,424	$ 11,916
Employee compensation and benefits	2,990	4,545
Legal expense	4,127	—
Professional services and other	1,861	1,882
Total accrued liabilities	$ 12,402	$ 18,343

6. Segment Reporting

The Company operates as a single operating segment, which is the business of developing and commercializing therapeutics. The Company's chief operating decision maker, or CODM, its chief executive officer, reviews financial information on an aggregate basis for the purpose of allocating resources and assessing performance. When deciding how to allocate resources, the CODM reviews the financial results of the Company's drug candidate programs. The measure of segment assets is reported on the consolidated balance sheet as total assets.

The table below is a summary of the segment profit or loss, including significant segment expenses (in thousands):

	Year Ended December 31,	
	2024	2023
Research and development expenses:		
Fosgonimeton (ATH-1017)	$ 41,510	$ 66,524
ATH-1105	8,567	$ —
ATH-1020	495	704
Preclinical programs and other costs	3,390	8,219
Personnel-related costs, excluding stock-based compensation	12,289	13,952
Total research and development expenses	66,251	89,399
General and administrative expenses	22,631	24,475
Other segment expenses[(a)]	12,020	11,592
Total operating expenses	100,902	125,466
Loss from operations	(100,902)	(125,466)
Grant income	—	157
Other income, net	3,962	7,637
Net loss	$ (96,940)	$ (117,672)

[(a)]Other segment expenses includes stock-based compensation and depreciation expenses.

7. Commitments and Contingencies

Legal Proceedings

From time to time, the Company is subject to various legal proceedings or claims that arise in the ordinary course of business. The Company accrues a liability when the Company's management believes that it is both probable that a liability has been incurred and the amount of loss can be reasonably estimated. The following is a brief description of the more significant legal proceedings.

Securities Class Actions

Starting in June 2021, putative securities class action lawsuits were filed in the U.S. District Court for the Western District of Washington against the Company and certain of its current and former members of management and the board of directors. After these lawsuits were consolidated and lead plaintiffs were appointed to represent the putative class, lead plaintiffs filed a consolidated amended complaint on January 7, 2022, which asserted violations of Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 and Sections 11, 12, and 15 of the Securities Act. The consolidated amended complaint alleged that the IPO and SPO registration statements and/or other public statements were materially false and misleading because they omitted to state that certain of the Company's former CEO's published doctoral research papers at WSU contained allegedly improperly altered images. Lead plaintiffs sought unspecified compensatory damages, as well as equitable and injunctive relief on behalf of themselves and the purported class. On July 29, 2022, the court issued an order granting in part and denying in part the defendants' motion to dismiss. The order dismissed the Section 10(b) and Section 20(a) claims arising under the Exchange Act, dismissed the Section 11 claim arising under the Securities Act as to all defendants other than the Company and its former CEO, dismissed the Section 12(a)(2) claim arising under the Securities Act as to the lead plaintiffs, and dismissed the Section 15 claim arising under the Securities Act against all defendants other than the Company's former CEO.

On November 4, 2022, the Company and its former CEO filed their individual answers to the consolidated amended complaint. In mid-November 2022, the parties began conducting fact discovery.

On March 29, 2024, following a mediation and the parties' agreement in the fourth quarter of 2022 to settle the securities class action for $10 million subject to the court's approval, the court entered an order preliminarily approving a settlement of the securities class action.

On November 1, 2024, following class notice and a final approval hearing, the court entered a final written judgment and order granting final approval of the settlement and closed the case.

As a result of the foregoing, the Company recorded a legal settlement expense of $10.0 million in operating expenses in the fourth quarter of 2022. An accrued liability of $10.0 million was recorded on the accompanying condensed consolidated balance sheets as of December 31, 2023. Additionally, the Company recorded an insurance recovery of $1.6 million in operating expenses in the fourth quarter of 2023 and an insurance recovery receivable of $1.6 million on the accompanying condensed consolidated balance sheets as of December 31, 2023. This insurance recovery represents the amount of the settlement covered by the Company's insurers. The Company and its insurance providers paid the settlement fee during 2024 and no further liability exists following the court granting final approval of the settlement and closing the case in November 2024.

Shareholder Derivative Actions

Starting in April 2022, shareholder derivative actions were filed in the U.S. District Court for the Western District of Washington against certain current and former members of the Company's board of directors. The derivative complaints alleged that the Company's board of directors breached its fiduciary duties by failing to prevent alleged misstatements in the Company's public filings, failing to discover altered images in certain research papers, and failing to take appropriate action. The derivative complaints asserted claims for violations of Section 14(a) of the Exchange Act as well as claims for breach of fiduciary duty, contribution and indemnification, aiding and abetting, and waste of corporate assets.

On May 26, 2022, the court issued an order consolidating the derivative cases and staying them until further order of the court. On March 18, 2024, following a mediation and the parties entering into a stipulation of settlement to settle the consolidated derivative action for certain corporate governance reforms and the payment of a fee and expense award to plaintiffs' counsel, plaintiffs filed an unopposed motion for preliminary approval of a settlement of the derivative action. On July 18, 2024, the court entered an order and judgment granting plaintiffs' motion for final approval of derivative settlement, finding the

settlement to be fair, reasonable, and adequate to the settling parties and the Company's shareholders, and dismissing the derivative action with prejudice.

The Company paid the fee and expense award related to this shareholder derivative action settlement during the third quarter of 2024.

Government Investigation

In November 2022, the Company received a Civil Investigative Demand from the Civil Division of the Department of Justice, or the Demand. The Demand sought documents and information relating to the Company's relationship with WSU, certain of its grant applications in 2016 and 2019 with the NIH, and the Company's receipt of an NIH grant in 2020. The Company cooperated with the Department of Justice with respect to the Demand.

In September 2024, the Company reached an agreement in principle (subject to approvals within the Department of Justice and the Office of Inspector General of the U.S. Department of Health and Humans Service) to settle the Department of Justice's claims, including alleged violations of the False Claims Act in connection with the NIH grant applications and the Company's receipt of an NIH grant in connection with one of those applications. This agreement also included the same claims alleged in a confidential, sealed *qui tam* complaint. On December 31, 2024, the Company entered into a settlement agreement with the Department of Justice, OIG-HHS, and the *qui tam* lawsuit relator in which the Company agreed to pay approximately $4.1 million.

The Company recorded a legal expense of $4.1 million based on developments in the third quarter of 2024 and a corresponding accrued liability on the accompanying consolidated balance sheets as of December 31, 2024. The Company paid the $4.1 million settlement in January 2025.

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. To date the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company enters 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.

Operating Leases

The Company has operating leases for laboratory and office facilities in Bothell, Washington that expire in August 2027. The initial terms of the leases range from 6.3 to 7 years and the Company has options to extend the leases for an additional five years that it is not reasonably certain to exercise. As of December 31, 2024, the Company was not party to any finance leases.

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

	December 31, 2024
2025	494
2026	509
Thereafter	346
Total undiscounted lease payments	1,349
Present value adjustment for minimum lease commitments	(132)
Net lease liability	$ 1,217

The weighted average remaining lease term and the weighted average discount rate used to determine the operating lease liability were as follows:

	December 31, 2024
Weighted average remaining lease term (years)	2.7
Weighted average discount rate	8.1 %

Operating lease expense was $353,000 and $353,000 for the years ended December 31, 2024 and 2023, respectively. Separately, variable lease expense was $149,000 and $186,000 for operating leases during the years ended December 31, 2024 and 2023, respectively.

8. 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 Company's 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:

	December 31,	
	2024	2023
Shares issuable upon the exercise of outstanding common stock options and the vesting of outstanding common restricted stock units granted	10,234,971	7,130,956
Shares available for future grant under the 2020 Equity Incentive Plan	1,666,381	3,158,094
Shares available for future grant under the Employee Stock Purchase Plan	1,338,444	1,128,732
Shares available for future grant under the 2024 Inducement Equity Incentive Plan	350,000	—
Total	13,589,796	11,417,782

The Company's 2020 Equity Incentive Plan, or the 2020 Plan, provides for annual increases in the number of shares that may be issued under the 2020 Plan on January 1, 2021 and each subsequent January 1, thereafter, by a number of shares equal to the least of (1) 3,230,000 shares, (2) 5% of the

number of shares of common stock issued and outstanding on the immediately preceding December 31, and (3) an amount determined by the Company's board of directors.

The Company's 2020 Employee Stock Purchase Plan, or the ESPP, provides for annual increases in the number of shares that may be issued under the ESPP on January 1, 2021 and each subsequent January 1, thereafter, by a number of shares equal to the least of (1) 646,000 shares, (2) 1% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, and (3) an amount determined by the Company's board of directors.

Effective January 1, 2024, the Company's 2020 Plan and ESPP reserves increased by 1,908,630 shares and 381,726 shares, respectively.

In February 2024, the board of directors adopted the Athira Pharma, Inc. 2024 Inducement Equity Incentive Plan, or the 2024 Inducement Plan, and, subject to the adjustment provisions of the 2024 Inducement Plan, reserved 750,000 shares of the Company's common stock for issuance pursuant to equity awards granted under the 2024 Inducement Plan.

Effective January 1, 2025, the Company's 2020 Plan and ESPP reserves increased by 1,952,047 shares and 390,409 shares, respectively.

9. Stock-based Compensation

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

	Year Ended December 31,	
	2024	2023
Research and development	$ 4,043	$ 4,003
General and administrative	7,006	6,620
Total stock-based compensation expense	$ 11,049	$ 10,623

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 fair value of each share of common stock is based on the closing price of the Company's common stock on the date of grant, or other relevant determination date, as reported on The Nasdaq Global Select Market.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.
- *Expected Volatility*—Because the Company was previously privately held and did not have any trading history for its common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded life sciences companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on the similar size, stage in life cycle or area of specialty. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.
- *Expected Term*—The expected term represents the period that the stock-based awards are expected to be outstanding and is determined using the simplified method (based on the midpoint between the vesting date and the end of the contractual term) as the Company has limited history of relevant stock option exercise activity.

- *Expected Dividend Yield*—The Company has never paid dividends on its common stock and has no plans to pay dividends going forward. Therefore, it used an expected dividend yield of zero.

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

	Year Ended December 31,	
	2024	2023
Risk-free interest rate	4.13 %	3.54 %
Expected volatility	97.21 %	99.18 %
Expected term (in years)	5.88	5.84
Expected dividend yield	—	—

The grant date fair value of restricted stock units is based upon the fair market value of the Company's common stock based on its closing price as reported on the date of grant on the Nasdaq Global Select Market.

The fair value of options granted during the years ended December 31, 2024 and 2023 was $10.6 million and $9.8 million, respectively. The fair value of restricted stock units granted during the year ended December 31, 2024 and 2023 was $0.4 million and $0.5 million, respectively.

Stock Option Activity

Changes in shares available for grant under the 2020 Plan and the 2024 Inducement Plan during the year ended December 31, 2024 were as follows:

	Shares Available for Grant
Shares available for grant at December 31, 2023	3,158,094
2020 Plan reserve increase on January 1, 2024	1,908,630
Shares reserved upon adoption of the 2024 Inducement Plan	750,000
Options and restricted stock units granted	(5,986,613)
Options and restricted stock units forfeited, cancelled, or expired	2,186,270
Shares available for grant at December 31, 2024	2,016,381

A summary of stock option activity under the 2020 Plan and the 2024 Inducement Plan for the year ended December 31, 2024 was as follows:

	Shares	Weighted-Average Exercise price per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2023	6,820,869	$ 7.97	8.24	$ 387
Granted	5,052,871	2.64		
Exercised	(75,660)	0.16		
Forfeited/expired	(2,185,770)	4.21		
Balance at December 31, 2024	9,612,310	$ 6.08	8.08	$ 130
Expected to vest	4,055,037	$ 3.79	8.82	$ 87
Options exercisable	5,557,273	$ 7.75	7.53	$ 43

The total fair value of options granted that vested during the years ended December 31, 2024 and 2023 was $11.0 million and $9.8 million, respectively.

The aggregate intrinsic value in the table above is calculated as the difference between the exercise price of the underlying options and the estimated fair value of the Company's common stock underlying all options that were in-the-money at December 31, 2024. The aggregate intrinsic value of options exercised was $0.2 million and $0.2 million during the year ended December 31, 2024 and 2023, respectively, determined as of the date of option exercise. As of December 31, 2024, there was $9.8 million of total unrecognized compensation cost related to non-vested stock options. The Company expects to recognize this cost over a remaining weighted-average period of 1.99 years. The Company utilizes newly issued shares to satisfy option exercises.

Stock options outstanding and exercisable under the 2020 Plan and the 2024 Inducement Plan consisted of the following at December 31, 2024:

Exercise Price ($)	Options Outstanding	Options Exercisable
0.43 to 0.71	964,067	310,581
1.04 to 4.22	5,771,807	2,834,921
8.93 to 19.94	2,528,788	2,136,223
20.55 to 29.41	347,648	275,548
Total	9,612,310	5,557,273

Restricted Stock Unit Activity

A summary of restricted stock unit, or RSU, activity for the year ended December 31, 2024 is as follows:

	Share Equivalent	Weighted-Average Grant Date Fair Value
Non-vested at December 31, 2023	310,087	$ 11.44
Granted	933,742	0.46
Cancelled	(500)	2.51
Vested	(620,668)	5.94
Non-vested at December 31, 2024	622,661	$ 0.46

As of December 31, 2024, there was $0.2 million of total unrecognized compensation cost related to non-vested RSUs. The Company expects to recognize this cost over a remaining weighted-average period of 0.77 years.

Employee Stock Purchase Plan

Under the ESPP, eligible employees can authorize payroll deductions for amounts up to the lesser of 15% of their qualifying wages or the statutory limit under the U.S. Internal Revenue Code. The ESPP provides for offering periods of six months in duration with one purchase period per offering period beginning May 18 and November 18 of each year. Participants in an offering period will be granted the right to purchase shares of our common stock at a price per share that is 85% of the lesser of the fair market value of the shares at (1) the first day of the offering period or (2) the end of each purchase period within the offering period. A maximum of 10,000 shares of common stock may be purchased by each participant at the purchase date during the offering period. The fair market value of the ESPP options granted is determined using the Black-Scholes model and is amortized on a straight-line basis. Stock-based

compensation expense recognized during the years ended December 31, 2024 and 2023 associated with the ESPP was $0.1 million and $0.1 million, respectively. During the year ended December 31, 2024, the Company issued 172,014 shares of common stock to employees under the ESPP.

10. Income Taxes

Components of Income and Income Tax

The Company did not record a provision (benefit) for income taxes for the years ended December 31, 2024 and 2023. Net loss is attributable to the following tax jurisdictions (in thousands):

	Year Ended December 31,	
	2024	2023
United States	$ (96,910)	$ (117,440)
Foreign	(30)	(232)
Net Loss	$ (96,940)	$ (117,672)

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,	
	2024	2023
Federal statutory income tax rate	21.0 %	21.0 %
State taxes	—	—
Stock-based compensation	(1.8)	(1.1)
Non-deductible expenses and others	(0.9)	(0.1)
Tax credits	3.1	4.2
Change in valuation allowance	(21.4)	(24.0)
Effective income tax rate	— %	— %

Deferred Tax Assets and Liabilities

The components of the Company's deferred tax assets and liabilities were as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 43,414	$ 31,342
Research and development tax credit carryforwards	12,362	9,327
Accrued liabilities	538	2,828
Stock-based compensation	2,867	2,564
Operating lease liability	256	333
Other	258	180
Capitalized research and development	32,540	25,182
Total deferred tax assets	92,235	71,756
Deferred tax liabilities:		
Right of use asset	(170)	(221)
Prepaid expenses and other	(82)	(75)
Investments	(34)	(214)
Total deferred tax liabilities	(286)	(510)
Less valuation allowance	(91,949)	(71,246)
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, 2024, 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 $20.7 million and $28.3 million during 2024 and 2023, respectively.

At December 31, 2024, the Company has federal net operating loss and tax credit carryforwards of $9.5 million and $16.5 million, respectively, which expire over a period of 7 to 13 years. Net operating loss carryforwards of $196.0 million were generated after 2017, and therefore do not expire. As of December 31, 2024, the Company also had state net operating loss carryforwards of $3.9 million, which expire over a period of 17 to 20 years.

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 for uncertain tax positions were as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Beginning balance	$ 3,109	$ 1,406
Additions for tax positions taken in prior years	—	182
Additions for tax positions taken in the current year	1,012	1,521
Ending balance	$ 4,121	$ 3,109

If the unrecognized tax benefits for uncertain tax positions as of December 31, 2024 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 consolidated financial statements. At December 31, 2024, 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.

11. 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 made matching contributions of $0.5 million and $0.5 million during the years ended December 31, 2024 and 2023, respectively.

12. Net Loss Per Share Attributable to Common Stockholders

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

	Year Ended December 31,	
	2024	2023
Stock options to purchase common stock	9,612,310	6,820,869
Non-vested Restricted Stock Units	622,661	310,087
Employee stock purchase plan	8,507	3,495
Total	10,243,478	7,134,451

13. Corporate Restructuring

The Company currently estimates that it will incur costs of approximately $2.9 million for termination benefits relating to the Restructuring, substantially all of which the Company recognized during the year ended December 31, 2024.

The Company expensed the following costs associated with the termination benefit payments resulting from the Restructuring (in thousands):

	Year Ended December 31, 2024
Research and development expense	1,495
General and administrative expense	1,392
Total severance expense	2,887

As of December 31, 2024, the accrued liability balance associated with the Restructuring is $0.4 million and is included in the accrued expenses line of the accompanying consolidated balance sheet. Cash paid during the year ended December 31, 2024 associated with the termination benefits was $2.5 million.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures

Our disclosure controls and procedures are designed to ensure that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation and supervision of our chief executive officer and our principal financial and accounting officer, have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Based on such evaluation, our chief executive officer and principal financial and accounting officer have concluded that as of such date, our disclosure controls and procedures were, in design and operation, effective at a reasonable assurance level.

Management's annual report on internal control over financial reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f) and Rule 15d-15(f). Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2024 based on the criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. As a result of that assessment, our management has concluded that our internal control over financial reporting was effective as of December 31, 2024.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on our internal control over financial reporting due to an exemption established by the JOBS Act for emerging growth companies.

Changes in Internal Control

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Annual Report on Form 10-K that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on the Effectiveness of Controls

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, in designing and evaluating the disclosure controls and procedures, management recognizes that any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurance of achieving the desired control objectives. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

Item 9B. Other Information.

During our last fiscal quarter, no director or officer, as defined in Rule 16a-1 (f) of the Exchange Act, adopted or terminated a “Rule 10b5-1 trading arrangement” or any “non-Rule 10b5-1 trading arrangement,” each as defined in Item 408 of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

We maintain a Code of Business Conduct and Ethics that incorporates our code of business conduct and ethics applicable to all employees, including all directors and executive officers. Our Code of Business Conduct and Ethics is published on our Investors website at https://investors.athira.com/ under "Governance." We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendments to, or waiver from, a provision of our Code of Business Conduct and Ethics by posting such information on the website address and location specified above.

We have an Insider Trading Policy that governs the purchase, sale, and other dispositions of our securities by our directors, officers and employees, and the Company itself, that we believe are reasonably designed to promote compliance with insider trading laws, rules and regulations and the listing standards of Nasdaq. A copy of our Insider Trading Policy is filed with this Annual Report on Form 10-K as Exhibit 19.1.

The remaining information required by this Item 10 of Form 10-K will be included in our definitive proxy statement to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2024 in connection with the solicitation of proxies for our 2025 Annual Meeting of Stockholders, or 2025 Proxy Statement, and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item 11 of Form 10-K will be included in our 2025 Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 of Form 10-K, including with respect to our equity compensation plans, will be included in our 2025 Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 of Form 10-K will be included in our 2025 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 of Form 10-K will be included in our 2025 Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) List the following documents filed as a part of the report:

(1) All financial statements;

See Index to Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

All financial statement schedules have been omitted because the required information was not applicable or was not present in amounts sufficient to require submission of the schedules, or because the information required is included in the financial statements or the accompanying notes.

(3) Exhibits

The exhibits listed in the following Index to Exhibits are filed, furnished or incorporated by reference as part of this Annual Report on Form 10-K.

Index to Exhibits

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Company	10-Q	001-39503	3.1	November 12, 2020
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company dated May 23, 2024	8-K	001-39503	3.1	May 29, 2024
3.3	Amended and Restated Bylaws of the Company	8-K	001-39503	3.1	November 18, 2022
4.1	Specimen Common Stock Certificate of the Registrant	S-1/A	333-248428	4.1	September 14, 2020
4.2	Description of Capital Stock				
10.1**	Form of Director and Executive Officer Indemnification Agreement	S-1	333-248428	10.1	August 26, 2020
10.2**	2014 Equity Incentive Plan, as amended	S-1/A	333-248428	10.2	September 9, 2020
10.3**	2020 Equity Incentive Plan	S-1/A	333-248428	10.5	September 9, 2020
10.4**	Form of Stock Option Agreement under the 2020 Equity Incentive Plan	S-1/A	333-248428	10.6	September 9, 2020
10.5**	Form of Restricted Stock Award Agreement under the 2020 Equity Incentive Plan	S-1/A	333-248428	10.7	September 9, 2020
10.6**	Form of RSU Agreement under the 2020 Equity Incentive Plan	S-1/A	333-248428	10.8	September 9, 2020

10.7**	2020 Employee Stock Purchase Plan, as amended and Form of Subscription Agreement Thereunder	10-K	001-39503	10.8	March 23, 2023
10.8	Lease agreement, dated July 20, 2020, by and between the Registrant and North Creek Parkway Center Investors, LP	S-1/A	333-248428	10.11	September 9, 2020
10.9**	Outside Director Compensation Policy, as amended	10-K	001-39503	10.10	March 23, 2023
10.10**	Executive Incentive Compensation Plan	S-1/A	333-248428	10.13	September 9, 2020
10.11**	Confirmatory Employment Letter between the Registrant and Mark Litton, Ph.D.	S-1/A	333-248428	10.15	September 9, 2020
10.12**	Confirmatory Employment Letter between the Registrant and Kevin Church, Ph.D.	S-1/A	333-248428	10.16	September 9, 2020
10.13**	Amended and Restated Change in Control and Severance Agreement between the Registrant and Mark Litton, Ph.D.	8-K	001-39503	10.1	January 31, 2022
10.14**	Employment Offer Letter between the Registrant and Mark Worthington	10-Q	001-39503	10.3	August 16, 2021
10.15**	Change in Control and Severance Agreement between the Registrant and Mark Worthington	10-Q	001-39503	10.4	August 16, 2021
10.16	First Amendment to Lease by and between the Registrant and Nitrogen Propco 2020, L.P., as successor-in-interest to North Creek Parkway Center Investors, L.P., dated June 28, 2021	10-Q	001-39503	10.5	August 16, 2021
10.17**	Change in Control and Severance Agreement between the Registrant and Kevin Church	10-K	001-39503	10.28	March 28, 2022
10.18	Controlled Equity Offering Sales Agreement[SM], dated January 6, 2023, among the Registrant, Cantor Fitzgerald & Co. and BTIG, LLC	8-K	001-39503	10.1	January 6, 2023
10.19**	2024 Inducement Equity Incentive Plan and related form agreements	8-K	001-39503	10.1	February 22, 2024
10.20**	Employment Offer Letter between the Registrant and Javier San Martin	10-Q/A	001-39503	10.1	August 9, 2024
10.21**	Change in Control and Severance Agreement between the Registrant and Javier San Martin	10-Q/A	001-39503	10.2	August 9, 2024
10.22**	Employment Offer Letter between the Company and Robert Renninger	8-K	001-39503	10.1	September 17, 2024
10.23**	Change in Control Agreement between the Company and Robert Renninger	8-K	001-39503	10.2	September 17, 2024
10.24**	Employment Offer Letter between the Registrant and Andrew Gengos	8-K	001-39503	10.1	May 22, 2023

10.25**	Change in Control and Severance Agreement between the Registrant and Andrew Gengos	8-K	001-39503	10.2	May 22, 2023
10.26**	Separation Agreement and Release between Andrew Gengos and Athira Pharma, Inc. dated October 3, 2024	8-K	001-39503	10.1	October 7, 2024
10.27**	Employment Offer Letter between the Registrant and Rachel Lenington	10-Q	001-39503	10.1	August 16, 2021
10.28**	Change in Control and Severance Agreement between the Registrant and Rachel Lenington	10-Q	001-39503	10.2	August 16, 2021
10.29**	Separation Agreement and Release between Rachel Lenington and Athira Pharma, Inc. dated October 1, 2024	8-K	001-39503	10.2	October 7, 2024
19	Insider Trading Policy, as amended				
21.1	List of Subsidiaries of the Registrant	S-1/A	333-24828	21.1	September 9, 2020
23.1	Consent of Independent Registered Public Accounting Firm				
24.1	Power of Attorney (included in signature pages hereto)				
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2	Certification of Principal Accounting and Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
32.2*	Certification of Principal Accounting and Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
97	Amended and Restated Compensation Recovery Policy				
101.INS	Inline XBRL Instance Document				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				

101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted in Inline XBRL and included in Exhibit 101)

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

** Indicates a management contract or compensatory plan.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

Athira Pharma, Inc.

Date: February 27, 2025

By: /s/ Mark Litton
Mark Litton
President and Chief Executive Officer (*Principal Executive Officer*)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Mark Litton and Robert Renninger, and each one of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in their name, place and stead, in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with Exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Mark Litton Mark Litton	President, Chief Executive Officer and Director (*Principal Executive Officer*)	February 27, 2025
/s/ Robert Renninger Robert Renninger	Senior Vice President, Finance and Accounting (*Principal Financial and Accounting Officer*)	February 27, 2025
/s/ Kelly A. Romano Kelly A. Romano	Chairwoman of the Board of Directors	February 27, 2025
/s/ Joseph Edelman Joseph Edelman	Director	February 27, 2025
/s/ John M. Fluke, Jr. John M. Fluke, Jr.	Director	February 27, 2025
/s/ James A. Johnson James A. Johnson	Director	February 27, 2025
/s/ Barbara Kosacz Barbara Kosacz	Director	February 27, 2025
/s/ Michael Panzara Michael Panzara	Director	February 27, 2025
/s/ Grant Pickering Grant Pickering	Director	February 27, 2025

Exhibit 4.2

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2024, we had one class of securities, our common stock, registered under Section 12 of the Securities Exchange Act of 1934, as amended. These securities are listed on the Nasdaq Global Select Market under the symbol "ATHA."

Our authorized capital stock consists of 900,000,000 shares of common stock, par value $0.0001 per share, and 100,000,000 shares of preferred stock, par value $0.0001 per share.

The following is 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 our annual report on Form 10-K for the period ended December 31, 2024, and to the applicable provisions of Delaware and Washington law.

Common Stock

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.

Voting Rights

Each share of common stock held as of the applicable record date 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 do not provide for cumulative voting rights. Because of this, the holders of a plurality of the voting power of the shares of common stock present in person or represented by proxy at the meeting of stockholders and 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, cast affirmatively or negatively, shall be the act of the stockholders, except as otherwise provided by law, our certificate of incorporation, our bylaws or the rules of any applicable stock exchange on which our securities are listed. The holders of a majority of the voting power of the capital 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, unless otherwise required by law, our certificate of incorporation, our bylaws or the rules of any applicable stock exchange on which our securities are listed.

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 fully paid and nonassessable.

Preferred Stock

Our board of directors has 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. No shares of preferred stock are outstanding.

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

- at or subsequent to such time 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, or any direct or indirect majority-owned subsidiary of the corporation, and the interested stockholder or any other entity if the merger or consolidation is caused by the interested stockholder;

- any sale, lease, exchange, mortgage, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation or any direct or indirect majority-owned subsidiary of the corporation;

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

- subject to exceptions, any transaction involving the corporation, or any direct or indirect majority-owned subsidiary of the corporation, that has the effect of increasing the proportionate share of the stock or any class or series of the corporation or such subsidiary 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.

These provisions may have the effect of delaying, deferring or preventing changes in control in our Company.

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;

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

- liquidating or dissolving the target corporation.

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

- 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 our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees or our stockholders, (3) any action asserting a claim against us 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 us 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, against any person in connection with any offering of our securities, including, without limitation and for the avoidance of doubt, any auditor, underwriter, expert, control person or other defendant.

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 Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royall Street, Canton, Massachusetts 02021.

Exhibit 10.10

ATHIRA PHARMA, INC.

OUTSIDE DIRECTOR COMPENSATION POLICY

As amended and restated on September 12, 2024

Athira Pharma, Inc. (the "Company") believes that the granting of equity and cash compensation to members of the Company's Board of Directors (the "Board," and members of the Board, "Directors") represents an effective tool to attract, retain and reward Directors who are not employees of the Company ("Outside Directors"). This Outside Director Compensation Policy (the "Policy") is intended to formalize the Company's policy regarding cash compensation and grants of equity awards to its Outside Directors. Unless otherwise defined herein, capitalized terms used in this Policy will have the meaning given such term in the Company's 2020 Equity Incentive Plan, as amended from time to time, or if such plan no longer is in use at the time of the grant of an equity award, the meaning given such term or similar term in the equity plan then in place under which the equity award is granted (the "Plan"). Each Outside Director will be solely responsible for any tax obligations incurred by such Outside Director as a result of the equity awards and cash and other compensation such Outside Director receives under this Policy.

1. Effective Date. This Policy will be effective as of the day immediately prior to the effective date of the first registration statement that is filed by the Company and declared effective pursuant to Section 12(b) of the U.S. Securities Exchange Act of 1934, as amended, with respect to any class of the Company's securities (the effective date of such registration statement, the "Registration Date," and the effective date of this Policy, the "Effective Date").

2. Cash Compensation

2.1 Board Member Annual Cash Retainer. Following the Effective Date, each Outside Director will be paid an annual cash retainer of $40,000. There are no per-meeting attendance fees for attending Board meetings or meetings of any committee of the Board.

2.2 Additional Annual Cash Retainers. Following the Effective Date, each Outside Director who serves as the Chair of the Board, or the chair or a member of a committee of the Board, will be eligible to earn additional annual fees as follows:

Chair of the Board:	$30,000
Audit Committee Chair:	$15,000
Audit Committee Member:	$7,500
Compensation Committee Chair:	$10,000
Compensation Committee Member:	$5,000
Nominating and Corporate Governance Committee Chair:	$8,000
Nominating and Corporate Governance Committee Member:	$4,000

Compliance Committee Chair:	$10,000
Compliance Committee Member:	$5,000

For clarity, each Outside Director who serves as the chair of a committee will receive only the additional annual fee as the chair of the committee and not the additional annual fee as a member of such committee while serving as such chair, provided, that the Outside Director who serves as the Chair of the Board will receive the annual fee for services provided in such role as well as the annual fee as an Outside Director.

2.3 Payment Timing and Proration. Each annual cash retainer under this Policy will be paid quarterly in arrears on a prorated basis to each Outside Director who has served in the relevant capacity at any time during the immediately preceding fiscal quarter of the Company ("Fiscal Quarter"), and such payment will be made no later than thirty (30) days following the end of such immediately preceding Fiscal Quarter. For clarity, an Outside Director who has served as an Outside Director, as a member of an applicable committee (or chair thereof) during only a portion of the relevant Fiscal Quarter will receive a prorated payment of the quarterly installment of the applicable annual cash retainer(s), calculated based on the number of days during such Fiscal Quarter such Outside Director has served in the relevant capacities. For clarity, an Outside Director who has served as an Outside Director or as a member of an applicable committee (or chair thereof) from the Effective Date through the end of the Fiscal Quarter containing the Effective Date (the "Initial Period"), as applicable, will receive a prorated payment of the quarterly installment of the applicable annual cash retainer(s), calculated based on the number of days during the Initial Period that such Outside Director has served in the relevant capacities.

3. Equity Compensation. Outside Directors will be eligible to receive all types of Awards (except Incentive Stock Options) under the Plan, including discretionary Awards not covered under this Policy. All grants of Awards to Outside Directors pursuant to Sections 3.2, 3.3, and 3.4 of this Policy will be automatic and nondiscretionary, except as otherwise provided herein, and will be made in accordance with the following provisions:

3.1 No Discretion. No person will have any discretion to select which Outside Directors will be granted Awards under this Policy or to determine the number of Shares to be covered by such Awards (except as provided in Sections 3.5.4 and 10 below).

3.2 Initial Awards. Each individual who first becomes an Outside Director following the Effective Date automatically will be granted an award of Options (an "Initial Award") to purchase 41,800 Shares. The grant date of the Initial Award will be the first Trading Day on or after the date on which such individual first becomes an Outside Director (such first date as an Outside Director, the "Initial Start Date"), whether through election by the stockholders of the Company or appointment by the Board to fill a vacancy. If an individual was an Inside Director, becoming an Outside Director due to termination of the individual's status as an Employee will not entitle the Outside Director to an Initial Award. Each Initial Award will be scheduled to vest as to one thirty-sixth (1/36th) of the Shares subject to the Initial Award on a monthly basis following the Initial Award's grant date on the same day of the month as such grant date (or on the last day of the month, if there is no corresponding day in such month), subject to the Outside Director remaining a Service Provider through the applicable vesting date.

3.3 Annual Award. On the first Trading Day immediately following each Annual Meeting of the Company's stockholders (an "Annual Meeting"), each Outside Director who, as of the date of such Annual Meeting, has been in continuous service as an Outside Director since the date of the most recently preceding Annual Meeting, automatically will be granted an award of Options to purchase 20,900 Shares. An Outside Director who, as of the date of such Annual Meeting, has not been in continuous service as an Outside Director since the date of the most recently preceding Annual Meeting, automatically will be granted a prorated award of Options, with the number of Options granted pursuant to such prorated award equal to the product of 20,900 multiplied by the quotient of (i) the number of whole months of continuous service as an Outside Director completed as of the date of such Annual Meeting divided by (ii) twelve (12), rounded down to the nearest whole share (up to a maximum of 20,900 shares) (the awards described in this Section 3.3, each, an "Annual Award"). The Annual Award will be scheduled to vest as to all of the Shares subject to the Annual Award on the earlier of (i) the one (1) year anniversary of the date the Annual Award is granted or (ii) the day immediately before the date of the next Annual Meeting that occurs after the Annual Award's grant date, subject to the Outside Director remaining a Service Provider through the applicable vesting date.

3.4 IPO Award. Effective as of the Registration Date, each Outside Director will be granted an award of Options (the "IPO Award") to purchase 27,742 Shares. Each IPO Award will be scheduled to vest as to one thirty-sixth (1/36th) of the Shares subject to the IPO Award on a monthly basis following the Vesting Commencement Date on the same day of the month as the Vesting Commencement Date (or the last day of the month, if there is no corresponding day in a given month) over a period of three (3) years from the Vesting Commencement Date, so that all of the Shares subject to the IPO Award will be scheduled to be vested by three-year anniversary of the Vesting Commencement Date, subject to the Outside Director remaining a Service Provider through the applicable vesting date. The Vesting Commencement Date of any IPO Award granted to each Outside Director other than James Johnson will be the Registration Date. The Vesting Commencement Date of any IPO Award granted to James Johnson will be August 26, 2020.

3.5 Additional Terms of Initial Awards, Annual Awards and IPO Awards. The terms and conditions of each Initial Award, Annual Award and IPO Award (each, a "Policy Award") will be as follows.

3.5.1 The term of each Policy Award will be ten (10) years, subject to earlier termination as provided in the Plan.

3.5.2 The per Share exercise price of each Policy Award will be equal to one hundred percent (100%) of the Fair Market Value per Share on such Policy Award's grant date. For purposes of clarity, the per Share exercise price of an IPO Award will be equal to the initial Share price to the public as set forth in the final prospectus included within the registration statement on Form S-1 filed with the Securities and Exchange Commission for the Company's initial public offering of its Common Stock.

3.5.3 Each Policy Award will be granted under and subject to the terms and conditions of the Plan and the applicable form of Award Agreement previously approved by the Board or its Committee, as applicable, for use thereunder.

3.5.4 The Board or its Committee, as applicable and in its discretion, may change and otherwise revise the terms of Policy Awards to be granted in the future pursuant to this Policy, including without limitation the number of Shares subject thereto and type of Award.

4. Change in Control. In the event of a Change in Control, each Outside Director will fully vest in his or her outstanding Company equity awards as of immediately prior to the Change in Control, including any Policy Award, provided that the Outside Director continues to be an Outside Director through the date of such Change in Control.

5. Annual Compensation Limit. No Outside Director may be granted, in any Fiscal Year, Awards with values (based on their grant date fair value determined in accordance with U.S. generally accepted accounting principles), and be provided any other compensation (including without limitation any cash retainers or fees) in amounts that, in any Fiscal Year, in the aggregate, exceed $500,000, provided that such amount is increased to $750,000 in the Fiscal Year of his or her initial service as an Outside Director. Any Awards or other compensation provided to an individual (a) for his or her services as an Employee, or for his or her services as a Consultant other than as an Outside Director, or (b) prior to the Registration Date, will be excluded for purposes of this Section 5.

6. Travel Expenses. Each Outside Director's reasonable, customary and properly documented travel expenses to meetings of the Board and any of its committees, as applicable, will be reimbursed by the Company.

7. Adjustments. In the event that any dividend or other distribution (whether in the form of cash, Shares, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, reclassification, repurchase, or exchange of Shares or other securities of the Company, or other change in the corporate structure of the Company affecting the Shares occurs (other than any ordinary dividends or other ordinary distributions), the Administrator, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under this Policy, will adjust the number and class of the shares of stock issuable pursuant to Policy Awards.

8. Section 409A. In no event will cash compensation or expense reimbursement payments under this Policy be paid after the later of (a) the fifteenth (15th) day of the third (3rd) month following the end of the Company's taxable year in which the compensation is earned or expenses are incurred, as applicable, or (b) the fifteenth (15th) day of the third (3rd) month following the end of the calendar year in which the compensation is earned or expenses are incurred, as applicable, in compliance with the "short-term deferral" exception under Section 409A. It is the intent of this Policy that this Policy and all payments hereunder be exempt from or otherwise comply with the requirements of Section 409A so that none of the compensation to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities or ambiguous terms herein will be interpreted to be so exempt or comply. In no event will the Company or any of its Parents or Subsidiaries have any responsibility, liability, or obligation to reimburse, indemnify, or hold harmless an Outside Director (or any other person) for any taxes imposed, or other costs incurred, as a result of Section 409A.

9. Stockholder Approval. The initial adoption of this Policy will be subject to approval by the Company's stockholders prior to the Effective Date. Unless otherwise required by applicable law, following such approval, this Policy will not be subject to approval by the Company's

stockholders, including, for clarity, as a result of or in connection with any action taken with respect to this Policy as contemplated in Section 10.

10.Revisions. The Board or any committee of the Board that has been designated appropriate authority with respect to Outside Director compensation (or with respect to any applicable element or elements thereof, authority with respect to such element or elements) (the "Committee") may amend, alter, suspend or terminate this Policy at any time and for any reason. Further, the Board may provide for cash, equity, or other compensation to Outside Directors in addition to the compensation provided under this Policy. No amendment, alteration, suspension or termination of this Policy will materially impair the rights of an Outside Director with respect to compensation that already has been paid or awarded, unless otherwise mutually agreed between the Outside Director and the Company. Termination of this Policy will not affect the Board's or the Committee's ability to exercise the powers granted to it with respect to Awards granted under the Plan pursuant to this Policy before the date of such termination, including without limitation such applicable powers set forth in the Plan.

* * *

Exhibit 19

ATHIRA PHARMA, INC.

INSIDER TRADING POLICY

(As amended and restated on September 12, 2024)

A. POLICY OVERVIEW

Athira Pharma, Inc. (together with any subsidiaries, collectively the "**Company**") has adopted this Insider Trading Policy (the "**Policy**") to help you comply with the federal and state securities laws and regulations that govern trading in securities and to help the Company minimize its own legal and reputational risk.

It is your responsibility to understand and follow this Policy. Insider trading is illegal and a violation of this Policy. In addition to your own liability for insider trading, the Company, as well as individual directors, officers and other supervisory personnel, could face liability. Even the appearance of insider trading can lead to government investigations or lawsuits that are time-consuming, expensive and can lead to criminal and civil liability, including damages and fines, imprisonment and bars on serving as an officer or director of a public company, not to mention irreparable damage to both your and the Company's reputation.

For purposes of this Policy, the Company's General Counsel and Chief Compliance Officer serves as the Compliance Officer. The Compliance Officer may designate others, from time to time, to assist with the execution of his or her duties under this Policy.

B. POLICY STATEMENT

1. No Trading on Material Nonpublic Information. It is illegal for anyone to trade in securities on the basis of material nonpublic information. If you are in possession of material nonpublic information about the Company, you are prohibited from:

    a. using it to transact in securities of the Company;

    b. disclosing it to other directors, officers, employees, consultants, contractors, or advisors whose roles do not require them to have the information;

    c. disclosing it to anyone outside of the Company, including family, friends, business associates, investors or consulting firms, without prior written authorization from the Compliance Officer; or

    d. using it to express an opinion or make a recommendation about trading in the Company's securities.

In addition, if you learn of material nonpublic information through your service with the Company that could be expected to affect the trading price of the securities of another company, you cannot (x) use that information to trade, directly or indirectly through others, or (y) provide that information to another person in order to trade, in the securities of that other company. Any such action will be deemed a violation of this Policy.

2. No Disclosure of Confidential Information. You may not at any time disclose material nonpublic information about the Company or about another company that you obtained in

connection with your service with the Company to friends, family members or any other person or entity that the Company has not authorized to know such information. In addition, you must handle the confidential information of others in accordance with any related non-disclosure agreements and other obligations that the Company has with them and limit your use of the confidential information to the purpose for which it was disclosed.

If you receive an inquiry for information from someone outside of the Company, such as a stock analyst, or a request for sensitive information outside the ordinary course of business from someone outside of the Company, such as a business partner, vendor, supplier or salesperson, then you should refer the inquiry to the Compliance Officer. Responding to a request yourself may violate this Policy and, in some circumstances, the law. Please consult the Company's External Communications Policy for more details.

3. Definition of Material Nonpublic Information. "**Material information**" means information that a reasonable investor would be substantially likely to consider important in deciding whether to buy, hold or sell securities or would view as significantly altering the total mix of information available in the marketplace about the issuer of the securities. In general, any information that could reasonably be expected to affect the market price of a security is likely to be material. Either positive or negative information may be material.

It is not possible to define all categories of "material" information. However, some examples of information that could be regarded as material include, but are not limited to:

e. significant developments in research and development, relating to the Company's preclinical studies or clinical trials, including, without limitation, status, results and communications with regulatory agencies, or relating to intellectual property;

f. financial results, key metrics, financial condition, earnings pre-announcements, guidance, projections or forecasts, particularly if inconsistent with the Company's guidance or the expectations of the investment community;

g. restatements of financial results, or material impairments, write-offs or restructurings;

h. changes in independent auditors, or notification that the Company may no longer rely on an audit report;

i. business plans or budgets;

j. creation of significant financial obligations, or any significant default under or acceleration of any financial obligation;

k. impending bankruptcy or financial liquidity problems;

l. significant developments involving business relationships, including execution, modification or termination of significant agreements or orders with customers, suppliers, distributors, manufacturers or other business partners;

m. significant information relating to the operation of a product or service, such as new products or services, major modifications or performance issues, defects or recalls, significant pricing changes or other announcements of a significant nature;

n. significant legal or regulatory developments, whether positive or negative, actual or threatened, including litigation or resolving litigation;

o. major events involving the Company's securities, including calls of securities for redemption, adoption of stock repurchase programs, option repricings, stock splits, changes in dividend policies, public or private securities offerings, modification to the rights of security holders or notice of delisting;

p. significant corporate events, such as a pending or proposed merger, joint venture or tender offer, a significant investment, the acquisition or disposition of a significant business or asset or a change in control of the Company;

q. major personnel changes, such as changes in senior management or employee layoffs;

r. data breaches or other cybersecurity events;

s. updates regarding any prior material disclosure that has materially changed; and

t. the existence of a special blackout period.

"**Material nonpublic information**" means material information that is not generally known or made available to the public. Even if information is widely known throughout the Company, it may still be nonpublic. Generally, in order for information to be considered public, it must be made generally available through media outlets or SEC filings.

After the release of information, a reasonable period of time must elapse in order to provide the public an opportunity to absorb and evaluate the information provided. As a general rule, at least two full trading days must pass after the dissemination of information before such information is considered public.

As a rule of thumb, if you think something might be material nonpublic information, it probably is. You can always reach out to the Compliance Officer if you have questions.

C. PERSONS COVERED BY THIS POLICY

This Policy applies to you if you are a director, officer, employee, consultant, contractor or advisor of the Company, both inside and outside of the United States. To the extent applicable to you, this Policy also covers your immediate family members, persons with whom you share a household, persons who are your economic dependents and any entity whose transactions in securities you influence, direct or control. You are responsible for making sure that these other individuals and entities comply with this Policy.

This Policy continues to apply even if you leave the Company or are otherwise no longer affiliated with or providing services to the Company, for as long as you remain in possession of material nonpublic information. In addition, if you are subject to a trading blackout under this Policy at the time you leave the Company, you must abide by the applicable trading restrictions until at least the end of the relevant blackout period.

D. TRADING COVERED BY THIS POLICY

Except as discussed in Section H (*Exceptions to Trading Restrictions*), this Policy applies to all transactions involving the Company's securities or other companies' securities for which you possess

material nonpublic information obtained in connection with your service with the Company. This Policy therefore applies to:

4. any purchase, sale, loan or other transfer or disposition of any equity securities (including common stock, options, restricted stock units, warrants and preferred stock) and debt securities (including debentures, bonds and notes) of the Company and such other companies, whether direct or indirect (including transactions made on your behalf by money managers), and any offer to engage in the foregoing transactions;

5. any disposition in the form of a gift of any securities of the Company;

6. any distribution to holders of interests in an entity if the entity is subject to this Policy; and

7. any other arrangement that generates gains or losses from or based on changes in the prices of such securities including derivative securities (for example, exchange-traded put or call options, swaps, caps and collars), hedging and pledging transactions, short sales and certain arrangements regarding participation in benefit plans; and any offer to engage in the foregoing transactions.

There are no exceptions from insider trading laws or this Policy based on the size of the transaction or the type of consideration received.

E. TRADING RESTRICTIONS

Subject to the exceptions set forth below, this Policy restricts trading during certain periods and by certain people as follows:

8. Quarterly Blackout Periods. Except as discussed in Section H (*Exceptions to Trading Restrictions*), all directors, officers and those employees identified by the Company must refrain from conducting transactions involving the Company's securities during quarterly blackout periods. Individuals subject to quarterly blackout periods will be informed by the Compliance Officer that they are listed on the covered persons list maintained by the Compliance Officer (the "Covered Persons List"). To the extent applicable to you, quarterly blackout periods also cover your immediate family members, persons with whom you share a household, persons who are your economic dependents, and any entity whose transactions in securities you influence, direct or control. Even if you are not specifically identified as being subject to quarterly blackout periods, you should exercise caution when engaging in transactions during quarterly blackout periods because of the heightened risk of insider trading exposure.

Quarterly blackout periods will start at the end of the last day of each fiscal quarter and will end at the start of the third full trading day following the Company's earnings release.

The prohibition against trading during the blackout period also means that brokers cannot fulfill open orders on your behalf or on behalf of your immediate family members, persons with whom you share a household, persons who are your economic dependents, or any entity whose transactions in securities you influence, direct or control, during the blackout period, including "limit orders" to buy or sell stock at a specific price or better and "stop orders" to buy or sell stock once the price of the stock reaches a specified price. If you are subject to blackout periods or pre-clearance requirements, you should so inform any broker with whom such an open order is placed at the time it is placed.

From time to time, the Company may identify other persons who should be subject to quarterly blackout periods, and the Compliance Officer may update and revise the Covered Person's List as appropriate.

9. Special Blackout Periods. The Company always retains the right to impose additional or longer trading blackout periods at any time on any or all of its directors, officers, employees, consultants, contractors and advisors. The Compliance Officer will notify you if you are subject to a special blackout period by providing to you a notice in writing or via email. If you are notified that you are subject to a special blackout period, you may not engage in any transaction involving the Company's securities until the special blackout period has ended other than the transactions that are covered by the exceptions below. You also may not disclose to anyone else that the Company has imposed a special blackout period. To the extent applicable to you, special blackout periods also cover your immediate family members, persons with whom you share a household, persons who are your economic dependents, and any entity whose transactions in securities you influence, direct or control.

10. Regulation BTR Blackouts. Directors and officers may also be subject to trading blackouts pursuant to Regulation Blackout Trading Restriction, or Regulation BTR, under U.S. federal securities laws. In general, Regulation BTR prohibits any director or officer from engaging in certain transactions involving the Company's securities during periods when 401(k) plan participants are prevented from purchasing, selling or otherwise acquiring or transferring an interest in certain securities held in individual account plans. Any profits realized from a transaction that violates Regulation BTR are recoverable by the Company, regardless of the intentions of the director or officer effecting the transaction. In addition, individuals who engage in such transactions are subject to sanction by the SEC as well as potential criminal liability. The Company will notify directors and officers if they are subject to a blackout trading restriction under Regulation BTR. Failure to comply with an applicable trading blackout in accordance with Regulation BTR is a violation of law and this Policy.

F. PROHIBITED TRANSACTIONS

You may not engage in any of the following types of transactions other than as noted below, regardless of whether you have material nonpublic information or not.

11. Short Sales. You may not engage in short sales (meaning the sale of a security that must be borrowed to make delivery) or "sell short against the box" (meaning the sale of a security with a delayed delivery) if such sales involve the Company's securities.

12. Derivative Securities and Hedging Transactions. You may not, directly or indirectly, (a) trade in publicly-traded options, such as puts and calls, and other derivative securities with respect to the Company's securities (other than stock options, restricted stock units and other compensatory awards issued to you by the Company) or (b) purchase financial instruments (including prepaid variable forward contracts, equity swaps, collars and exchange funds), or otherwise engage in transactions, that hedge or offset, or are designed to hedge or offset, any

decrease in the market value of Company equity securities either (i) granted to you by the Company as part of your compensation or (ii) held, directly or indirectly, by you.

13. Pledging Transactions. You may not pledge the Company's securities as collateral for any loan or as part of any other pledging transaction.

14. Margin Accounts. You may not hold the Company's common stock in margin accounts.

G. PRE-CLEARANCE OF TRADES

The Company's directors and officers and any other persons identified on the Covered Persons List of this Policy as being subject to pre-clearance requirements must obtain pre-clearance prior to trading the Company's securities. If you are subject to pre-clearance requirements, you should submit a pre-clearance request to the Compliance Officer at least two business days prior to your desired trade date. The pre-clearance request must be made on the form provided by the Compliance Officer. The person requesting pre-clearance will be asked to certify that he or she is not in possession of material nonpublic information about the Company. The Compliance Officer is under no obligation to approve a transaction submitted for pre-clearance and may determine not to permit the transaction.

If the Compliance Officer is the requester, then the Company's President and Chief Executive Officer, or their delegate, must pre-clear or deny any trade. All trades must be executed within two business days of any pre-clearance.

Even after preclearance, a person may not trade the Company's securities if they become subject to a blackout period or aware of material nonpublic information prior to the trade being executed.

From time to time, the Company may identify other persons who should be subject to the pre-clearance requirements set forth above, and the Compliance Officer may update and revise the Covered Persons List as appropriate.

H. EXCEPTIONS TO TRADING RESTRICTIONS

There are no unconditional "safe harbors" for trades made at particular times, and all persons subject to this Policy should exercise good judgment at all times. Even when a quarterly blackout period is not in effect, you may be prohibited from engaging in transactions involving the Company's securities because you possess material nonpublic information, are subject to a special blackout period or are otherwise restricted under this Policy.

Other than the limited exceptions set forth below, any other exceptions to this Policy must be approved by the Compliance Officer, in consultation with the Company's board of directors or an independent committee of the board of directors.

The following are certain limited exceptions to the quarterly and special blackout period restrictions and pre-clearance requirements imposed by the Company under this Policy:

15. stock option exercises where the purchase price of such stock options is paid in cash and there is no other associated market activity;

16. receipt and vesting of stock options, restricted stock units, restricted stock or other equity compensation awards from the Company;

17. purchases pursuant to the employee stock purchase plan; however, this exception does not apply to subsequent sales of the shares;

18. net share withholding with respect to equity awards where shares are withheld by the Company in order to satisfy tax withholding requirements, (*x*) as required by either the Company's board of directors (or a committee thereof) or award agreement governing such equity award or (*y*) as you elect, if permitted by the Company, so long as the election is irrevocable and made in writing at a time when a trading blackout is not in place and you are not in possession of material nonpublic information;

19. sell to cover transactions, where shares are sold on your behalf upon vesting of equity awards and sold in order to satisfy tax withholding requirements, (*x*) as required by either the Company's board of directors (or a committee thereof) or the award agreement governing such equity award or (*y*) as you elect, if permitted by the Company, so long as the election is irrevocable and made in writing at a time when a trading blackout is not in place and you are not in possession of material nonpublic information; however, this exception does not apply to any other market sale for the purposes of paying required withholding;

20. transactions made pursuant to a valid 10b5-1 trading plan approved by the Company (see Section I (*10b5-1 Trading Plans*) below);

21. purchases of the Company's stock in the 401(k) plan resulting from periodic contributions to the plan based on your payroll contribution election; *provided, however,* that the blackout period restrictions and pre-clearance requirements do apply to elections you make under the 401(k) plan to (a) increase or decrease the amount of your contributions under the 401(k) plan if such increase or decrease will increase or decrease the amount of your contributions that will be allocated to a Company stock fund, (b) increase or decrease the percentage of your contributions that will be allocated to a Company stock fund, (c) move balances into or out of a Company stock fund, (d) borrow money against your 401(k) plan account if the loan will result in liquidation of some or all of your Company stock fund balance, and (e) prepay a plan loan if the pre-payment will result in the allocation of loan proceeds to a Company stock fund;

22. transfers by will or the laws of descent or distribution and, provided that prior written notice is provided to the Compliance Officer, distributions or transfers (such as certain tax planning or estate planning transfers) that effect only a change in the form of beneficial interest without changing your pecuniary interest in the Company's securities; and

23. changes in the number of the Company's securities you hold due to a stock split or a stock dividend that applies equally to all securities of a class, or similar transactions.

If there is a Regulation BTR blackout (and no quarterly or special blackout period), then the limited exceptions set forth in Regulation BTR will apply Please be aware that even if a transaction is subject to an exception to this Policy, you will need to separately assess whether the transaction complies with applicable law.

I. 10B5-1 TRADING PLANS

The Company permits its directors, officers and employees to adopt written 10b5-1 trading plans in order to mitigate the risk of trading on material nonpublic information. These plans allow for individuals to enter into a prearranged trading plan as long as the plan is not established or modified during a blackout period or when the individual is otherwise in possession of material nonpublic information. To be approved

by the Company and qualify for the exception to this Policy, any 10b5-1 trading plan adopted by a director, officer or employee must be submitted to the Compliance Officer for approval and comply with the requirements set forth in the Requirements for Trading Plans attached as Exhibit A. If the Compliance Officer is the requester, then the Company's Chief Executive Officer, or their delegate, must approve the written 10b5-1 trading plan.

J. SECTION 16 COMPLIANCE

All of the Company's officers and directors and certain other individuals are required to comply with Section 16 of the Securities and Exchange Act of 1934 and related rules and regulations which set forth reporting obligations, limitations on "short swing" transactions, which are certain matching purchases and sales of the Company's securities within a six-month period, and limitations on short sales.

To ensure transactions subject to Section 16 requirements are reported on time, each person subject to these requirements must provide the Company with detailed information (for example, trade date, number of shares, exact price, *etc.*) about his or her transactions involving the Company's securities.

The Company is available to assist in filing Section 16 reports, but the obligation to comply with Section 16 is personal. If you have any questions, you should check with the Compliance Officer.

K. VIOLATIONS OF THIS POLICY

Company directors, officers, employees, consultants, contractors and advisors who violate this Policy will be subject to disciplinary action by the Company, including ineligibility for future Company equity or incentive programs or termination of employment or an ongoing relationship with the Company. The Company has full discretion to determine whether this Policy has been violated based on the information available.

There are also serious legal consequences for individuals who violate insider trading laws, including large criminal and civil fines, significant imprisonment terms and disgorgement of any profits gained or losses avoided. You may also be liable for improper securities trading by any person (commonly referred to as a "tippee") to whom you have disclosed material nonpublic information that you have learned through your position at the Company or made recommendations or expressed opinions about securities trading on the basis of such information.

Please consult with your personal legal and financial advisors as needed. Note that the Company's legal counsel, both internal and external, represent the Company and not you personally. There may be instances where you suffer financial harm or other hardship or are otherwise required to forego a planned transaction because of the restrictions imposed by this Policy or under securities laws. If you were aware of the material nonpublic information at the time of the trade, it is not a defense that you did not "use" the information for the trade. Personal financial emergency or other personal circumstances are not mitigating factors under securities laws and will not excuse your failure to comply with this Policy. In addition, a blackout or trading-restricted period will not extend the term of your options. As a consequence, you may be prevented from exercising your options by this Policy or as a result of a blackout or other restriction on your trading, and as a result your options may expire by their term. In such instances, the Company cannot extend the term of your options and has no obligation or liability to replace the economic value or lost benefit to you. It is your responsibility to manage your economic interests and to consider potential trading restrictions when determining whether to exercise your options.

L. PROTECTED ACTIVITY NOT PROHIBITED

Nothing in this Policy, or any related guidelines or other documents or information provided in connection with this Policy, shall in any way limit or prohibit you from engaging in any of the protected activities set forth in the Company's Whistleblower Policy, as amended from time to time.

M. REPORTING

If you believe someone is violating this Policy or otherwise using material nonpublic information that they learned through their position at the Company to trade securities, you should report it to the Compliance Officer, or if the Compliance Officer is implicated in your report, then you should report it in accordance with the Company's Whistleblower Policy.

N. AMENDMENTS

The Company reserves the right to amend this Policy at any time, for any reason, subject to applicable laws, rules and regulations, and with or without notice, although it will attempt to provide notice in advance of any change. Unless otherwise permitted by this Policy, any amendments must be approved by the Board of Directors of the Company.

EXHIBIT A

REQUIREMENTS FOR TRADING PLANS

For transactions under a trading plan to be exempt from (A) the prohibitions in the Company's Insider Trading Policy (the "**Policy**") of Athira Pharma, Inc. (together with any subsidiaries, collectively the "**Company**") with respect to transactions made while aware of material nonpublic information and (B) the pre-clearance procedures and blackout periods established under the Policy, the trading plan must comply with the affirmative defense set forth in Exchange Act Rule 10b5-1 and must meet the following requirements (collectively, the "**Trading Plan Requirements**"):

1. The trading plan must be in writing and signed by the person adopting the trading plan.

2. The trading plan must be adopted at a time when:

   a. the person adopting the trading plan is not aware of any material nonpublic information; and

   b. there is no quarterly, special or other trading blackout in effect with respect to the person adopting the plan.

3. The trading plan must be entered in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1, and the person adopting the trading plan must act in good faith with respect to the trading plan.

4. The trading plan must include representations, that on the date of adoption of the trading plan, the person adopting the trading plan:

   a. is not aware of material nonpublic information about the securities or the Company; and

   b. is adopting the trading plan in good faith and not as part of a plan or scheme to evade prohibitions of Rule 10b5-1.

5. The person adopting the trading plan may not have entered into or altered a corresponding or hedging transaction or position with respect to the securities subject to the trading plan and must agree not to enter into any such transaction while the trading plan is in effect.

6. The first trade under the trading plan may not occur until the expiration of a cooling-off period consisting of the later of (a) 90 calendar days after the adoption of the trading plan and (b) two business days after the filing by the Company of its financial results in a Form 10-Q or Form 10-K for the completed fiscal quarter in which the trading plan was adopted (but, in any event, this required cooling-off period is subject to a maximum of 120 days after adoption of the trading plan).

7. The trading plan must have a minimum term of one year (starting from the date of adoption of the trading plan).

8. No transactions may occur during the term of the trading plan (except for the "Exceptions to Trading Restrictions" identified in the Policy and *bona fide* gifts) except for those transactions specified in the trading plan. In addition, the person adopting the trading plan may not have an outstanding (and may not subsequently enter into any additional) trading plan except as permitted by Rule 10b5-1. For example, as contemplated by Rule 10b5-1, a person may adopt a new trading plan before the scheduled termination date of an existing trading plan, so long as the first scheduled trade under the new trading plan does not occur prior to the last scheduled trade(s) of the existing trading plan and otherwise complies with these guidelines. Termination of the existing trading plan prior to its scheduled termination date may impact the timing of the first trade or the availability of the affirmative defense for the new trading plan; therefore, persons adopting a new trading plan are advised to exercise caution and consult with the Compliance Officer prior to the early termination of an existing trading plan.

9. Any modifications or change to the amount, price or timing of transactions under the trading plan is deemed the termination of the trading plan, and the adoption of a new trading plan ("**Modification**"). Therefore, a Modification must be submitted to the Compliance Officer for approval in accordance with Section I of the Policy and is subject to the same conditions as a new trading plan as set forth in Sections 1 through 8 herein.

10. Within the one year preceding the adoption or Modification of a trading plan, a person may not have otherwise adopted or made a Modification to a plan more than once.

11. A person may adopt a trading plan designed to cover a single trade only once in any consecutive 12-month period except as permitted by Rule 10b5-1

12. If the person that adopted the trading plan terminates the plan prior to its stated duration, he or she may not trade in the Company's securities until after the expiration of 30 calendar days following termination, and then only in accordance with the Policy.

13. The Company must be promptly notified of any termination of the trading plan, including any suspension of trading under the trading plan.

14. The Company must have authority to require the suspension of the plan if there are legal, regulatory or contractual restrictions applicable to the Company or the person that adopted the trading plan, or to require the cancellation of the trading plan at any time, subject to any reasonable broker notice requirements as may be set forth in the trading plan.

15. If the trading plan grants discretion to a stockbroker or other person with respect to the execution of trades under the trading plan:

a. the person adopting the trading plan may not exercise any subsequent influence over how, when or whether to effect purchases or sales under the plan;

b. the person adopting the trading plan may not confer with the person administering the trading plan regarding the Company or its securities; and

c. the person administering the trading plan must provide prompt notice to the Company of the execution of a transaction pursuant to the plan.

16. All transactions under the trading plan must be in accordance with applicable law.

17. Any exceptions to the Trading Plan Requirements must be approved by the Compliance Officer or, in the case of directors and officers who are subject Section 16 of the Securities Exchange Act of 1934, by the Compliance Officer in consultation with the Company's board of directors or an independent committee of the board of directors.

18. The trading plan (including any Modification) must meet such other requirements as the Compliance Officer may determine.

Exhibit A

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Form S-3 No. 333-282738 of Athira Pharma, Inc.; and

(2) Form S-8 Nos. 333-277276 pertaining to the 2020 Equity Incentive Plan, the 2020 Employee Stock Purchase Plan, and the 2024 Inducement Equity Incentive Plan; 333-270792, 333-263907, and 333-254735 pertaining to the 2020 Equity Incentive Plan and the 2020 Employee Stock Purchase Plan; and 333-248910 pertaining to the 2020 Equity Incentive Plan, the 2020 Employee Stock Purchase Plan, and the 2014 Equity Incentive Plan, as amended, of Athira Pharma, Inc.

of our report dated February 27, 2025, with respect to the consolidated financial statements of Athira Pharma, Inc., included in this Annual Report (Form 10-K) of Athira Pharma, Inc. for the year ended December 31, 2024.

/s/ Ernst & Young LLP

Seattle, Washington
February 27, 2025

Exhibit 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a)

AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark Litton, certify that:

1. I have reviewed this Annual Report on Form 10-K of Athira Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2025

/s/ Mark Litton

Mark Litton

President and Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a)

AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert Renninger, certify that:

1. I have reviewed this Annual Report on Form 10-K of Athira Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2025

/s/ Robert Renninger

Robert Renninger

Senior Vice President, Finance and Accounting

(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Athira Pharma, Inc. (the "Company") for the fiscal year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark Litton, President and Chief Executive Officer (*Principal Executive Officer)* of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 27, 2025

/s/ Mark Litton
Mark Litton
President and Chief Executive Officer
(Principal Executive Officer)

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

Exhibit 32.2

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

In connection with the Annual Report on Form 10-K of Athira Pharma, Inc. (the "Company") for the fiscal year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert Renninger, Senior Vice President, Finance and Accounting (*Principal Financial and Accounting Officer)* of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 27, 2025

/s/ Robert Renninger
Robert Renninger
Senior Vice President, Finance and Accounting
(Principal Financial and Accounting Officer)

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

Exhibit 97

ATHIRA PHARMA, INC.

COMPENSATION RECOVERY ("CLAWBACK") POLICY

(As amended and restated on September 12, 2024)

Athira Pharma, Inc. (the "**Company**") is committed to strong corporate governance. As part of this commitment, the Company's Board of Directors (the "**Board**") has adopted this Amended and Restated Compensation Recovery ("**Clawback**") Policy (the "**Policy**"). The Policy is intended to further the Company's pay-for-performance philosophy and to comply with applicable laws by providing rules relating to the reasonably prompt recovery of certain compensation received by Covered Executives in the event of an Accounting Restatement or Retraction of Scientific Results. The application of the Policy to Covered Executives is not discretionary, except to the limited extent provided below, and applies without regard to whether a Covered Executive was at fault. Capitalized terms used in the Policy are defined below, and the definitions have substantive impact on its application so reviewing them carefully is important to your understanding.

The Policy is intended to comply with, and will be interpreted in a manner consistent with, Section 10D of the Securities Exchange Act of 1934 (the "**Exchange Act**"), with Exchange Act Rule 10D-1 and with the listing standards of the national securities exchange (the "**Exchange**") on which the securities of the Company are listed, including any official interpretive guidance.

Persons Covered by the Policy

The Policy is binding and enforceable against all Covered Executives. A "**Covered Executive**" is each individual who is or was ever designated as an "officer" by the Board in accordance with Exchange Act Rule 16a-1(f) (a "**Section 16 Officer**"). The Compensation Committee may (but is not obligated to) request or require a Covered Executive to sign and return to the Company an acknowledgement that such Covered Executive will be bound by and comply with the terms of the Policy. The Policy is binding on each Covered Executive whether or not the Covered Executive signs and/or returns any acknowledgment.

Administration of the Policy

The Compensation Committee (the "**Compensation Committee**") of the Board has full delegated authority to administer the Policy. The Compensation Committee is authorized to interpret and construe the Policy and to make all determinations necessary, appropriate, or advisable for the administration of the Policy. In addition, if determined in the discretion of the Board, the Policy may be administered by the independent members of the Board or another committee of the Board made up of independent members of the Board, in which case all references to the Compensation Committee will be deemed to refer to the independent members of the Board or the other Board committee, as applicable. All determinations of the Compensation Committee will be final and binding and will be given the maximum deference permitted by law.

Events Requiring Application of the Policy

If the Company is required to (A) prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (an "**Accounting Restatement**"), or (B) to retract a scientific publication or correct a material scientific finding in a scientific publication (as determined by the Board or Compliance Committee of the Board), where such retraction or correction is due to fraudulent or intentional misconduct, gross negligence, or a material violation of a Company policy or the policy of a scientific publication related to scientific integrity (a "**Retraction of Scientific Results**"), then the Compensation Committee must determine the Excess Compensation, if any, that must be recovered. The Company's obligation to recover Excess Compensation is not dependent on if or when restated financial statements are filed or the scientific finding is retracted.

Compensation Covered by the Policy

The Policy applies to certain **Incentive-Based Compensation** (certain terms used in this Section are defined below) that is **Received** on or after October 2, 2023 (the "**Effective Date**") during the Covered Period while the Company has a class of securities listed on a national securities exchange. Such Incentive-Based Compensation is considered "**Clawback Eligible Incentive-Based Compensation**" if the Incentive-Based Compensation is Received by a person after such person became a Section 16 Officer and the person served as a Section 16 Officer at any time during the performance period for the Incentive-Based Compensation. "**Excess Compensation**" means the amount of Clawback Eligible Incentive-Based Compensation that exceeds the amount of Clawback Eligible Incentive-Based Compensation that otherwise would have been Received had such Clawback Eligible Incentive-Based Compensation been determined based on the restated amounts, as if the retracted scientific publication that was subject of the Retraction of Scientific Results had not been published, or based on the corrected material scientific finding, as applicable. Excess Compensation must be computed without regard to any taxes paid and is referred to in the listings standard of the Exchange as "erroneously awarded compensation".

Determining Excess Compensation for Certain Incentive-Based Compensation

To determine the amount of Excess Compensation for Incentive-Based Compensation based on stock price or total shareholder return, where it is not subject to mathematical recalculation directly from the information in an Accounting Restatement or Retraction of Scientific Results:

- The amount must be based on a reasonable estimate of the effect of the Accounting Restatement or Retraction of Scientific Results on the stock price or total shareholder return upon which the Incentive-Based Compensation was Received; and

- The Company must maintain documentation of the determination of that reasonable estimate and provide that documentation to the Exchange.

Repayment of Excess Compensation

The Company must recover Excess Compensation reasonably promptly and Covered Executives are required to repay Excess Compensation to the Company. Subject to applicable law, the Company may recover Excess Compensation by requiring the Covered Executive to repay such amount to the Company by direct payment to the Company or such other means or combination of means as the Compensation Committee determines to be appropriate (these determinations do not need to be identical as to each Covered Executive). These means include (but are not limited to):

a) requiring reimbursement of cash Incentive-Based Compensation previously paid;

b) seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards (including, but not limited to, time-based vesting awards), without regard to whether such awards are Incentive-Based Compensation or vest based on the achievement of performance goals;

c) offsetting the amount to be recovered from any unpaid or future compensation to be paid by the Company or any affiliate of the Company to the Covered Executive, including, but not limited to, payments of severance that might otherwise be due in connection with a Covered Executive's termination of employment and without regard to whether such amounts are Incentive-Based Compensation;

d) cancelling outstanding vested or unvested equity awards (including, but not limited to, time-based vesting awards), without regard to whether such awards are Incentive-Based Compensation; and/or

e) taking any other remedial and recovery action permitted by law, as determined by the Compensation Committee.

The repayment of Excess Compensation must be made by a Covered Executive notwithstanding any Covered Executive's belief (whether or not legitimate) that the Excess Compensation had been previously earned under applicable law and therefore not subject to clawback.

In addition to its rights to recovery under the Policy, the Company or any affiliate of the Company may take any legal actions it determines appropriate to enforce a Covered Executive's obligations to the Company or to discipline a Covered Executive. Failure of a Covered Executive to comply with their obligations under the Policy may result in (without limitation) termination of that Covered Executive's employment, institution of civil proceedings, reporting of misconduct to appropriate governmental authorities, reduction of future compensation opportunities or change in role. The decision to take any actions described in the preceding sentence will not be subject to the approval of the Compensation Committee and can be made by the Board, any committee of the Board, or any duly authorized officer of the Company or of any applicable affiliate of the Company. For avoidance of doubt, any decisions of the Company or the Covered Executive's employer to discipline a Covered Executive or terminate the employment of a Covered Executive are independent of determinations under the Policy. For example, if a Covered Executive was involved in activities that led to an Accounting Restatement or Retraction of Scientific Results, the Company's decision as to whether or not to terminate such Covered Executive's employment would be made under its employment arrangements with such Covered Executive and the requirement to apply this no-fault and non-discretionary Policy will not be determinative of whether any such termination is for cause, although failure to comply with the Policy might be something that could result in a termination for cause depending on the terms of such arrangements.

Limited Exceptions to the Policy

The Company must recover the Excess Compensation in accordance with the Policy except to the limited extent that any of the conditions set forth below is met, and the Compensation Committee determines that recovery of the Excess Compensation would be impracticable:

A. The direct expense paid to a third party to assist in enforcing the Policy would exceed the amount to be recovered. Before reaching this conclusion, the Company must make a reasonable attempt to

recover such Excess Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange; or

B. Recovery would violate a law in the country in which the Company is incorporated where that law was adopted prior to November 28, 2022. Before reaching this conclusion, the Company must obtain an opinion of local counsel, acceptable to the Exchange, that recovery would result in such a violation, and must provide such opinion to the Exchange; or

C. Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the legal requirements as such.

Defined Terms in the Policy

The capitalized terms in the Policy have the following meaning, unless clearly required otherwise by the context.

"**Determination Date**" means the earliest to occur of:

A. The date the Board, a committee of the Board, or one or more of the officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement or Retraction of Scientific Results; and

B. The date a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement.

"**Covered Period**" means the three completed fiscal years immediately preceding the Determination Date. In addition, Covered Period can include certain transition periods resulting from a change in the Company's fiscal year.

"**Financial Reporting Measures**" are measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and total shareholder return are also Financial Reporting Measures. A Financial Reporting Measure need not be presented within the financial statements or included in a filing with the Securities and Exchange Commission.

"**Incentive-Based Compensation**" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure or a Published Scientific Performance Goal. For the avoidance of doubt, no compensation that is potentially subject to recovery under the Policy will be earned until the Company's right to recover under the Policy has lapsed.

The following items of compensation are not Incentive-Based Compensation under the Policy: salaries, bonuses paid solely at the discretion of the Compensation Committee or the Board that are not paid from a bonus pool that is determined by satisfying a Financial Reporting Measure or a Published Scientific Performance Goal, bonuses paid solely upon satisfying one or more subjective standards and/or completion of a specified employment period, non-equity incentive plan awards earned solely upon satisfying one or more strategic measures or operational measures, and equity awards for which the grant is not contingent upon achieving any Financial Reporting Measure or Published Scientific Performance Goal and vesting is contingent solely upon completion of a specified employment period (e.g., time-based vesting equity awards) and/or attaining one or more non-Financial Reporting Measures or Published Scientific Performance Goals.

"**Policy"** means this Amended and Restated Compensation Recovery ("Clawback") Policy, as it may be amended from time to time.

Incentive-Based Compensation is "**Received**" under the Policy in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained or scientific finding was published, as the case may be, even if the payment, vesting, settlement or grant of the Incentive-Based Compensation occurs after the end of that period. For the avoidance of doubt, the Policy does not apply to Incentive-Based Compensation for which the Financial Reporting Measure or Published Scientific Performance Goal, as applicable, is attained prior to the Effective Date.

"**Published Scientific Performance Goal**" means a published scientific performance goal material (as determined by the Board or Compliance Committee of the Board) to the Company.

"**Retraction of Scientific Results Determination Date**" means the date the Board, or the Compliance Committee of the Board, or one or more of the officers of the Company authorized to take such action if Board action is not required, concludes that a material Retraction of Scientific Results occurred.

Other Important Information in the Policy

The Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 that are applicable to the Company's Chief Executive Officer and Chief Financial Officer, as well as any other applicable laws, regulatory requirements, rules, or pursuant to the terms of any existing Company policy or agreement providing for the recovery of compensation.

Notwithstanding the terms of any of the Company's organizational documents (including, but not limited to, the Company's Bylaws), any corporate policy or any contract (including, but not limited to, any indemnification agreement), neither the Company nor any affiliate of the Company will indemnify or provide expense advancement for any Covered Executive against any loss of Excess Compensation. Neither the Company nor any affiliate of the Company will pay for or reimburse insurance premiums for an insurance policy that covers potential recovery obligations. In the event that the Company is required to recover Excess Compensation pursuant to the Policy from a Covered Executive who is no longer an employee, the Company will be entitled to seek recovery in order to comply with applicable law, regardless of the terms of any release of claims or separation agreement that individual may have signed.

The Compensation Committee or Board may review and modify the Policy from time to time.

If any provision of the Policy or the application of any such provision to any Covered Executive is adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provisions of the Policy or the application of such provision to another Covered Executive, and the invalid, illegal or unenforceable provisions will be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

The Policy will terminate and no longer be enforceable when the Company ceases to be listed issuer within the meaning of Section 10D of the Exchange Act.

ACKNOWLEDGEMENT

- I acknowledge that I have received and read the Amended and Restated Compensation Recovery ("Clawback") Policy (the "**Policy**") of Athira Pharma, Inc. (the "**Company**").

- I understand and acknowledge that the Policy applies to me, and all of my beneficiaries, heirs, executors, administrators or other legal representatives and that the Company's right to recovery in order to comply with applicable law will apply, regardless of the terms of any release of claims or separation agreement I have signed or will sign in the future.

- I agree to be bound by and to comply with the Policy and understand that determinations of the Compensation Committee (as such term is used in the Policy) will be final and binding and will be given the maximum deference permitted by law.

- I understand and agree that my current indemnification rights, whether in an individual agreement or the Company's organizational documents, exclude the right to be indemnified for amounts required to be recovered under the Policy.

- I understand that my failure to comply in all respects with the Policy is a basis for termination of my employment with the Company and any affiliate of the Company as well as any other appropriate discipline.

- I understand that neither the Policy, nor the application of the Policy to me, gives rise to a resignation for good reason (or similar concept) by me under any applicable employment agreement or arrangement.

- I acknowledge that if I have questions concerning the meaning or application of the Policy, it is my responsibility to seek guidance from the General Counsel and Chief Compliance Officer (the "**Compliance Officer**"), Human Resources or my own personal advisers.

- I acknowledge that neither this Acknowledgement nor the Policy is meant to constitute an employment contract.

Please review, sign and return this form to the Compliance Officer.

Covered Executive

____

(*print name*)

____

(*signature*)

____

(*date*)