

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the United States Department of Health and Human Services (collectively the “United States”), Athira Pharma, Inc., formerly M3 Biotechnology, Inc. (“Athira”), and Andrew Mallon (“Relator”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Athira is a biopharmaceutical company located in Bothell, Washington that researches and develops treatments for neurodegenerative diseases, which include Alzheimer’s disease.

B. Athira applied for NIH funding in 2016 for grant application 1 R42 AG055246-01 (“Small molecule neurotrophic factor (HGF) allosteric activator for the treatment of age-related cognitive decline”) and received NIH funding in 2019 for grant award 1R01 AG068268-01 (“A randomized, placebo-controlled, double-blind study to evaluate safety and efficacy of NDX-1017 treatment in Alzheimer’s dementia patients”).

C. On June 21, 2021, Relator filed a qui tam action in the United States District Court for the Western District of Washington captioned *United States ex rel. Mallon v. Athira Pharma, Inc.*, Civil Action No. 21-853-RSL, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the Civil Action). Relator filed an amended complaint on March 26, 2022.

D. The United States contends that it has certain civil claims against Athira arising from its failure to report allegations of research misconduct in violation of 42

C.F.R. Part 93 and requirements incorporated in the terms and conditions of the NIH grant application process and grant award. These allegations related to Athira's former Chief Executive Officer Leen Kawas falsifying and manipulating images in her doctoral dissertation and published research papers. Between January 1, 2016 and June 20, 2021, Athira did not report these allegations of research misconduct to NIH in Research Progress Performance Reports, or to the HHS Office of Research Integrity in Small Business Organization Statements, Institutional Assurances, or Annual Reports on Possible Research Misconduct. Athira referenced Kawas's falsified research in grant applications submitted to NIH, including 1R42 AG055246-01 and 1R01 AG068268-01. NIH funded 1R01 AG068268 in 2019. This conduct is referred to below as the Covered Conduct.

D. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Athira shall pay to the United States \$4,068,698 (the "Settlement Amount"), of which \$2,034,349 is restitution, by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the

Western District of Washington no later than 10 days after the Effective Date of this Agreement.

2. Conditioned upon the United States receiving the Settlement Amount and as soon as feasible after receipt, the United States shall pay \$203,434.90 to Relator by electronic funds transfer (the “Relator’s Share”).

3. Athira shall pay to Relator \$58,500 for attorneys’ fees and costs pursuant to 3730(h). Relator will separately provide instructions to Athira to make that payment no later than 30 days after the Effective Date of this Agreement.

4. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and upon the United States’ receipt of the Settlement Amount, the United States releases Athira from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of breach of contract, payment by mistake, unjust enrichment, and fraud.

5. Subject to the exceptions in Paragraph 6 below, and upon the United States’ receipt of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases Athira from any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

6. Notwithstanding the releases given in Paragraph 4 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in the Agreement, including the releases provided in Paragraph 4 for the Covered Conduct, any administrative liability or enforcement right, or any administrative remedy, including the suspension and debarment rights of any federal agency;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due; and
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

7. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).

Conditioned upon Relator's receipt of the Relator's Share, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever

discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

8. Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, releases Athira, and its officers, agents, and employees, from any liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs.

9. Athira waives and shall not assert any defenses Athira may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

10. Athira fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Athira has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct or the United States' investigation or prosecution thereof.

11. Athira agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47) incurred by or on behalf of Athira, and

its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) Athira's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement;
- (5) the payment Athira makes to the United States pursuant to this Agreement and any payments that Athira may make to Relator, including costs and attorneys fees,

are unallowable costs for government contracting purposes (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs will be separately determined and accounted for by Athira, and Athira shall not charge such Unallowable Costs directly or indirectly to any contract with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Agreement, Athira shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs included in payments previously sought by Athira or any of its subsidiaries or affiliates from the United States. Athira agrees that the United States, at a minimum,

shall be entitled to recoup from Athira any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. The United States, including the Department of Justice and/or the affected agencies, reserves its rights to audit, examine, or re-examine Athira's books and records and to disagree with any calculations submitted by Athira or any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by Athira, or the effect of any such Unallowable Costs on the amount of such payments.

12. Athira agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement, including without limitation any investigation concerning Athira's former Chief Executive Officer, Leen Kawas. Upon reasonable notice, Athira shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Athira further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

13. This Agreement is intended to be for the benefit of the Parties only.

14. Upon receipt of the payment described in Paragraph 1, above, the United States and Relator shall promptly sign and file in the Civil Action a Joint Stipulation of

Dismissal of the Civil Action pursuant to Rule 41(a)(1). The Civil Action shall be dismissed with prejudice as to the Relator and with prejudice as to the United States with regard to the Covered Conduct, but without prejudice to the United States as to any allegations outside the scope of the Covered Conduct.

15. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

16. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

17. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Western District of Washington. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

18. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

19. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

20. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.


21. This Agreement is binding on Athira's successors, transferees, heirs, and assigns.


22. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

23. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

24. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 12/20/24 BY: 
Nickolas Bohl
Assistant United States Attorney
Western District of Washington

DATED: 12/31/24 BY: 
Erin Collieran
Trial Attorney
Commercial Litigation Branch, Civil Division
United States Department of Justice

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES

DATED: 12/16/24 BY: SUSAN GILLIN Digitally signed by SUSAN GILLIN
Date: 2024.12.16 17:20:29 -05'00'
SUSAN E. GILLIN
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Service

ATHIRA PHARMA, INC. - DEFENDANT

DATED: _____ BY: _____
Mark Worthington
General Counsel, Athira Pharma, Inc.

DATED: _____ BY: _____
Gregory L. Watts
Counsel for Athira Pharma, Inc.

ANDREW MALLON - RELATOR

DATED: _____ BY: _____
Andrew Mallon

THE UNITED STATES OF AMERICA

DATED: _____ BY: _____

Nickolas Bohl
Assistant United States Attorney
Western District of Washington

DATED: _____ BY: _____

Erin Collieran
Trial Attorney
Commercial Litigation Branch, Civil Division
United States Department of Justice

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES

DATED: _____ BY: _____

SUSAN E. GILLIN
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Service

ATHIRA PHARMA, INC. - DEFENDANT

DATED: 12/9/2024 BY: 

Mark Worthington
General Counsel, Athira Pharma, Inc.

DATED: 12/9/24 BY: 

Gregory L. Watts
Counsel for Athira Pharma, Inc.

ANDREW MALLON - RELATOR

DATED: _____ BY: _____

Andrew Mallon

THE UNITED STATES OF AMERICA

DATED: _____ BY: _____

Nickolas Bohl
Assistant United States Attorney
Western District of Washington

DATED: _____ BY: _____

Erin Collieran
Trial Attorney
Commercial Litigation Branch, Civil Division
United States Department of Justice

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES

DATED: _____ BY: _____

SUSAN E. GILLIN
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Service

ATHIRA PHARMA, INC. - DEFENDANT

DATED: _____ BY: _____

Mark Worthington
General Counsel, Athira Pharma, Inc.

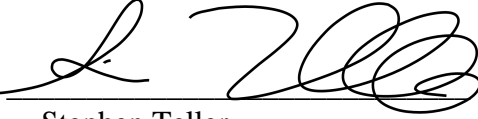
DATED: _____ BY: _____

Gregory L. Watts
Counsel for Athira Pharma, Inc.

ANDREW MALLON - RELATOR

DATED: 15-Dec-2024 BY: _____


Andrew Mallon

DATED: _____ BY: 
Stephen Teller
Counsel for Andrew Mallon