

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 Office of Inspector General (“OIG-HHS”) of the Department of Health and Human Services (“HHS”), the Defense Health Agency (“DHA”), acting on behalf of the TRICARE Program, (collectively, the “United States”), Assertio Therapeutics, Inc., f/k/a/ Depomed, Inc. (“Assertio”) and Relators Nicole Novellino and Noelle Webb (“Relators”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. Assertio is a Delaware corporation with its principal place of business in Lake Forest, Illinois. From 2013 to 2017, Assertio manufactured and sold Lazanda, a transmucosal immediate-release fentanyl (“TIRF”) drug approved by the Food and Drug Administration (“FDA”) for the management of breakthrough cancer pain in opioid tolerant adult cancer patients.

B. On October 30, 2017, Noelle Webb filed a qui tam action in the United States District Court for the District of Columbia captioned *United States ex rel. Webb v. Depomed, Inc.*, Case No. 1:17-cv-02309-JDB, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). On April 26, 2018, an Amended Complaint was filed in the Civil Action, adding Nicole Novellino as a relator. The United States intervened in the Civil Action on July 3, 2024, as to allegations that Assertio caused false claims for reimbursement under Medicare Part D and TRICARE to be submitted for Lazanda.

C. The United States contends that Assertio submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C.

§§ 1395-1395lll (“Medicare”) and the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”).

D. Medicare covers only drugs that are used for a medically accepted indication, which means a use that is approved under the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, or a use which is supported by one or more citations included or approved for inclusions in one of the specified compendia. *See* 42 U.S.C. § 1395w-102(e)(1), (e)(4); *id.* § 1396r-8(g)(1)(B)(i), (k)(6); 42 C.F.R. § 423.100. TRICARE regulations define off-label use of drugs approved by the FDA as “[a] use other than an intended use for which the prescription drug . . . is legally marketed under the FDCA or the Public Health Services Act,” including “any use that is not included in the approved labeling” of the drug. *See* 32 C.F.R. § 199.2. TRICARE does not cover off-label uses of drugs unless such off-label use is proven medically necessary, safe, and effective by medical literature, national organizations, or technology assessment bodies and in accordance with nationally accepted standards of practice in the medical community. *See* 32 C.F.R. § 199.4(g)(15)(i)(A).

E. The United States contends that it has certain civil claims against Assertio arising from Assertio’s marketing and sale of Lazanda during the period from August 1, 2013, through December 31, 2017 (hereinafter referred to as the “Covered Conduct”). Specifically, the United States alleges the following:

- Assertio, then known as Depomed, Inc., acquired the rights to manufacture and market Lazanda in July 2013. Lazanda, a fentanyl nasal spray, was approved by the FDA in June 2011 for the management of breakthrough pain in cancer patients, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. The FDA has never expanded the approved use of Lazanda, and the compendia recognized by the

Centers for Medicare and Medicaid Services (“CMS”) do not support any other indications.

- After acquiring Lazanda in July 2013, Assertio focused its marketing on pain specialists who were prescribing high volumes of TIRF products, including those who were flagged for diversion or who were later indicted. Assertio placed high-volume TIRF prescribers on its speakers’ bureau and advisory boards. Assertio developed its “Signature Support Program” to ensure that Lazanda prescriptions would be approved by insurance companies, including Medicare Part D plans.
- As a result of Assertio’s marketing, prescribers wrote Lazanda prescriptions for Medicare and TRICARE beneficiaries who did not have breakthrough cancer pain.
- As a result of the foregoing conduct, the United States contends that Assertio caused false claims to be submitted to Medicare and TRICARE from thirteen prescribers, which are identified in a separate letter from the United States to Assertio.

F. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relators’ reasonable expenses, attorneys’ fees and costs.

G. This Agreement is neither an admission of liability by Assertio, nor a concession by the United States or Relators that their claims were not well-founded.

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. Assertio shall pay to the United States three million, six hundred thousand dollars (\$3,600,000) (the “Settlement Amount”) and interest on the Settlement Amount at a rate of 4.25% per annum from December 9, 2024, of which \$1,800,000 is restitution, no later than ten days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

2. Conditioned upon the United States receiving the Settlement Amount and as soon as feasible after receipt, the United States shall pay \$657,000 to Relators by electronic funds transfer (“Relators’ Share”).

3. Relators and Assertio have separately resolved Relators’ claims for expenses, attorneys’ fees and costs.

4. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and upon the United States’ receipt of the Settlement Amount plus interest due under Paragraph 1, the United States releases Assertio, together with its current and former parent corporations; direct and indirect subsidiaries; affiliates and/or brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them (the “Released Assertio Parties”), 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 theory of unjust enrichment.

5. Subject to the exceptions in Paragraph 6 below, and upon the United States’ receipt of the Settlement Amount, plus interest due under Paragraph 1, Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, release the Released Assertio

Parties from any civil monetary claim the Relators have 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 Paragraphs 4 and 5 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 this Agreement, any administrative liability or enforcement right, including mandatory or permissive exclusion from Federal health care programs;
- 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. Relators and their 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 Relators' receipt of the Relators' Share, Relators and their 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. Relators, for themselves, and for their heirs, successors, attorneys, agents, and assigns, release the Released Assertio Parties, and their officers, agents, and employees, from any liability to Relators arising from the facts and circumstances alleged by the Relators in the Civil Action, the Covered Conduct, or the filing of the Civil Action, or under 31 U.S.C. § 3730(d), or any other statute or legal authority, including for expenses or attorneys' fees and costs.

9. Assertio waives and shall not assert any defenses Assertio 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. Assertio 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 Assertio 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. Notwithstanding the foregoing, Assertio reserves all defenses to all claims reserved by the United States pursuant to paragraph 6.

11. Assertio fully and finally releases the Relators from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Assertio has asserted, could have asserted, or may assert in the future against the Relators, related to the facts and circumstances alleged by the Relators in the Civil Action, the Covered Conduct, or the Relators' investigation and prosecution of the Civil Action.

12. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (*e.g.*, Medicare Administrative Contractor, fiscal intermediary, carrier), TRICARE contractor, or any state payer, related to the Covered Conduct; and Assertio agrees not to resubmit to any Medicare contractor, TRICARE contractor, or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

13. Assertio agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Assertio, 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) Assertio'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; and
- (5) the payment Assertio makes to the United States pursuant to this Agreement and any payments that Assertio may make to Relators, including costs and attorneys' fees

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program ("FEHBP") (hereinafter referred to as "Unallowable Costs").

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Assertio, and Assertio shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Assertio or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Assertio further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Assertio or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of

the Unallowable Costs. Assertio agrees that the United States, at a minimum, shall be entitled to recoup from Assertio any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Assertio or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Assertio or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Assertio's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

14. Assertio agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Assertio 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. Assertio 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.

15. Except to the extent this Agreement grants a release to persons or entities other than the Parties, this Agreement is intended to be for the benefit of the Parties only. The Parties

do not release any claims against any person or entity other than those identified herein, except to the extent provided for in Paragraph 16 (waiver for beneficiaries paragraph), below.

16. Assertio agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors based upon the claims identified within the scope of Covered Conduct.

17. Upon receipt of the payment described in Paragraph 1, above, the United States and Relators shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action, in its entirety, pursuant to Rule 41(a)(1). Such dismissal shall be with prejudice as to all of Relators' claims, with prejudice as to the United States' claims as to the Covered Conduct, and without prejudice to the United States as to all other claims.

18. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement, with the exception of the expenses, attorney's fees and costs referred to in Paragraph 3, which are addressed in a separate agreement.

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

20. 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 District of Columbia. 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.

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

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

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

24. This Agreement is binding on Assertio's successors, transferees, heirs, and assigns.

25. This Agreement is binding on Relators' successors, transferees, heirs, and assigns.

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

27. This Agreement is effective once all Parties have signed it and on the date of signature of the last signatory to the Agreement ("Effective Date of this Agreement").

Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 5/8/25

BY: *Sarah M. Arni*
Sarah M. Arni
Senior Trial Counsel
Matthew Arrow
Trial Attorney
Natalie A. Waites
Assistant Director
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____
Darrell Valdez
Assistant United States Attorney
District of Columbia

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 Services

DATED: _____ for

BY: _____
Salvatore M. Maida
General Counsel
Defense Health Agency
United States Department of Defense

THE UNITED STATES OF AMERICA


DATED: _____

BY: _____

Sarah M. Arni
Senior Trial Counsel
Matthew Arrow
Trial Attorney
Natalie A. Waites
Assistant Director
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 5/7/205

BY: _____


Darrell Valdez
Assistant United States Attorney
District of Columbia

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 Services

DATED: _____
for

BY: _____

Salvatore M. Maida
General Counsel
Defense Health Agency
United States Department of Defense

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

Sarah M. Arni
Senior Trial Counsel
Matthew Arrow
Trial Attorney
Natalie A. Waites
Assistant Director
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____

Darrell Valdez
Assistant United States Attorney
District of Columbia

DATED: 5/7/25

BY: _____

SUSAN GILLIN

Digitally signed by SUSAN
GILLIN
Date: 2025.05.07 17:13:22
-04'00'

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 Services

DATED: _____

for

BY: _____

Salvatore M. Maida
General Counsel
Defense Health Agency
United States Department of Defense

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____
Sarah M. Arni
Senior Trial Counsel
Matthew Arrow
Trial Attorney
Natalie A. Waites
Assistant Director
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: _____

BY: _____
Darrell Valdez
Assistant United States Attorney
District of Columbia

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 Services


DATED: 05/07/2025
for

BY: _____
BLEY.PAUL.NICHOLAS.1099873821
LAS.1099873821
Salvatore M. Maida
General Counsel
Defense Health Agency
United States Department of Defense

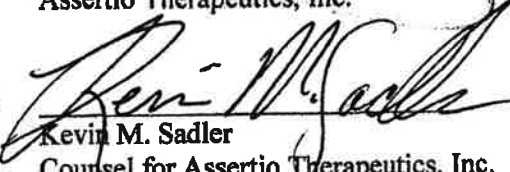
Digitally signed by
BLEY.PAUL.NICHOLAS.10998738
21
Date: 2025.05.07 09:37:39 -04'00'

DEFENDANT

DATED: May 8, 2025

BY: 
Brendan O'Grady, CEO
Assertio Therapeutics, Inc.

DATED: May 8, 2025

BY: 
Kevin M. Sadler
Counsel for Assertio Therapeutics, Inc.

NOELLE WEBB AND NICOLE NOVELLINO- RELATORS

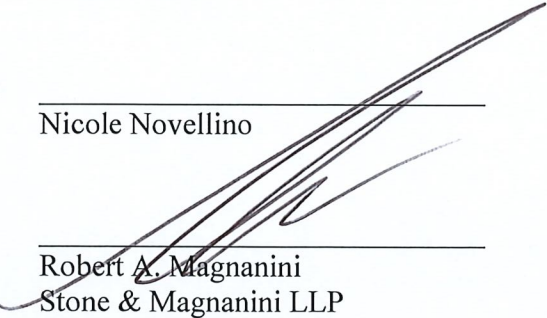
DATED: 5/8/2025 _____

BY:  _____
Noelle Webb

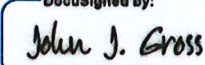
DATED: _____

BY: _____
Nicole Novellino

DATED: 5/8/25 _____

BY:  _____
Robert A. Magnanini
Stone & Magnanini LLP
Counsel for Relators

DATED: 5/8/2025 _____

BY:  _____
John J. Gross
The Weiser Law Firm, P.C.
Counsel for Relators

NOELLE WEBB AND NICOLE NOVELLINO- RELATORS


DATED: _____

BY: _____
Noelle Webb

DATED: 5/8/25

BY:  _____
Nicole Novellino

DATED: 5/8/25

BY:  _____
Robert A. Magnanini
Stone & Magnanini LLP
Counsel for Relators

DATED: _____

BY: _____
John J. Gross
The Weiser Law Firm, P.C.
Counsel for Relators