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") (collectively, the "United States"), and Somerset Lifesciences, Inc. ("Somerset") (all hereafter collectively referred to as the "Parties"), through their authorized representatives.

RECITALS

A. Somerset is a privately-owned pharmaceutical company that primarily markets generic injectable and ophthalmic drugs. Somerset is based in Somerset, New Jersey.

B. In December 2015, the U.S. Food and Drug Administration ("FDA") approved Somerset's Abbreviated New Drug Application ("ANDA") 206306 for olopatadine hydrochloride ophthalmic solution USP, 0.1% ("Olopatadine"). Olopatadine is a generic version of the brand name drug Pataday Twice Daily Relief (olopatadine hydrochloride ophthalmic solution), 0.1%, f/k/a Patanol ("Pataday"), which is manufactured by Alcon Laboratories, Inc. Pataday is the reference listed drug ("RLD") for Olopatadine. Pataday and Olopatadine were initially approved by the FDA to be sold as prescription-only ("Rx") and not over-the-counter ("OTC"). On or about February 14, 2020, the FDA approved a full Rx-to-OTC switch for Pataday. At this point, absent a meaningful difference between the Rx and OTC versions of Pataday, federal law required updated labeling on Olopatadine to reflect that its RLD had switched to OTC and was no longer Rx-only, or seek to withdraw the ANDA. However, Somerset continued to sell Olopatadine as Rx-only.

C. Medicare Part D provides coverage for "covered Part D drugs," which is defined under 42 C.F.R. § 423.100 to include drugs "that may be dispensed only upon a prescription" and does not include OTC products.

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D. The United States contends that it has certain civil claims against Somerset arising from Somerset manufacturing, labeling, marketing, and selling Olopatadine as Rx-only from February 14, 2020 until October 17, 2023. During this time, Olopatadine's RLD was approved as OTC and was no longer approved as Rx-only. Still, Somerset continued to label Olopatadine as Rx-only and sold it into the market, which the United States contends caused claims for Olopatadine to be submitted to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll ("Medicare"). The United States contends that this caused the government to pay federal funds it should not have and caused Somerset to indirectly receive federal funds from Medicare to which it was not entitled. This conduct is referred to below as the "Covered Conduct."

E. This Agreement is neither an admission of liability by Somerset, nor a concession by the United States that its contentions relating to the Covered Conduct are 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 Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Somerset agrees to pay the United States the sum four million dollars ($4,000,000) plus interest (the "Settlement Amount"), all of which constitutes restitution, no later than 10 business 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. Subject to the exceptions in Paragraph 3 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount due under Paragraph 1, the United States releases Somerset together with its current and former parents, divisions, subsidiaries,

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successors, and assigns from any civil monetary claim the United States has for the Covered Conduct under the common law theories of payment by mistake and unjust enrichment.

3. Notwithstanding the release given in Paragraph 2 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 liability arising under 31 U.S.C. §§ 3729–3733 (the False Claims Act);

c. Any criminal liability;

d. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory or permissive exclusion from Federal health care programs;

e. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

f. Any liability based upon obligations created by this Agreement;

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; or

i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

4. Somerset waives and shall not assert any defenses Somerset 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

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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.

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

6. 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) or any state payer, related to the Covered Conduct; and Somerset agrees not to resubmit to any Medicare 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.

7. Somerset 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 Somerset 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;

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(3) Somerset'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 Somerset makes to the United States pursuant to this Agreement;

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 Somerset, and Somerset 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 Somerset or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Somerset 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 Somerset or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information

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reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Somerset agrees that the United States, at a minimum, shall be entitled to recoup from Somerset 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 Somerset or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Somerset 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 Somerset's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

8. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 9 (waiver for beneficiaries paragraph), below.

9. Somerset 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 defined as Covered Conduct.

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

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

12. This Agreement is governed by the laws of the United States. The exclusive 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.

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

14. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the person or entity indicated below.

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

16. This Agreement is binding on Somerset's successors, transferees, heirs, and assigns.

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

18. This Agreement is effective 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.

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THE UNITED STATES OF AMERICA

DATED: _____ BY: VINCENT VACCARELLA Digitally signed by VINCENT VACCARELLA Date: 2026.10.08 12:16:03 -04'00'

Vincent Vaccarella
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

SOMERSET LIFESCIENCES, INC.

DATED: 10/15/26 BY: _____

Veerappan Subramanian
CEO & Chairman

DATED: 10/15/26 BY: _____

D. Jacques Smith
Nadia A. Patel
ArentFox Schiff LLP
Counsel for Somerset Lifesciences, Inc.

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