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") and the Defense Health Agency ("DHA"), acting on behalf of the TRICARE Program (collectively, the "United States"); defendant Veloxis Pharmaceuticals, Inc. ("Veloxis"); and Toulsor1, Inc. and the Settlor and current sole Beneficiary of the First Amended and Restated Toulsor1 Trust executed on July 9, 2026 ("Toulsor1 Trust") (together, "Relator"), through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

RECITALS

A. Veloxis Pharmaceuticals, Inc., a Delaware corporation headquartered in Cary, North Carolina, manufactures, markets, and sells in the United States a kidney transplant immunosuppression drug, known as Envarsus XR ("Envarsus").

B. On August 21, 2020, Relator filed a *qui tam* action against Veloxis Pharmaceuticals A/S in the United States District Court for the District of Massachusetts captioned *United States et al. ex rel. Toulsor1, Inc. v. Veloxis Pharmaceuticals A/S*, No. 1:20-cv-11575-FDS (D. Mass.), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) ("the Civil Action"). On August 4, 2021, Relator filed an Amended Complaint in the Civil Action naming the settling party, Veloxis, as a defendant. On June 29, 2026, with respect to the claims in the Civil Action against Veloxis, the United States filed a Notice of Partial Intervention for Purposes of Settlement that disclosed the names of the settling parties and the identity of [redacted].

C. The United States contends that Veloxis 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"); the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid"); and the TRICARE Program, 10 U.S.C. §§ 1071-1110b ("TRICARE").

D. Separately, Veloxis and the United States Attorney's Office for the District of Massachusetts will enter into a Deferred Prosecution Agreement ("Deferred Prosecution Agreement") as to a one-count Information, pursuant to which Veloxis will admit to conspiracy to commit violations of the Federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, in violation of 18 U.S.C. § 371, during the years 2016 through 2023.

E. Veloxis admits, acknowledges, and accepts responsibility for the facts as set forth in Exhibit C hereto and for the following additional facts:

(1) During the period of January 1, 2016 to June 30, 2023, Veloxis manufactured and sold Envarsus, an extended-release drug approved by the U.S. Food & Drug Administration ("FDA") for use as an immunosuppressant in adult kidney transplant recipients. Envarsus competed against other medications, including a low-cost generic, for market share. Due to the availability of the cheaper generic, Veloxis initially struggled to gain market share for Envarsus. In an effort to increase Envarsus's market share, Veloxis promoted Envarsus to influential health care professionals, including surgeons, nephrologists, nurse practitioners, pharmacists, and administrators at strategically important transplant centers and hospitals in Exhibit A hereto ("Hospitals"). Veloxis also encouraged the specialty pharmacies in Exhibit B hereto ("Pharmacies") to purchase Envarsus to dispense to transplant patients discharged from Hospitals.

(2) During the period of January 1, 2016 to June 30, 2023, Veloxis engaged in aggressive marketing efforts to increase sales of Envarsus. Veloxis's marketing tactics included paying kickbacks to surgeons, nephrologists, nurse practitioners, pharmacists, and administrators of the Hospitals in the form of lavish meals, alcoholic beverages, expensive trips, resort stays,

gifts, and purported consulting fees. Veloxis paid those kickbacks to induce those surgeons, nephrologists, nurse practitioners, pharmacists, and administrators to prescribe, recommend purchasing or ordering of, and/or arrange for prescriptions of, Envarsus. Veloxis concealed those kickbacks in a variety of ways, including by (a) falsifying company expense reports and business records as to the recipients, amounts, and purpose of the payments; (b) paying transplant health care professionals of the Hospitals pursuant to consulting agreements for purported consulting work that was not actually performed; and (c) failing to properly report to the Centers for Medicare & Medicaid Services ("CMS") pursuant to the Open Payments Program ("OPP"), 42 U.S.C. § 1320a-7h, the amounts of Veloxis' payments or transfers of value to surgeons and nephrologists of the Hospitals.

(3) During the period of July 1, 2017 to March 31, 2023, Veloxis knowingly and willfully paid thousands of dollars in kickbacks to the Pharmacies in the form of per-patient and per-month payments to induce those pharmacies to purchase Envarsus. Veloxis made the payments pursuant to purported Enhanced Services Agreements ("ESAs") that Veloxis entered into with the Pharmacies. At the direction of Veloxis's former Chief Executive Officer ("CEO"), former Vice President of Market Access, and former Vice President of Sales, Veloxis offered the payments specified in the ESAs to the Pharmacies to induce them to begin or continue purchasing Envarsus instead of competitor drugs, including a cheaper generic. Veloxis disguised the unlawful purpose of the kickback payments to the Pharmacies by falsely describing the payments in the ESAs as being for data and/or adherence services provided to or for Veloxis. In fact, Veloxis paid the Pharmacies thousands of dollars per month regardless of whether the Pharmacies provided any data, provided the specified data fields, or provided the data in the specified format. Even when the Pharmacies sent the data to Veloxis, typically no one at Veloxis reviewed or used the data. Likewise, Veloxis paid the Pharmacies on a per-patient, per-month basis for purported adherence

services, but did not know and never confirmed whether the Pharmacies actually performed any services to justify the payments.

(4) During the period of March 31, 2020 to March 31, 2023, as specified in Exhibit C hereto, Veloxis employees knowingly falsified company expense reports to conceal or understate the amounts of transfers of value to surgeons, nephrologists, nurse practitioners, pharmacists, and administrators of the Hospitals by adding the names of non-attendees to lists of attendees of certain meals or events (to artificially reduce the purported per-person cost attributed to the physician attendees), omitting the names of physician attendees, and falsely labeling certain physician expenses using a category for non-physician expenses. For calendar years 2019 to 2022, Veloxis reported to CMS, under the OPP, 42 U.S.C. § 1320a-7h, the payments and transfers of value to physicians of the Hospitals that were reflected in Veloxis employees' falsified expense reports, which resulted in Veloxis underreporting, or failing to report, the true amounts of its payments or transfers of value to those physicians of the Hospitals.

F. The following conduct is referred to below as the Covered Conduct:

(1) The United States contends that it has certain civil claims against Veloxis for knowingly causing the submission of claims to Medicare, Medicaid, and TRICARE during the period of January 1, 2016 to June 30, 2023 for Envarsus prescriptions written by healthcare providers at the Hospitals or filled by the Pharmacies during the time periods specified in Exhibits A and B hereto that were false or fraudulent because of the conduct described in Recitals E(2)–(3) above and Exhibit C hereto, by which Veloxis knowingly and willfully paid kickbacks to the Hospitals and Pharmacies to induce prescriptions of Envarsus in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b).

(2) The United States contends that it has claims against Veloxis under OPP and associated regulations, 42 C.F.R. §§ 403.900–.914 ("OPP Regulations"), during the period of

March 31, 2020 to March 31, 2023 because of the conduct described in Recital E(4) above and Exhibit C hereto, by which Veloxis knowingly failed to report to CMS through its OPP the amounts of Veloxis's payments or transfers of value to physicians of the Hospitals.

G. Veloxis received credit under the United States Department of Justice's guidelines for taking disclosure, cooperation, and remediation into account in False Claims Act cases, Justice Manual § 4-4.112. The cooperation Veloxis provided included identifying individuals involved in or responsible for the Covered Conduct; facilitating interviews with current and former employees; performing and disclosing facts and material not known to the government but relevant to its investigation as gathered during Veloxis's internal investigation; proactively identifying key documents, including inculpatory evidence, in the voluminous materials collected and produced in response to the Department of Justice's subpoena; engaging outside consultants to conduct a damages analysis; facilitating the collection of evidence from third-parties; identifying and separating individuals responsible for the misconduct, including, terminating their employment, obtaining the CEO's resignation, and terminating contractual arrangements with healthcare providers and pharmacies involved in the misconduct; admitting liability and accepting responsibility for the misconduct; and improving its compliance program including hiring a new Chief Compliance Officer and additional personnel.

H. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of the Federal FCA Settlement Amount (defined in Paragraph 1 below) and to Relator's reasonable expenses, attorneys' fees and costs. Relator claims entitlement under separate state false claims laws to a share of the proceeds of the State Settlement Amount (defined in Paragraph 1 below) and to Relator's reasonable expenses, attorneys' fees and costs.

I. Veloxis has entered into, or will be entering into, separate settlement agreements described below in Paragraph 1(a)(ii) ("Medicaid State Settlement Agreements") with the certain

states ("Medicaid Participating States") in settlement of the conduct released in those separate Medicaid State Settlement Agreements. Relator claims entitlement under 31 U.S.C. § 3730(d), and State equivalents, to a share of the proceeds of the Medicaid State Settlement Agreements.

In consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Veloxis shall pay to the United States the sums specified in this Paragraph under the terms and conditions specified herein.

a. With respect to the Covered Conduct in Recital F(1) above, Veloxis shall pay to the United States and the Medicaid Participating States the sum of Thirty-Four Million Four Hundred Fifty Thousand Dollars ($34,450,000.00) plus interest at the rate of four and one-quarter percent (4.25%) per annum from April 16, 2026, and continuing until and including the date of payment ("FCA Settlement Amount") as follows:

(i) Veloxis shall pay to the United States the sum of Twenty-One Million Two Hundred and Eleven Thousand Two Hundred and Fifty Dollars and Ninety-Nine Cents ($21,211,250.99), of which Twelve Million One Hundred Twenty Thousand Seven Hundred and Fourteen Dollars and Eighty-Five Cents ($12,120,714.85) is restitution, plus accrued interest as set forth above ("Federal FCA Settlement Amount"), no later than thirty (30) calendar days after the Effective Date (defined below) by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

(ii) Veloxis shall pay to the Medicaid Participating States the total sum of Thirteen Million Two Hundred Thirty-Eight Thousand Seven Hundred and Forty-Nine Dollars and One Cent ($13,238,749.01), of which Seven Million Five Hundred Sixty-Four Thousand Nine Hundred and Ninety-Nine Dollars and Forty-Three Cents ($7,564,999.43) is restitution, plus

accrued interest as set forth above ("State Settlement Amount"), pursuant to written instructions from the National Association of Medicaid Fraud Control Units ("NAMFCU") State Team and under the terms and conditions of the separate agreements that Veloxis has entered into, or will enter into, with the Medicaid Participating States.

b. With respect to the OPP Covered Conduct in Recital F(2) above, Veloxis shall pay to the United States the sum of One Million Five Hundred Fifty Thousand Dollars ($1,550,000.00) plus interest at the rate of four and one-quarter percent (4.25%) per annum from January 23, 2026, and continuing until and including the date of payment ("OPP Settlement Amount"), no later than thirty (30) calendar days after the Effective Date by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice.

2. a. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, subject to Paragraph 14 (concerning default) below, and conditioned upon the United States' receipt of the Federal FCA Settlement Amount, the United States releases Veloxis together with its current and former parent corporations; direct and indirect subsidiaries; divisions; current or former corporate owners; and the corporate successors and assigns of any of them (collectively, the "Veloxis Parties") from any civil or administrative monetary claim the United States has for the Covered Conduct in Recital F(1) 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 payment by mistake, unjust enrichment, and fraud. This Agreement does not release any claims of any State.

b. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, subject to Paragraph 14 (concerning default) below, and conditioned upon the United States' receipt of the OPP Settlement Amount, the United States releases the Veloxis Parties from

any civil or administrative monetary claim the United States has for the Covered Conduct in Recital F(2) above pursuant to the OPP or OPP Regulations.

3. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, subject to Paragraph 14 (concerning default) below, and conditioned upon the United States' receipt of the Federal FCA Settlement Amount, Relator, for itself and for its heirs, successors, attorneys, agents, and assigns, releases Veloxis 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.

4. In consideration of the obligations of Veloxis in this Agreement and the Corporate Integrity Agreement ("CIA"), entered into between OIG-HHS and Veloxis, and upon the United States' receipt of full payment of the Federal FCA Settlement Amount and OPP Settlement Amount, the OIG-HHS shall release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Veloxis under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this paragraph and in Paragraph 5 (concerning reserved claims) below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Veloxis from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 5, below.

5. Notwithstanding the releases given in Paragraphs 2 and 4 above 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 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.

6. Relator and its 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). In connection with this Agreement and this Civil Action, Relator and its heirs, successors, attorneys, agents, and assigns agree that neither this Agreement, any intervention by the United States in the Civil Action in order to dismiss the Civil Action or any claims therein, nor any dismissal of the Civil Action or any claims therein,

shall waive or otherwise affect the ability of the United States to contend that provisions in the False Claims Act, including 31 U.S.C. §§ 3730(d)(3) and 3730(e), bar Relator from sharing in the proceeds of this Agreement. Moreover, the United States and Relator and its heirs, successors, attorneys, agents, and assigns agree that they each retain all of their rights pursuant to the False Claims Act on the issue of the share percentage, if any, that Relator should receive of any proceeds of the Federal FCA Settlement Amount, and that no agreements concerning the Relator's share of the Federal FCA Settlement Amount have been reached to date.

7. Relator, for itself, and for its heirs, successors, attorneys, agents, and assigns, releases Veloxis, and its officers, agents, and employees, from any liability to Relator arising from the filing of the Civil Action except as to its rights under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs. Conditioned upon Relator's receipt of attorneys' fees and costs under 31 U.S.C. § 3730(d), once determined, Relator and its heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge Veloxis, and its heirs, successors, attorneys, agents, assigns, 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 attorneys' fees and costs associated with the Covered Conduct in the Agreement.

8. Veloxis waives and shall not assert any defenses Veloxis 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.

9. Veloxis 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 Veloxis 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 Civil Action, the Covered Conduct, or the United States' investigation or prosecution thereof.

10. Veloxis fully and finally releases the Relator from any claims that Veloxis has asserted, could have asserted, or may assert in the future against the Relator, related to the Civil Action, the Covered Conduct, or the Relator's investigation and prosecution thereof but reserves its right to dispute Relator's claims for attorneys' fees, costs, and expenses of every kind and however denominated under 31 U.S.C. § 3730(d).

11. 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 carrier or payer, or any state payer, related to the Covered Conduct; and Veloxis agrees not to resubmit to any Medicare contractor, TRICARE carrier or payer, 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.

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

(1) the matters covered by this Agreement and any plea agreement or deferred prosecution agreement;

(2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

(3) Veloxis's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);

(4) the negotiation and performance of this Agreement and any plea agreement or deferred prosecution agreement;

(5) the payment Veloxis makes to the United States pursuant to this Agreement and any payments that Veloxis may make to Relator, including costs and attorneys' fees; and

(6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS;

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). However, nothing in paragraph 12.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Veloxis.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Veloxis, and Veloxis 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 the Veloxis Parties to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Veloxis further agrees that within ninety (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 the Veloxis Parties, 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. Veloxis agrees that the United States, at a minimum, shall be entitled to recoup from Veloxis 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 the Veloxis Parties on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on the Veloxis Parties' 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 the Veloxis Parties' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

13. Veloxis agrees to cooperate fully, truthfully, completely, and forthrightly with the United States' investigation(s) of, and/or legal proceeding(s) against, individuals and entities not released in this Agreement. Veloxis agrees to encourage, and not impair, the cooperation of Veloxis's directors, officers, and employees, and to use its best efforts to make available, and encourage, the cooperation of Veloxis's former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Veloxis 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 their possession, custody, or control relating to the Covered Conduct, the individuals or entities referenced in the Covered Conduct, the healthcare providers who prescribed Envarsus, or the pharmacies that filled Envarsus prescriptions.

14. The Federal FCA Settlement Amount and OPP Settlement Amount represent the amounts the United States are willing to accept in compromise of its civil claims against Veloxis arising from the Covered Conduct pursuant to the terms and conditions in this Agreement.

a. Veloxis shall be in default of this Agreement (Default) if Veloxis fails to pay the Federal FCA Settlement Amount and/or the OPP Settlement Amount as provided in Paragraph 1 above, or if Veloxis fails to comply materially with any other term or condition of this Agreement, including Paragraph 13 above (concerning cooperation).

b. If Veloxis fails to pay the Federal FCA Settlement Amount and/or the OPP Settlement Amount as provided in Paragraph 1 above, the United States will provide a written Notice of Default, and Veloxis shall have an opportunity to cure such Default within seven (7) calendar days from the date of receipt of the Notice of Default by making the payment due and paying any additional interest accruing under the Settlement Agreement up to the date of payment. Notice of Default will be delivered to Veloxis or to such other representative as Veloxis

shall designate in advance in writing. If Veloxis fails to cure the Default within seven (7) calendar days of receiving the Notice of Default and in the absence of an agreement with the United States to a modified payment schedule (Uncured Default), any remaining unpaid balance(s) of the Federal FCA Settlement Amount and OPP Settlement Amount shall become immediately due and payable, and interest on the remaining unpaid balance shall thereafter accrue at the rate of twelve percent (12%) per annum, compounded daily from the date of Default, on the remaining unpaid total (principal and interest balance).

c. In the event of Uncured Default, or a failure to comply materially with Paragraph 13 above (concerning cooperation), Veloxis agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement, and bring any civil and/or administrative claim, action, or proceeding against Veloxis for the claims that would otherwise be covered by the releases provided in Paragraphs 2 and 4 above, with any recovery reduced by the amount of any payments previously made by Veloxis to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action; (iii) offset the remaining unpaid balance from any amounts due and owing to the Veloxis Parties by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States pursues a collection action, Veloxis agrees immediately to pay the United States the greater of (i) a ten percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States opts to rescind this Agreement pursuant to this Paragraph, Veloxis waives and agrees not to plead, argue, or otherwise raise any defenses of statute

of limitations, laches, estoppel or similar theories, to any civil or administrative claims that (i) are filed by the United States against Veloxis within one hundred twenty (120) days of written notification that this Agreement has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date. Veloxis agrees not to contest any offset, recoupment, and/or collection action undertaken by the United States pursuant to this Paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

d. In the event of Uncured Default, or a failure to comply materially with Paragraph 13 above (concerning cooperation), OIG-HHS may exclude Veloxis from participating in all Federal healthcare programs (Exclusion for Default). OIG-HHS will provide written notice of any such exclusion to Veloxis. Veloxis waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Veloxis wishes to apply for reinstatement, Veloxis must submit a written request for reinstatement to OIG-HHS in accordance with the provisions of 42 C.F.R. §§ 1001.3001–.3005. Veloxis will not be reinstated unless and until OIG-HHS approves such request for reinstatement. The option for Exclusion for Default is in addition to, and not in lieu of, the options identified in this Agreement or otherwise available.

15. 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 16 (waiver for beneficiaries paragraph), below.

16. Veloxis 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.

17. Upon receipt of the Federal FCA Settlement Amount and the OPP Settlement Amount, the Parties 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 Joint Stipulation of Dismissal shall be with prejudice as to the Relator's claims in the Civil Action against Veloxis and with prejudice as to the United States' and the Relator's claims as to the Covered Conduct and consistent with the terms and conditions of this Agreement. The Joint Stipulation of Dismissal shall be without prejudice to the United States as to any other claims in the Civil Action against Veloxis not addressed by the Covered Conduct.

18. Except as provided in Paragraphs 7 and 10 above, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

19. Each Party and signatory to this Agreement represents that it freely and voluntarily enters in to 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 Massachusetts. 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 Veloxis's successors, transferees, heirs, and assigns.

25. This Agreement is binding on Relator's 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 on the date of signature of the last signatory to the Agreement ("Effective Date"). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

[SIGNATURE PAGE(S) AND EXHIBITS A, B, AND C FOLLOW]

THE UNITED STATES OF AMERICA

DATED: 8/10/2026 BY: 

CHRISTOPHER TERRANOVA
Assistant Director
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 8/10/2026 BY: 

STEVEN T. SHAROBEM
LINDSEY E. WEINSTEIN
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

DATED: 8/5/2026 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: _____ BY: _____

SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of Defense

THE UNITED STATES OF AMERICA

DATED: _____ BY: _____

CHRISTOPHER TERRANOVA
Assistant Director
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 8/10/2026 BY: _____

STEVEN T. SHAROBEM
LINDSEY E. WEINSTEIN
Assistant United States Attorneys
United States Attorney's Office
District of Massachusetts

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: 8/10/2026 BY: BORKENHAGEN.WESTON.EARL.1138755149 Digitally signed by BORKENHAGEN.WESTON.EARL.1138755149 Date: 2026.08.10 07:29:43 -04'00'

SALVATORE M. MAIDA
General Counsel
Defense Health Agency
United States Department of Defense

For

VELOXIS

DATED: 5 Aug 2026 BY: _____

STACY G. WHEELER
Chief Executive Officer
Veloxis Pharmaceuticals, Inc.

DATED: 6 Aug. 2026 BY: _____

D. JACQUES SMITH
NADIA PATEL
ArentFox Schiff LLP
Counsel for Veloxis Pharmaceuticals, Inc.

RELATOR

DATED: Aug 3, 2026 BY: 

MARK KLEIMAN
Officer and Director of Toulsor1, Inc. and
Trustee of the Toulsor1 Trust, signing after disclosure to and with the consent of the Settlor and current sole Beneficiary of the Toulsor1 Trust

DATED: Aug. 3, 2026 BY: 

MARK KLEIMAN
POOJA RAJARAM
Kleiman/Rajaram

ERICA A. KELTON
EMILY STABILE
Phillips & Cohen LLP

Counsel for Relator

EXHIBIT A

Hospital	Start Date	End Date
Barnes-Jewish Hospital	1/1/2016	6/30/2023
Brigham and Women's Hospital	9/1/2017	6/30/2023
George Washington University Hospital	10/1/2016	6/30/2023
Hospital of the University of Pennsylvania	3/16/2021	6/30/2023
Johns Hopkins Hospital	3/23/2018	6/30/2023
Loyola University Medical Center	3/22/2022	6/30/2023
Medical University of South Carolina	5/1/2020	6/30/2023
Northwestern Hospital	10/1/2016	6/30/2023
Rush University Medical Center	1/11/2020	6/30/2023
Saint Barnabas Medical Center	10/1/2017	6/30/2023
Tampa General Hospital	5/17/2021	6/30/2023
University of Arizona Medical Center	10/1/2021	6/30/2023
University of California San Francisco Medical Center	2/21/2020	6/30/2023
University of Colorado Hospital	8/20/2020	6/30/2023
University of Illinois Medical Center	5/9/2019	6/30/2023
University of Maryland Medical Center	1/11/2020	6/30/2023
University of Pittsburgh Medical Center	7/7/2021	6/30/2023
Yale New Haven Hospital	5/20/2018	6/30/2023

EXHIBIT B

Pharmacy	Start Date	End Date
Alphascript, Inc.	4/14/2018	2/9/2023
Bala Ganapati Inc d/b/a Bergen Pharmacy	7/1/2017	3/31/2023
Goodsense Pharmacy	9/28/2020	3/31/2023
Guy Brewer Pharmacy	3/20/2022	3/31/2023
Integris Baptist Medical Ctr	1/8/2020	3/31/2023
LeMed Pharmacy	5/9/2020	3/31/2023
The Honolulu Pharmacy	8/21/2017	5/20/2022
The Transplant Pharmacy	4/1/2020	3/24/2022
Total Care Rx, Inc.	9/1/2018	3/31/2023

EXHIBIT C

Relevant Entities and Individuals

1. Veloxis Pharmaceuticals, Inc. ("Veloxis" or the "Company") is a pharmaceutical company, incorporated in Delaware, with a principal place of business in Cary, North Carolina. Veloxis is owned by Asahi Kasei Corporation, headquartered in Tokyo, Japan. Veloxis does business throughout the United States, including in the District of Massachusetts.

2. Employee 1 was an executive at Veloxis who served as Veloxis's Vice President of Market Access[1] between July 2016 and June 1, 2022, and as Vice President of Sales between October 2021 and March 22, 2023.

3. Employee 2 was an employee at Veloxis who served as: a Transplant Account Manager, Senior Transplant Specialist, and Senior Transplant Account Manager between June 29, 2015 and December 3, 2019; a National Account Executive in Market Access between December 3, 2019 and August 9, 2021; and the Director of Access and Patient Support between August 9, 2021 and March 22, 2023.

4. Employee 3 was an employee at Veloxis who served in Market Access as: a Regional Account Executive between November 2014 and July 2016; a National Account Executive between August 2016 and June 2022; and a Strategic Accounts Manager between June 2022 and March 22, 2023.

5. Employee 4 was an employee at Veloxis who served first as a Transplant Account Manager and then as: a Key Account Manager between August 2018 and August 2021; a National Account Executive in Market Access between August 2021 and April 2022; and a Regional Sales Director between April 2022 and June 2023.

[1] "Market Access" was a business unit within Veloxis intended to promote insurance coverage of and access to Envarsus.

6. Surgeon 1 was a surgeon at a Washington, D.C. hospital who specialized in organ transplant surgery.

7. Surgeon 2 was a surgeon at a Colorado hospital who specialized in organ transplant surgery.

8. Surgeon 3 was a surgeon at a Pennsylvania hospital who specialized in organ transplant surgery.

9. Nephrologist 1 was a nephrologist who worked for an Illinois-based hospital and later an Arizona-based hospital.

10. Pharmacist 1 was a pharmacist affiliated with a Massachusetts-based hospital.

11. Pharmacist 2 was a pharmacist affiliated with an Illinois-based hospital.

12. Pharmacist 3 was a pharmacist who served as the Director of Transplant Research for an Illinois-based hospital.

13. Pharmacist 4 was a pharmacist affiliated with a Colorado-based hospital.

14. Administrator 1 was a hospital administrator employed at a New Jersey-based hospital.

Veloxis's Sale of Envarsus XR

15. During the relevant period, Veloxis manufactured and sold a single drug, Envarsus XR ("Envarsus"). Envarsus is a specialized extended release once-a-day drug approved by the U.S. Food & Drug Administration ("FDA") for use as an immunosuppressant in adult kidney transplant recipients. The active pharmaceutical ingredient in Envarsus is tacrolimus, a calcineurin inhibitor. Envarsus is one of several tacrolimus-based drugs that the FDA has approved for use in adult kidney transplant recipients.

16. Kidney transplant surgery involves the transplantation of a kidney from a (living or deceased) donor into a patient suffering from end-stage renal disease or other forms of kidney failure.

17. Following transplant surgery, kidney transplant recipients require daily immunosuppressant drugs for the lifespan of the transplanted kidney to prevent rejection of the transplanted organ by the recipient's immune system. Generally, the average lifespan of a transplanted kidney is between 12 and 15 years for a kidney transplanted from a deceased donor and between 12 and 20 years for a kidney transplanted from a living donor.

18. The most common immunosuppressant drug regimen for kidney transplant recipients involves a combination of a tacrolimus-based drug, like Envarsus, together with other immunosuppressants.

19. On or about July 10, 2015, the FDA approved Envarsus for use in adult kidney transplant patients converted from another tacrolimus-based immunosuppressant drug regimen. On or about December 19, 2018, the FDA approved Envarsus for *de novo* use with kidney transplant patients, *i.e.* for use in new kidney transplant patients as part of an initial immunosuppressant drug regimen.

20. During the relevant period, Envarsus competed against tacrolimus-based drugs, including the generic form of tacrolimus, for market share. Tacrolimus is a calcineurin inhibitor, a neurotoxic and nephrotoxic class of immunosuppressants, that when used to manage various autoimmune disorders, serves as essential components for immunosuppression in organ transplantation. Unlike generic tacrolimus, which kidney transplant patients needed to take twice a day, Envarsus needed to be taken only once a day and achieved the same therapeutic effect with a lower dose of tacrolimus. However, generic tacrolimus, with a wholesale acquisition cost

("WAC") of approximately $200 to $400 per month, cost much less than Envarsus, which had a WAC of approximately $800 to $1,200 per month.

21. Veloxis marketed Envarsus primarily to surgeons, nephrologists, nurse practitioners, and other health care professionals affiliated with transplant centers and hospitals who could prescribe or order the administration of Envarsus. Veloxis also marketed Envarsus to pharmacists affiliated with transplant centers and hospitals who were responsible for the purchase and clinical review of the medications that transplant health care professionals administered. In addition, Veloxis marketed Envarsus to specialty pharmacies which could purchase and dispense Envarsus for transplant patients after their discharge from the transplant center and/or hospital.

22. Due to the availability of the cheaper generic tacrolimus (and other brand drugs), Veloxis struggled to gain market share in the years immediately following the FDA's conversion use approval of Envarsus.

23. Beginning in or around 2017, in an effort to increase market share, Veloxis implemented a marketing strategy pursuant to which the Company promoted Envarsus to health care professionals at strategically important transplant centers and hospitals who could influence the placement of Envarsus on the formulary and/or protocol of their respective transplant center and/or hospital.

24. Placing Envarsus on "formulary" meant that a transplant center and/or hospital permitted its transplant health care professionals to prescribe and administer Envarsus, along with other treatment options for kidney transplant patients.

25. Placing Envarsus on "protocol" meant that a transplant center and/or hospital standardized the use of Envarsus for kidney transplant patients—that is, it lays out the circumstances in which Envarsus would be used as the default tacrolimus drug for kidney transplant patients absent a clinical need for another form of treatment.

26. The influential health care professionals to whom Veloxis promoted Envarsus included individuals who either served on their transplant center's and/or hospital's pharmacy and therapeutics ("P&T") committee, which typically made the determination to place a drug on formulary and/or protocol, or whose position and influence at the transplant center and/or hospital was significant enough to steer the P&T Committee's decision-making in this regard.

27. Veloxis benefitted financially from Envarsus's placement on a transplant center's and/or hospital's formulary or protocol, as a formulary placement meant that the transplant center and/or hospital would likely purchase Envarsus and, more favorably, a protocol placement guaranteed a transplant center's and/or hospital's purchase of Envarsus.

28. In or around April 2019, approximately four months after the FDA approved Envarsus for *de novo* use, the FDA announced a shortage of generic tacrolimus. As a result of the shortage, generic tacrolimus became difficult for transplant centers and hospitals to procure, while Envarsus was readily attainable. Veloxis viewed the shortage as a major financial opportunity. The Company increased its marketing efforts targeted at transplant health care professionals who could influence the placement of Envarsus on formulary and/or protocol at transplant centers and/or hospitals in response to the shortage of generic tacrolimus.

29. The shortage, the FDA's *de novo* approval, and Veloxis's increased marketing efforts, resulted in increased sales of Envarsus.

30. As described further below, Veloxis's marketing efforts — which continued during the relevant time period — involved tactics that violated the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS"), including but not limited to: taking transplant health care professionals to expensive dinners and on lavish trips under the guise of Market Access "advisory

boards"[2] and making payments to transplant health care professionals pursuant to consulting agreements[3] for purported consulting work that was not actually performed. In many instances, Veloxis employees submitted falsified company expense reports to conceal their illegal marketing efforts. This false reporting resulted in Veloxis's failure to properly report to the Centers for Medicare & Medicaid Services ("CMS") pursuant to the Open Payments Program ("OPP"), 42 U.S.C. § 1320a-7h, the sums it paid to transplant health care professionals, which further obscured the Company's illegal activities.

Legal Framework

A. The Anti-Kickback Statute

31. The AKS was enacted in 1972 following congressional concern that remuneration provided to those who can influence health care decisions would create incentives in conflict with the best interests of patients or would result in goods and services being provided that are medically unnecessary, of poor quality, or harmful to a vulnerable patient population. Congress strengthened the AKS by amendments in 1977, 1987, and 2010, to ensure that kickbacks masquerading as legitimate transactions did not evade the statute's reach. *See* Social Security Amendments of 1972, Pub. L. No. 62-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b; Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93; Patient Protection and Affordable Care Act, Pub. L. No. 111-148. To

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[2] Veloxis's Market Access "advisory boards" were comprised of members of Veloxis's Market Access team and various transplant health care professionals. The purported purpose of this advisory board program was for transplant health care professionals to provide strategic guidance and feedback to Veloxis on how to convince insurers to cover and reimburse Envarsus.

[3] During the relevant period, Veloxis entered into consulting agreements with various transplant health care professionals. The agreements, which often contained little to no detail about the work to be performed in exchange for compensation, set forth the amount to be paid by Veloxis to the transplant health care professional per hour of work performed and the total hours of work authorized per year.

protect the Medicare and Medicaid programs, among other federal health care programs, from these harms, Congress enacted a prohibition against the payment of kickbacks in any form.

32. Section (b) of the AKS bars the solicitation, receipt, offer, or payment of "illegal remunerations." 42 U.S.C. § 1320a-7b(b). As relevant here, Subsection (b)(2) bars the offer or payment of illegal remuneration and makes it illegal to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person … to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." *Id*. § 1320a-7b(b)(2).

33. The AKS does not define or otherwise restrict the broad ordinary meanings of "item," "service," or "good." The terms "good" and "item" under the AKS include prescription drugs such as Envarsus.

34. The AKS defines remuneration to include anything of value, including "cash" or "in-kind" payments. 42 U.S.C. § 1320a-7b(b)(2). Payments, gifts, or meals provided by a pharmaceutical company to health care professionals to induce them to write prescriptions for the company's pharmaceutical products that are ultimately paid for by federal health care programs are all examples of such illegal remuneration.

35. The AKS defines a "Federal health care program" to mean "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government," except for the health insurance program for federal employees. 42 U.S.C. § 1320a-7b(f). Medicare, Medicaid, and TRICARE—as described further below—are all "health care benefit programs" within the meaning of 18 U.S.C. § 24(b), and "Federal health care program(s)" under the AKS.

B. The Open Payments Program

36. Concerned that physicians' treatment decisions could be affected by their financial interests, Congress enacted in 2010 a national disclosure program relating to such financial interests. 42 U.S.C. § 1320a-7h. Initially, it was referred to as the Physician Payment Sunshine Act, but the disclosure program is now known as the Open Payments program. All manufacturers operating in the United States and "engaged in the prosecution, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply" must report certain information about physician payments and ownership interests. 42 U.S.C. § 1320a-7h(e)(9).

37. Pursuant to the Open Payments program, "any applicable manufacturer that provides a payment or other transfer of value" to a physician is required to report to the U.S. Department of Health and Human Services ("HHS") information about the payment or transfer, unless a reporting exclusion applies. 42 U.S.C. § 1320a-7h(a)(1)(A). For each qualifying payment or other transfer of value to a physician, an applicable manufacturer or group purchasing organization must report to HHS, among other things, the physician's name, business address, specialty, and National Provider Identifier ("NPI"); the amount of the payment or transfer; the date(s) on which the payment or transfer was provided; and descriptions of the form and nature of the payment or transfer. *Id.*

38. Applicable manufacturers are required to report the specified information on the 90th day of each calendar year, for payments and ownership interests in the preceding calendar year. 42 U.S.C. § 1320a-7h(a)(1)(A).

39. Under the Open Payments program, HHS makes certain information about the payments and ownership interests available to the public through a searchable website. 42 U.S.C.

§ 1320a-7h(c)(1)(C); *see also* https://www.cms.gov/priorities/key-initiatives/open-payments (last visited January 12, 2026).

40. Veloxis is considered a manufacturer and Envarsus is considered a covered drug under the Open Payments program.

The Relevant Federal Health Care Programs

41. Medicare is a federally funded health care program administered by the Centers for Medicare and Medicaid Services ("CMS"), a federal agency under HHS. 42 U.S.C. § 1395c *et seq*. To be eligible for Medicare, a person must be over the age of 65, be disabled, or have end-stage renal disease. Individuals who are insured or receive benefits through Medicare are often referred to as Medicare "beneficiaries."

42. The Medicare program has four "parts." Parts A and B are commonly known as "traditional" or "original" Medicare. Part D provides prescription drug benefits, for drugs including Envarsus, to Medicare beneficiaries. All persons enrolled in Medicare Part A or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. HHS, through CMS, contracts with private companies (often known as "sponsors") that are authorized to sell Part D insurance coverage. CMS regulates and subsidizes such companies pursuant to one-year, annually renewable contracts. Part D sponsors enter into subcontracts with many pharmacies to provide drugs to the Medicare beneficiaries enrolled in their plans.

43. Medicaid is a jointly funded federal and state health care program that provides certain health benefits to the disabled, as well as to individuals and families with low incomes and resources.

44. TRICARE is the uniformed services health care program for U.S. military members, retirees, and their families.

45. For eligible beneficiaries, Medicare, Medicaid, and TRICARE cover the cost of Envarsus prescriptions.

Overview

46. During the relevant period, Veloxis, its employees, and its co-conspirators engaged in a scheme to pay improper remuneration (kickbacks) to transplant health care professionals to induce those transplant health care professionals to prescribe, order, or recommend prescribing or ordering Envarsus for kidney transplant recipients.

47. These kickbacks took several forms. Veloxis provided improper remuneration to transplant health care professionals in the form of lavish meals, expensive trips and resort stays, and personal gifts. Veloxis also made large payments to transplant health care professionals under the guise of consulting agreements. These excessive payments were not for work that was actually performed but, instead, were for time spent in a manner inconsistent with the intended purpose of consulting.

48. To carry out the conspiracy, Veloxis, its employees, and its co-conspirators:

a. hosted lavish meals for transplant surgeons, nephrologists, pharmacists, a hospital administrator, and other health care professionals for the purpose of inducing those individuals to prescribe, order, or recommend prescribing or ordering Envarsus;

b. organized lavish retreats—involving flights, hotel stays, and meals at high-end restaurants—for transplant surgeons, nephrologists, pharmacists, a hospital administrator, and other health care professionals—for the purpose of inducing those individuals to prescribe, order, or recommend prescribing or ordering Envarsus;

c. purchased large quantities of alcohol for transplant surgeons, nephrologists, pharmacists, a hospital administrator, and other health care professionals in

connection with these lavish meals and retreats, belying any notion that their purpose was educational or otherwise legitimately work related;

d. paid for the attendance of spouses of transplant surgeons, nephrologists, pharmacists, a hospital administrator, and other health care professionals (who were not themselves healthcare professionals) at these lavish meals and retreats, again belying any notion that their intended purpose was educational or otherwise legitimately work related;

e. submitted falsified company expense reports to conceal these lavish meals and retreats—by falsely adding names to the list of attendees (to decrease the apparent cost per attendee of the meals) and omitting the names of health care professionals who did attend the meals (to avoid OPP reporting requirements);

f. approved payments to transplant surgeons, nephrologists, pharmacists, and other health care professionals for consulting work that they did not actually perform; and

g. provided gifts to transplant health care professionals, including in the form of expensive alcohol.

49. Additionally, in certain instances, Veloxis employees facilitated transplant health care professionals' efforts to avoid running afoul of their transplant center's and/or hospital's rules prohibiting the acceptance of improper remuneration, including in the form of trips and gifts, from pharmaceutical manufacturers. For example, in or around May 2022, Surgeon 2 requested that Veloxis permit him to attend a speaker program hosted by Veloxis during a transplant surgery conference "incognito without registering" and pay for associated expenses.

50. Veloxis intended the improper remuneration it provided to transplant health care professionals to result in increased Envarsus prescriptions, as demonstrated, in part, by

communications between Veloxis employees and certain transplant health care professionals. For example, in connection with Surgeon 2's request to attend the above-referenced speaker program, Employee 1 told Surgeon 2 that he (Employee 1) "need[ed] scripts. Lots of them." Several months prior, Employee 1 had told Surgeon 2 that he was "over Sales" and needed Surgeon 2 "more than ever," and that it was "[t]ime to open your Rolodex and make things happen."

51. Examples of the conduct described above include the following:

A. Market Access Advisory Board Retreats

i. September/October 2020: Scottsdale, Arizona

52. On or about September 30 through October 1, 2020, Veloxis, through Employees 1 and 2, hosted a market access "advisory board" retreat at a resort in Scottsdale, Arizona attended in person by Surgeon 2 and Pharmacists 2, 3, and 4. The event featured a stay at the resort and multiple lavish dinners for the retreat attendees. The lavish dinners included the consumption of high-end alcohol and were attended by spouses of certain retreat attendees.

53. At the time, Veloxis's internal policy limited the amount Market Access employees could spend on a meal for health care professionals to $125 per attendee.

54. On or about September 30, 2020, Veloxis paid more than $265 per attendee for a retreat dinner hosted at a high-end restaurant. Employee 1 submitted an expense report for the dinner and included the names of Employee 3 and three additional health care professionals (non-transplant surgeons) who did not actually attend the dinner.

55. Employee 1, on behalf of Veloxis, added the names of those four non-transplant surgeons to conceal the true cost of the meal (i.e., to artificially reduce the per attendee cost when that cost was in fact significantly higher).

56. During this same market access "advisory board" retreat, Veloxis paid more than $195 per attendee for a dinner at a high-end steakhouse on or about October 1, 2020. Pharmacist

4's wife also attended the dinner despite not being a member of Veloxis's market access advisory board. Veloxis's internal policy expressly prohibited any payments for a health care professional's spouse.

57. Employee 1, on behalf of Veloxis, submitted an expense report for the October 1, 2020 dinner that did not identify Surgeon 2 or Pharmacist 4's wife as attendees at the dinner, at least in part to avoid the Open Payments program's reporting requirements.

58. In addition to these dinners, Veloxis paid more than $486 per night for the hotel stays for Surgeon 2 and Pharmacists 2, 3, and 4 (and Pharmacist 4's wife) at the Scottsdale resort.

59. Veloxis also made consulting payments of more than $6,500 to Surgeon 2, $5,400 to Pharmacist 4, $4,600 to Pharmacist 3, and $3,400 to Pharmacist 2 for purportedly providing between eight and ten hours of consulting work during the retreat.

60. Veloxis's former CEO approved the falsified expense reports submitted by Employee 1 for all of the "advisory board" expenses.

ii. February 2021: Scottsdale, Arizona

61. On or about February 15 through 16, 2021, Veloxis, by and through Employees 1, 2, and 3 hosted a one-day market access "advisory board" retreat in Scottsdale, Arizona for Surgeon 2, Nephrologist 1, Pharmacist 3, and Pharmacist 4. Despite the market access advisory board taking place over the course of a single day, Veloxis paid for a three-night stay (over Valentine's Day weekend) at a Scottsdale resort for Nephrologist 1 and her husband, and for dinner costing approximately $276 for Nephrologist 1 and her husband (charged to their hotel room on Valentine's Day). Veloxis also paid for two dinners at high-end restaurants for Surgeon 2, Nephrologist 1, Pharmacist 3, Pharmacist 4, and certain of their spouses or guests.

62. In addition, Veloxis paid Nephrologist 1 approximately $1,725 for three hours of consulting work purportedly provided while Nephrologist 1 was staying at the resort with her husband for three nights with no bona fide work-related justification for this extended stay.

iii. July 2021: Vail, Colorado

63. On or about July 16, 2021, Veloxis, by and through Employees 1 and 2, hosted a Market Access "advisory board" retreat at a resort in Vail, Colorado for Surgeons 2 and 3, Pharmacist 4, and Administrator 1. The purported purpose of the retreat was to discuss strategy for addressing issues with a specific pharmacy benefit manager and "strategy for market access." In connection with the retreat, Veloxis paid for the resort stays as well as a lavish dinner for Surgeons 2 and 3, Pharmacist 4, and Administrator 1, and for certain of their spouses or guests.

64. Specifically, Veloxis, by and through Employees 1 and 2, paid more than $300 per attendee for dinner at a high-end sushi restaurant on or about July 16, 2021. Veloxis paid a total of more than $2,700 for the dinner. More than $700 of that amount was for alcohol.

65. Employee 1 submitted an expense report for the dinner that did not identify the spouses of Surgeon 3 and Pharmacist 4 as attendees despite their having attended the dinner. Instead, Employee 1 instructed Employee 2 to provide him (Employee 1) with the names of non-physicians whom Veloxis could falsely list as attendees on the expense report in order to artificially reduce the per attendee cost of the dinner, conceal the excessive amount of alcohol involved, and avoid OPP reporting requirements. Employee 2 provided the names of seven nurses and pharmacists who did not attend the dinner.

66. Veloxis paid more than $605 per person for the July 16, 2021 hotel stays for Surgeons 2 and 3, Pharmacist 4, and Administrator 1.

67. Employee 2 submitted an expense report for the hotel stays, and Employee 1 approved that expense report.

68. Veloxis also paid Surgeon 3 approximately $3,450 for six hours of purported consulting work; Pharmacist 4 approximately $1,275 for three hours of purported consulting work; and Administrator 1 approximately $1,275 for three hours of purported consulting work in connection with the retreat. Employee 1 approved these payments.

iv. December 2021: Philadelphia, Pennsylvania

69. On or about December 2, 2021, Veloxis, by and through Employees 1, 3, and 4, hosted a Market Access "advisory board" retreat in Philadelphia, Pennsylvania for Surgeons 1, 2, and 3, Pharmacist 4, and Administrator 1. The retreat involved stays at a high-end hotel as well as a lavish dinner. The purported purpose of the Market Access "advisory board" was to hold a "Market Access and Payer Discussion."

70. Veloxis paid more than $285 per attendee, for a total of more than $2,000, for this retreat dinner. More than $400 of the $2,000 was for high-end alcohol.

71. Veloxis paid more than $1,400 for Surgeon 2's two-night hotel stay and more than $700 for Administrator 1's one-night hotel stay.

72. Veloxis also made consulting payments to the attendees, with Administrator 1 alone receiving more than $3,100 for 7.5 hours of purported consulting work in connection with this retreat.

73. Prior to this retreat, Employee 2 exchanged text messages with Surgeon 2, who resided in Colorado, about scheduling the Market Advisory "advisory board" in Philadelphia in early December to coincide with the birthday of Surgeon 2's father, who resided near Philadelphia.

v. February 2022: Tucson, Arizona

74. On or about February 14 and 15, 2022, Veloxis, by and through Employee 2, hosted a Market Access "advisory board" retreat at a resort in Tucson, Arizona for Surgeons 2 and 3, Nephrologist 1, Pharmacist 2, and Administrator 1. The event involved a stay at the resort and

multiple lavish dinners, with the spouses of certain retreat attendees also in attendance. The purported purpose of the retreat was a "Consultants Meeting."

75. Veloxis paid for the resort stay of Nephrologist 1, who was then a physician at an Arizona-based hospital, and Nephrologist 1's spouse, despite the fact that they lived only about an hour away from the retreat location. This was the second consecutive year that Veloxis paid for Nephrologist 1 and her husband to stay at a resort over Valentine's Day.

B. Dinners for Health Care Professionals

i. Philadelphia, Pennsylvania Dinners

76. On or about March 16, 2021, Veloxis, by and through Employees 1 and 2, hosted a dinner at a high-end steakhouse in Philadelphia, Pennsylvania for Surgeons 2 and 3 and Administrator 1. Veloxis paid more than $250 per attendee for the dinner. Veloxis also paid approximately $1,300 for a two-night stay at a high-end hotel in Philadelphia for Surgeon 2, who, as noted above, had family in Philadelphia.

77. Employee 2 submitted, and Employee 1 approved, an internal expense report for the March 16, 2021 dinner that described the dinner as an "Internal Meeting" and did not identify Surgeons 2 and 3 or Administrator 1 as attendees.

78. Less than two months before the March 16, 2021 dinner, Employee 1 texted Employee 3 that Administrator 1's hospital was "making some noise" and that Administrator 1 had "earned a steak dinner." The day after the March 16, 2021 dinner, Employee 1 texted Employee 3 that he had a "phenomenal night" with Surgeons 2 and 3 and Administrator 1, and that "Sales are going up!"

79. On or about October 12, 2021, Veloxis, by and through Employees 1, 2, and 3, hosted a dinner at a high-end steakhouse in Philadelphia for Surgeon 3 and Administrator 1. Veloxis paid approximately $215 per attendee for the dinner. The purported purpose of the dinner

was "Training for the new [Regional Access Managers] Team." Employee 1 submitted an internal expense report for the dinner that did not identify Surgeon 3 or Administrator 1 as attendees, in part to avoid OPP reporting requirements. In addition, Employee 2 instructed Surgeon 3 and Administrator 1 to invoice Veloxis for three hours of purported consulting work in connection with the dinner.

ii. Other Dinners

80. On or about May 5, 2021, Veloxis, by and through Employees 1 and 2, hosted a dinner at a high-end seafood restaurant in Chicago, Illinois for Surgeon 3, Nephrologist 1, and Pharmacist 2. Veloxis paid approximately $400 per attendee for the dinner. Veloxis also paid for Surgeon 3's travel to Chicago for the dinner—approximately $428 for Surgeon 3's flight and approximately $671 for a one-night stay at a hotel. In addition, Veloxis paid Surgeon 3 approximately $2,300 for four hours of purported consulting work in connection with the dinner. Employee 2 submitted, and Employee 1 approved, an internal expense report that described the dinner as an "Internal meeting" despite the attendance of three (external) transplant health care professionals, and did not list Surgeon 3, Nephrologist 1, or Pharmacist 2 as attendees.

81. On or about January 13, 2022, after the May 5, 2021 dinner and the October 12, 2021 dinner (referenced in paragraph 78 above), Surgeon 3 sent Employee 1 a text message stating that he was "delivering all of [the Pennsylvania-based hospital] market for you." In response, Employee 1 told Surgeon 3 that he (Employee 1) had "just booked a table for 2 on Monday, January 24" at a high-end restaurant in Philadelphia, PA.

82. On or about April 22, 2022, Employee 3 and a Veloxis Medical Science Liaison ("MSL") hosted a dinner at a high-end steakhouse in West Hollywood, California for Surgeon 1. Employee 3 told the MSL that the dinner was intended to be an introductory meeting between Surgeon 1 and clinical representatives of a California-based hospital. In fact, the dinner did not

include any representatives from the California-based hospital. Only the MSL, Employee 3, and Surgeon 1 attended the dinner, for which Veloxis paid more than $663 per attendee. Employee 3 submitted, and Employee 1 approved, an expense report for the dinner that did not identify Surgeon 1 as an attendee, and falsely listed four non-healthcare professional attendees in order to conceal the illegitimate nature of the dinner, artificially reduce the per attendee cost of the dinner, and avoid OPP reporting requirements.

C. Consulting Agreements

83. During the relevant period, Veloxis entered into consulting agreements with health care professionals, including kidney transplant surgeons, nephrologists, and pharmacists, pursuant to which the Company paid certain health care professionals thousands of dollars for purported consulting work that was not in fact performed. In total, from 2016 through 2023, Veloxis paid health care professionals more than $800,000 in consulting fees and related expenses.

i. Consulting Agreement with Surgeon 1

84. On or about November 12, 2018, Veloxis entered into a consulting agreement with Surgeon 1 pursuant to which Veloxis agreed to pay Surgeon 1 $300 per hour for a maximum of 15 hours of consulting work per year. The agreement provided only a vague description of the work to be performed.

85. On or about February 14, 2022, Veloxis amended the agreement to increase the amount to $750 per hour and a 10-hour annual limit.

86. Surgeon 1 submitted invoices to Veloxis for consulting work that he did not actually perform and often for hours in excess of the maximum set by Veloxis' consulting agreement. Veloxis, through Employee 1, approved and paid these invoices despite, as described below, acknowledging that they reflected "massive overbilling."

87. Specifically, on or about April 22, 2020, Surgeon 1 sent Veloxis an invoice for 18 hours of purported consulting work related to "surgical interface." In a text message exchange, Employees 1 and 3 discussed whether Veloxis should pay this invoice. Employees 1 and 3 ultimately decided to approve/pay the invoice because "[h]is [i.e., Surgeon 1's] group will help us as we move along with greater volume and access challenges." Employee 1 sent the following text message to Employee 3 in reference to Surgeon 1: "He owes us. Massive over billing."

88. Later, beginning on or about December 6, 2021, Employees 3 and 4 exchanged text messages regarding Surgeon 1's submission of another invoice for 18 hours of purported consulting work in connection with an advisory board for which most other consultant attendees "submit[ed] 6-7 hours for dinner and [advisory] board." Employee 3 sent Employee 4 a text message stating that Surgeon 1 "does this all the time."

89. Veloxis also paid for personal travel for Surgeon 1. For example, on or about March 29, 2022, Surgeon 1 texted Employee 1 requesting that Veloxis pay for his trip to Los Angeles to "see a sick family member" with the pretext that the trip was to "visit with some transplant providers." Employee 1 approved Surgeon 1's invoices for this trip, and later, on or about May 7, 2022, Surgeon 1 texted Employee 1 thanking him for "making it possible to visit my cousin in California!" Employee 1 responded to Surgeon 1, "I hope so bro. My ass is on the like [sic] to sell more! I need to use everyone [sic] of your closest friends and please don't hold back!" Surgeon 1 replied, "No problem my man!" In connection with this trip, Employee 1 approved travel expenses for Surgeon 1 totaling more than $3,700, including over $1,700 for first class plane tickets, more than $1,500 for two nights of lodging, and more than $470 dollars for ground transportation, and approved Veloxis's payment of $5,250 to Surgeon 1 for consulting services related to Surgeon 1's personal travel.

90. During the relevant period, Veloxis paid Surgeon 1 a total of more than $100,000 in consulting fees and related expenses.

ii. Consulting Agreements with Pharmacist 1

91. Beginning in or around November 2015, Veloxis entered into a series of consulting agreements with a medical education company owned by Pharmacist 1. Under the terms of the agreements, all consulting work was to be performed by Pharmacist 1, who signed each of the agreements. By allowing Pharmacist 1 to enter into the agreement on behalf of his company (rather than in his personal capacity), Employee 3 understood that Veloxis helped Pharmacist 1 circumvent his employer's restrictions and reporting requirements related to working with pharmaceutical companies.

92. On various occasions in 2019, Pharmacist 1 requested that Veloxis increase the cap on his contractual consulting hours. Between approximately October 1, 2019 and January 2020, Veloxis increased Pharmacist 1's consulting hours from 25 to 145. In addition, in or around May 2020, Veloxis increased Pharmacist 1's hourly rate from $575/hour to $750/hour.

93. From 2016 through 2023, Veloxis paid Pharmacist 1 a total of more than $400,000 in consulting fees and related expenses.[4]

D. Gifts

94. Veloxis also provided gifts to certain transplant health care professionals, including in the form of expensive alcohol.

95. For example, on or about December 25, 2020, Employee 1 sent Surgeon 2 a bottle of gin "that is supposedly the best and it's not in Colorado." Employee 1 told Surgeon 2 that the gift was "[w]ell deserved. Every sip."

[4] In addition to paying Pharmacist 1 for purported consulting work, Veloxis also hosted and paid for multiple events held at a brewery and restaurant owned by Pharmacist 1.

96. Likewise, on or about March 1, 2022, Employee 1 texted Surgeon 1 that he (Employee 1) had "approved your tiny invoices today." Surgeon 1 responded, "Those invoices were just teasers! You owe me big time!? [sic]." Employee 1 replied, stating that he was "buying you [Pappy Van Winkle] on 24th."[5]

97. In certain instances, Veloxis employees facilitated consultants' efforts to avoid running afoul of their transplant center's and/or hospital's rules prohibiting the acceptance of monies, gifts, and trips from pharmaceutical manufacturers. For example, on or about May 10, 2022, Employee 1 texted a Veloxis sales manager, stating that Surgeon 2 wanted to attend a speaker program that Veloxis held in conjunction with a conference in Boston "incognito without registering." The next day, Employee 1 texted Surgeon 2 that he (Employee 1) "need[ed] scripts. Lots of them." After discussing "need[ing] to meet with cardiac transplant MDs," Surgeon 2 texted Employee 1, "I guess I need a room Friday" for the conference in Boston.

[5] Pappy Van Winkle is an expensive bourbon which ranges in price between approximately $800 and $4,000 a bottle.