UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA v. VELOXIS PHARMACEUTICALS, INC., Defendant	Criminal No. 26cr10221

DEFERRED PROSECUTION AGREEMENT

The United States Attorney's Office, by its attorney, Leah B. Foley, United States Attorney for the District of Massachusetts (the "Office"), and the Defendant, Veloxis Pharmaceuticals, Inc. (the "Company"), pursuant to authority granted by the Company's board of directors, hereby enter into the following Deferred Prosecution Agreement (the "Agreement"):

THE CRIMINAL INFORMATION AND ACCEPTANCE OF RESPONSIBILITY

1. The Company acknowledges and agrees that the Office will file the attached criminal information (the "Information") charging the Company with conspiracy to commit violations of the Federal Anti-Kickback Statute, contrary to Title 42, United States Code, Section 1320a-7b (the "Anti-Kickback Statute"), in violation of Title 18, United States Code, Section 371, during the years 2016 through 2023.

2. In so doing, the Company: (a) knowingly waives any right it may have to indictment on these charges, as well as all rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b) for the Term of this Agreement; (b) knowingly waives any legal or procedural defects in the Information; (c) knowingly waives any objection with respect to venue to any charges by the United States arising out of the conduct described in the Statement of Facts

attached hereto as Attachment A ("Statement of Facts") and consents to the filing of the Information, as provided under the terms of this Agreement, in the United States District Court for the District of Massachusetts; and (d) agrees that the charges in the Information and any charges arising from the conduct described in the Statement of Facts are not time-barred by the applicable statute of limitations on the date of the signing of this Agreement. The Office agrees to defer prosecution of the Company pursuant to the terms and conditions described below.

3. The Company admits, accepts, and acknowledges that it is responsible under United States law for the acts of its officers, directors, employees, and agents as charged in the Information, and as set forth in the Statement of Facts, and that the allegations described in the Information and the facts described in the Statement of Facts are true and accurate. The Company agrees that, effective as of the date the Company signs this Agreement, in any prosecution that is deferred by this Agreement, the Company will not dispute the Statement of Facts set forth in this Agreement, and, in any such prosecution, the Statement of Facts shall be admissible as: (a) substantive evidence offered by the government in its case-in-chief and rebuttal case; (b) impeachment evidence offered by the government on cross-examination; and (c) evidence at any sentencing hearing or other hearing. In addition, in connection therewith, the Company agrees not to assert any claim under the United States Constitution, Rule 410 of the Federal Rules of Evidence, Rule 11(f) of the Federal Rules of Criminal Procedure, the United States Sentencing Guidelines, or any other federal rule that the Statement of Facts should be suppressed or is otherwise inadmissible as evidence in any form.

PARALLEL CIVIL SETTLEMENT

4. Simultaneous with the execution of this Agreement, the Company and the United States are entering into a Civil Settlement Agreement to settle certain civil claims in connection

with the same conduct that is the subject of the Information and related conduct (the "Civil Settlement Agreement"). The Company shall make payment to the United States and the states as set forth in the Civil Settlement Agreement, for a total payment amount of $36,000,000 plus interest (the "Civil Settlement Agreement Payment").

TERM OF THE AGREEMENT

5. This Agreement is effective for a period beginning on the date on which the Information is filed and ending 36 months from that date (the "Term"). The Company expressly waives all rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution for the Term of this Agreement. Moreover, the Company agrees: (a) to join the government in seeking to exclude, pursuant to Title 18, United States Code, Section 3161(h)(2), the Term of this Agreement from the time within which trial of the offense charged in the Information must commence, for the purpose of allowing the Company to demonstrate its good conduct; and (b) to waive any rights to a speedy trial under Federal Rule of Criminal Procedure 48(b) for the Term of this Agreement. If the Court refuses to grant exclusion of time under the Speedy Trial Act, 18 U.S.C. § 3161(h)(2), all the provisions of this Agreement shall be deemed null and void, and the Term shall be deemed to have not begun, except that the statute of limitations for any prosecution relating to the conduct described in the Statement of Facts shall be tolled from the date on which this Agreement is signed until the date the Court refuses to grant the exclusion of time plus six months, and except for the provisions contained within Paragraph 3 of this Agreement.

6. The Company agrees that, in the event the Office determines in its sole discretion that the Company has knowingly violated any provision of this Agreement, or has failed to completely perform or fulfill each of the Company's obligations under this Agreement, an

extension of the Term of the Agreement may be imposed by the Office, in its sole discretion, for up to an additional 12-month period, without prejudice to the right of the Office to proceed as provided in Paragraphs 20 through 23 below. Any extension of the Agreement extends all terms of the Agreement. Conversely, the Office may, in its sole discretion, terminate the Agreement early.

RELEVANT CONSIDERATIONS

7. The Office enters into this Agreement based on the individual facts and circumstances presented by this case, including:

a. The nature and seriousness of the offense conduct, as described in the Statement of Facts;

b. The Company did not receive voluntary disclosure credit pursuant to the Department of Justice's Corporate Enforcement Policy ("DOJ CEP"), or pursuant to United States Sentencing Guidelines ("U.S.S.G." or "Sentencing Guidelines") § 8C2.5(g)(1), because it did not voluntarily and timely disclose the conduct described in the Statement of Facts;

c. The Company received credit for its cooperation with the Office's investigation pursuant to U.S.S.G. § 8C2.5(g)(2) because it cooperated with the Office's investigation and demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct; the Company also received credit for its cooperation and remediation pursuant to the DOJ CEP. Such cooperation included, among other things: (i) facilitating interviews with current and former Company employees; (ii) providing relevant facts and material not known to the government, obtained through the Company's internal investigation; (iii) making detailed presentations to the Office; (iv) proactively identifying key documents, including

inculpatory evidence, in the voluminous materials collected and produced by the Company; (v) identifying individuals involved in the criminal conduct; (vi) engaging outside consultants to conduct financial analyses; and (vii) facilitating collection of evidence from third parties;

d. The Company provided to the Office all relevant facts known to it, including information about the individuals involved in the conduct described in the attached Statement of Facts and conduct disclosed to the Office prior to the Agreement;

e. The Company also received credit pursuant to the DOJ CEP because it engaged in timely and appropriate remedial measures, including: (i) terminating employees who remained at the Company who were responsible for the offense conduct; (ii) updating and revising policies and procedures related to the Anti-Kickback Statute, including policies relating to expenses and expense reporting, interactions with health care providers, sales and marketing, Sunshine Act reporting, speaker programs, meals and entertainment, and the requirements of the Food, Drug, and Cosmetic Act; (iii) conducting employee training and implementation of updated policies; (iv) establishing a compliance committee with direct and regular reporting to the Board of Directors and hiring a new chief ethics and compliance officer and additional compliance personnel; (v) enhancing and publicizing disclosure and internal reporting programs; (vi) adopting and publicizing an enhanced disciplinary policy; (vii) implementing an enhanced internal audit program; (viii) developing and implementing an enhanced internal investigations process; and (ix) terminating agreements and relationships with third parties involved in the offense conduct;

f. The Company has no prior criminal history; and

g. The Company has agreed to continue to cooperate with the Office in any ongoing investigation or prosecution as described in Paragraph 9 below.

8. Accordingly, after consideration of (a) through (g) above, the Office believes that the appropriate resolution in this case is a deferred prosecution agreement with the Company; a criminal monetary penalty of $10,044,364, which reflects a reduction of 25 percent off the low-end of the otherwise-applicable Sentencing Guidelines fine range; and restitution, which will be satisfied by payment of the Civil Settlement Agreement Payment.

ONGOING COOPERATION AND DISCLOSURE REQUIREMENT

9. The Company shall cooperate fully with the Office in any and all matters relating to the conduct described in this Agreement and the Statement of Facts and any other conduct under investigation by the Office until the later of the date upon which all investigations and prosecutions arising out of such conduct are concluded, or the end of the Term. At the request of the Office, the Company shall also cooperate fully with other domestic or foreign law enforcement and regulatory authorities and agencies in any investigation of the Company, its affiliates, or any of its present or former officers, directors, employees, agents, and consultants, or any other party, in any and all matters relating to the conduct described in this Agreement and the Statement of Facts. The Company's cooperation pursuant to this Paragraph is subject to applicable law and regulations, as well as valid claims of attorney-client privilege or attorney work product doctrine. The Company agrees that its cooperation pursuant to this Paragraph shall include, but not be limited to, the following:

a. The Company represents that it has timely and truthfully disclosed all factual information with respect to its activities, those of its subsidiaries, and those of its present and former directors, officers, employees, agents, and consultants relating

to the conduct described in this Agreement and the Statement of Facts as well as any other conduct under investigation by the Office about which the Company has any knowledge. The Company further agrees that it shall promptly and truthfully disclose all factual information with respect to its activities, those of its subsidiaries, and those of its present and former directors, officers, employees, agents, and consultants about which the Company shall gain any knowledge or about which the Office may inquire. This obligation of truthful disclosure includes, but is not limited to, the obligation of the Company to provide to the Office, upon request, any document, record, or other tangible evidence about which the Office may inquire of the Company, including evidence that is responsive to any requests made prior to the execution of this Agreement.

b. Upon request of the Office, the Company shall designate knowledgeable employees, agents, or attorneys to provide to the Office the information and materials described in Paragraph 9(a) above on behalf of the Company. It is further understood that the Company must at all times provide complete, truthful, and accurate information to the Office.

c. The Company shall use its best efforts to make available for interviews or testimony, as requested by the Office, present or former officers, directors, employees, agents, and consultants of the Company. This obligation includes, but is not limited to, sworn testimony before a federal grand jury or in federal trials, as well as interviews with domestic or foreign law enforcement and regulatory authorities. Cooperation under this Paragraph shall include identification of

witnesses who, to the knowledge of the Company, may have material information regarding the matters under investigation.

d. With respect to any information, testimony, documents, records, or other tangible evidence provided to the Office pursuant to this Agreement, the Company consents to any and all disclosures, subject to applicable laws and regulations, to other governmental authorities, including United States authorities and those of a foreign government, of such materials as the Office, in its sole discretion, shall deem appropriate.

10. In addition to the obligations in Paragraph 9, during the Term, should the Company learn of any evidence or allegation of a violation of the Anti-Kickback Statute or violation of any U.S. anti-fraud laws by the Company, the Company shall promptly report such evidence or allegation to the Office.

PAYMENT OF MONETARY PENALTY

11. The Office and the Company agree that application of the Sentencing Guidelines to determine the applicable fine range yields the following analysis:

a. The value of the improper benefit conferred on the Company in return for the unlawful bribe payments described in the Statement of Facts is: $13,392,485.

b. Based upon U.S.S.G. § 2B4.1, the total offense level is 28, calculated as follows:

Offense Level		
Guideline Subsection	**Description**	**Score**
§ 2B4.1	Base offense level for commercial bribery	8
§ 2B4.1 / § 2B1.1	Value of the net benefit conferred as a result of the bribe is greater than $9,500,000 but not greater than $25,000,000	+20
TOTAL OFFENSE LEVEL		=28

c. Pursuant to U.S.S.G. § 8C2.4 and U.S.S.G. § 2B4.1's special instruction for organizational fines, the base fine is $13,392,485.

d. Based upon U.S.S.G. § 8C2.5, the culpability score is 5, calculated as follows:

Culpability Score		
Guideline Subsection	**Description**	**Score**
§ 8C2.5(a)	Start with 5 points	5
§ 8C2.5(b)(4)	Organization had 50 or more employees and an individual within substantial authority personnel participated in, condoned, or was willfully ignorant of the offense	+2
§ 8C2.5(g)(2)	Organization fully cooperated in the investigation and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct	–2
TOTAL		5

e. Under U.S.S.G. § 8C2.6, a culpability score of five results in a fine multiplier range of one to two. Therefore, the guideline fine range is $13,392,485 to $26,784,970.

12. The Office and the Company agree, based on the application of the Sentencing Guidelines, that the appropriate criminal penalty is $10,044,364. This reflects a 25 percent reduction from the low end of the Sentencing Guidelines fine range set forth in Paragraph 11(e).

13. The Company agrees to pay a monetary penalty in the amount of $10,044,364 to the Crime Victims Fund pursuant to 34 U.S.C. § 20101(b)(6)(A) no later than ten business days after the Agreement is fully executed. The Company and the Office agree that this penalty is appropriate given the facts and circumstances of this case, including the relevant considerations described in Paragraph 7 of this Agreement. The $10,044,364 penalty is final and shall not be refunded. Furthermore, nothing in this Agreement shall be deemed an agreement by the Office that $10,044,364 is the maximum penalty that may be imposed in any future prosecution, and the Office is not precluded from arguing in any future prosecution that the Court should impose a higher fine, although the Office agrees that under those circumstances, it will recommend to the Court that any amount paid under this Agreement should be offset against any fine the Court imposes as part of a

future judgment. The Company acknowledges that no tax deduction may be sought in connection with the payment of any part of this $10,044,364 penalty. The Company shall not seek or accept directly or indirectly reimbursement or indemnification from any source with regard to the penalty or disgorgement amounts that the Company pays pursuant to this Agreement, or any other agreement entered into with an enforcement authority or regulator concerning the facts set forth in the Statement of Facts.

CONDITIONAL RELEASE FROM LIABILITY

14. Subject to Paragraphs 20 through 23, the Office agrees, except as provided in this Agreement, that it will not bring any criminal or civil case against the Company or any of its subsidiaries relating to any of the conduct described in the Statement of Facts or the criminal Information filed pursuant to this Agreement. The Office, however, may use any information related to the conduct described in the Statement of Facts against the Company or any of its subsidiaries: (a) in a prosecution for perjury or obstruction of justice; (b) in a prosecution for making a false statement; (c) in a prosecution or other proceeding relating to any crime of violence; or (d) in a prosecution or other proceeding relating to a violation of any provision of Title 26 of the United States Code.

15. This Agreement does not provide any protection against prosecution for any future conduct by the Company or any of its subsidiaries or affiliates.

16. In addition, this Agreement does not provide any protection against prosecution of any individuals, regardless of their affiliation with the Company or any of its subsidiaries or affiliates.

CORPORATE COMPLIANCE PROGRAM

17. The Company represents that it has implemented and will continue to implement a compliance and ethics program designed to prevent and detect violations of the Anti-Kickback Statute throughout the Company's operations, including those of its subsidiaries, agents, and joint ventures, including, but not limited to, the minimum elements set forth in Attachment C to this Agreement. On the date the Term expires, the Company, by its Chief Executive Officer and Chief Ethics and Compliance Officer, will certify to the Office, in the form of executing the document attached as Attachment E to this Agreement, that the Company has met its compliance obligations pursuant to this Agreement. This certification will be deemed a material statement and representation by the Company to the executive branch of the United States for purposes of 18 U.S.C. § 1001, and it will be deemed to have been made in the judicial district in which this Agreement is filed.

DEFERRED PROSECUTION

18. In consideration of the undertakings agreed to by the Company herein, the Office agrees that any prosecution of the Company for the conduct set forth in the Statement of Facts be and hereby is deferred for the Term. To the extent there is conduct disclosed by the Company that is not set forth in the Statement of Facts, such conduct will not be exempt from further prosecution and is not within the scope of or relevant to this Agreement.

19. The Office further agrees that if the Company fully complies with all of its obligations under this Agreement, the Office will not continue the criminal prosecution against the Company described in Paragraph 1 and, at the conclusion of the Term, this Agreement shall expire. Within three months after the Agreement's expiration, the Office shall seek dismissal with prejudice of the Information filed against the Company described in Paragraph 1, and the Office

agrees not to file charges in the future against the Company based on the conduct described in this Agreement and the Statement of Facts. If, however, the Office determines during this three-month period that the Company breached the Agreement during the Term, as described in Paragraphs 20 through 23, the Office's ability to extend the Term, as described in Paragraph 6, or to pursue other remedies, including those described in Paragraphs 20 through 23 remains in full effect.

BREACH OF THE AGREEMENT

20. If, during the Term, the Company: (a) commits any felony under U.S. federal law; (b) provides in connection with this Agreement deliberately false, incomplete, or misleading information; (c) fails to cooperate as set forth in Paragraphs 9 and 10 of this Agreement; (d) fails to implement a compliance program as set forth in Paragraph 17 of this Agreement and Attachment C hereto; or (e) otherwise fails to completely perform or fulfill each of the Company's obligations under the Agreement, regardless of whether the Office becomes aware of such a breach after the Term is complete, the Company shall thereafter be subject to prosecution for any federal criminal violation of which the Office has knowledge, including, but not limited to, the charges in the Information described in Paragraph 1, which may be pursued by the Office in the U.S. District Court for the District of Massachusetts or any other appropriate venue. Determination of whether the Company has breached the Agreement and whether to pursue prosecution of the Company shall be in the Office's sole discretion. Any such prosecution may be premised on information provided by the Company. Any such prosecution relating to the conduct described in the Statement of Facts or relating to conduct known to the Office prior to the date on which this Agreement was signed that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement may be commenced against the Company, notwithstanding the expiration of the statute of limitations, between the signing of this Agreement and the expiration of the Term plus

one year. Thus, by signing this Agreement, the Company agrees that the statute of limitations with respect to any such prosecution that is not time-barred on the date of the signing of this Agreement shall be tolled for the Term plus one year. In addition, the Company agrees that the statute of limitations as to any violation of federal law that occurs during the Term will be tolled from the date upon which the violation occurs until the earlier of the date upon which the Office is made aware of the violation or the duration of the Term plus five years, and that this period shall be excluded from any calculation of time for purposes of the application of the statute of limitations.

21. In the event the Office determines that the Company has breached this Agreement, the Office agrees to provide the Company with written notice of such breach prior to instituting any prosecution resulting from such breach. Within 30 days of receipt of such notice or longer at the discretion of the Office, the Company shall have the opportunity to respond to the Office in writing to explain the nature and circumstances of such breach, as well as the actions the Company has taken to address and remediate the situation, which explanation the Office shall consider in determining whether to pursue prosecution of the Company. The parties expressly understand and agree that if the Company fails to make the above-noted presentation within such period, it shall be presumed that the Company is in willful and material breach of this Agreement. The parties further understand and agree that the Office's exercise of discretion under this Paragraph is not subject to review in any court or tribunal outside the Department of Justice and the Office.

22. In the event the Office determines that the Company has breached this Agreement: (a) all statements made by or on behalf of the Company to the Office or to the Court, including the Statement of Facts, and any testimony given by the Company before a grand jury, a court, or any tribunal, or at any legislative hearings, whether prior or subsequent to this Agreement, and any leads derived from such statements or testimony, shall be admissible in evidence in any and all

criminal proceedings brought by the Office against the Company or its subsidiaries; and (b) the Company and its subsidiaries shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal rule that any such statements or testimony made by or on behalf of the Company prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible. The decision whether conduct or statements of any current director, officer, or employee, or any person acting on behalf of, or at the direction of, the Company or its subsidiaries, will be imputed to the Company or its subsidiaries for the purpose of determining whether the Company or its subsidiaries have violated any provision of this Agreement shall be in the sole discretion of the Office.

23. The Company acknowledges that the Office has made no representations, assurances, or promises concerning what sentence may be imposed by the Court if the Company breaches this Agreement, and this matter proceeds to judgment. The Company further acknowledges that any such sentence is solely within the discretion of the Court and that nothing in this Agreement binds or restricts the Court in the exercise of such discretion.

24. On the date that the period of deferred prosecution specified in this Agreement expires, the Company, by the Chief Executive Officer of the Company and the Chief Ethics and Compliance Officer of the Company, will certify to the Office in the form of executing the document attached as Attachment D to this Agreement that the Company has met its disclosure obligations pursuant to Paragraph 9 of this Agreement. Each certification will be deemed a material statement and representation by the Company to the executive branch of the United States for purposes of 18 U.S.C. §§ 1001 and 1519, and will be deemed to have been made in the judicial district in which this Agreement is filed.

SALE, MERGER, OR OTHER CHANGE IN CORPORATE FORM OF COMPANY

25. Except as may otherwise be agreed by the parties in connection with a particular transaction, the Company agrees that in the event that, during the Term, it undertakes any change in corporate form, including if it sells, merges, or transfers business operations that are material to the Company's consolidated operations as they exist as of the date of the signing of this Agreement, whether such sale is structured as a sale, asset sale, merger, transfer, or other change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. The purchaser or successor in interest must also agree in writing that the Office's ability to determine a breach under this Agreement is applicable in full force to that entity. The Company agrees that the failure to include these provisions in the transaction will make any such transaction null and void. The Company shall provide notice to the Office at least 30 days prior to undertaking any such sale, merger, transfer, or other change in corporate form. The Office shall notify the Company prior to such transaction (or series of transactions) if the Office determines that the transaction(s) will have the effect of circumventing or frustrating the enforcement purposes of this Agreement. If at any time during the Term the Company engages in a transaction (or series of transactions) that has the effect of circumventing or frustrating the enforcement purposes of this Agreement, the Office may deem it a breach of this Agreement pursuant to Paragraphs 20 through 23 of this Agreement. Nothing herein shall restrict the Company from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the enforcement purposes of this Agreement, as determined by the Office.

PUBLIC STATEMENTS BY THE COMPANY

26. The Company expressly agrees that it shall not, through present or future attorneys, officers, directors, employees, agents, or any other person authorized to speak for the Company make any public statement, in litigation or otherwise, contradicting the acceptance of responsibility by the Company set forth above or the facts described in the Statement of Facts. Any such contradictory statement shall, subject to cure rights of the Company described below, constitute a breach of this Agreement, and the Company thereafter shall be subject to prosecution as set forth in Paragraphs 20 through 23 of this Agreement. The decision whether any public statement by any such person contradicting a fact contained in the Statement of Facts will be imputed to the Company for the purpose of determining whether it has breached this Agreement shall be at the sole discretion of the Office. If the Office determines that a public statement by any such person contradicts in whole or in part a statement contained in the Statement of Facts, the Office shall so notify the Company, and the Company may avoid a breach of this Agreement by publicly repudiating such statement(s) within five business days after notification. The Company shall be permitted to raise defenses and to assert affirmative claims in other proceedings relating to the matters set forth in the Statement of Facts provided that such defenses and claims do not contradict, in whole or in part, a statement contained in the Statement of Facts. This Paragraph does not apply to any statement made by any present or former officer, director, employee, or agent of the Company in the course of any criminal, regulatory, or civil case initiated against such individual, unless such individual is speaking on behalf of the Company.

27. The Company agrees that if it, its parent company, or any of its direct or indirect subsidiaries, issues a press release or holds any press conference in connection with this Agreement, the Company shall first consult with the Office to determine: (a) whether the text of

the release or proposed statements at the press conference are true and accurate with respect to matters between the Office and the Company; and (b) whether the Office has any objection to the release.

28. The Office agrees, if requested to do so, to bring to the attention of law enforcement and regulatory authorities the facts and circumstances relating to the nature of the conduct underlying this Agreement, including the nature and quality of the Company's cooperation and remediation. By agreeing to provide this information to such authorities, the Office is not agreeing to advocate on behalf of the Company, but rather is agreeing to provide facts to be evaluated independently by such authorities.

LIMITATIONS ON BINDING EFFECT OF AGREEMENT

29. This Agreement is binding on the Company and the Office but specifically does not bind any other component of the Department of Justice, other federal agencies, or any state, local, or foreign law enforcement or regulatory agencies, or any other authorities, although the Office will bring the cooperation of the Company and its compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by the Company.

NOTICE

30. Any notice to the Office under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, with copies by electronic mail, addressed to:

Chief, Health Care Fraud Unit
United States Attorney's Office for the District of Massachusetts
John Joseph Moakley United States Federal Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210

31. Any notice to the Company under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, with copies by electronic mail, addressed to:

General Counsel
Veloxis Pharmaceuticals, Inc.
2000 Regency Parkway, Suite 500
Cary, NC 27518

and

D. Jacques Smith and Michelle J. Shapiro
c/o ArentFox Schiff LLP
800 Boylston Street
Boston, MA 02199

32. Notice shall be effective upon actual receipt by the Office or the Company.

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COMPLETE AGREEMENT

33. This Agreement, including its attachments, sets forth all the terms of the agreement between the Company and the Office. No amendments, modifications, or additions to this Agreement shall be valid unless they are in writing and signed by the Office, the attorneys for the Company, and a duly authorized representative of the Company.

AGREED:

FOR VELOXIS PHARMACEUTICALS, INC.

Date: 5 AUG 2026 By:

Stacy G. Wheeler
Chief Executive Officer
naceuticals, Inc.

Date: 6 Aug. 2026 By:

D. Jacques Smith
Michelle J. Shapiro
ArentFox Schiff LLP
Counsel for Veloxis Pharmaceuticals, Inc.

FOR THE U.S. ATTORNEY'S OFFICE, DISTRICT OF MASSACHUSETTS

LEAH B. FOLEY
United States Attorney

Date: August 4, 2026 By:

MACKENZIE A. QUEENIN
Chief, Health Care Fraud Unit

LESLIE A. WRIGHT
Deputy Chief, Health Care Fraud Unit
CHRISTOPHER LOONEY
Assistant U.S. Attorney

COMPANY OFFICER'S CERTIFICATE

I have read this Agreement and carefully reviewed every part of it with outside counsel for Veloxis Pharmaceuticals, Inc. (the "Company"). I understand the terms of this Agreement and voluntarily agree, on behalf of the Company, to each of its terms. Before signing this Agreement, I consulted outside counsel for the Company. Counsel fully advised me of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

I have carefully reviewed the terms of this Agreement with the Board of Directors of the Company. I have advised and caused outside counsel for the Company to advise the Board of Directors fully of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into the Agreement.

No promises or inducements have been made other than those contained in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of the Company, in any way to enter into this Agreement. I am also satisfied with outside counsel's representation in this matter. I certify that I am the Chief Executive Officer and that I have been duly authorized by the Company to execute this Agreement on behalf of the Company.

Date: 5 AUG 2026

By: _____
Stacy G. Wheeler
Chief Executive Officer
Veloxis Pharmaceuticals, Inc.

CERTIFICATE OF COUNSEL FOR VELOXIS PHARMACEUTICALS, INC.

I am counsel for Veloxis Pharmaceuticals, Inc. (the "Company") in the matter covered by this Agreement. In connection with such representation, I have examined relevant Company documents and have discussed the terms of this Agreement with the Company Board of Directors. Based on our review of the foregoing materials and discussions, it is my opinion that the representative of the Company signing this Agreement has been duly authorized to enter into this Agreement on behalf of the Company and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of the Company and is a valid and binding obligation of the Company. Further, I have carefully reviewed the terms of this Agreement with the Board of Directors and the Chief Executive Officer, Stacy G. Wheeler. I have fully advised them of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement. To my knowledge, the decision of the Company to enter into this Agreement, based on the authorization of the Board of Directors, is an informed and voluntary one.

Date: 6 Aug. 2026

By: 

D. Jacques Smith
Michelle J. Shapiro
ArentFox Schiff LLP
Counsel for Veloxis Pharmaceuticals, Inc.

ATTACHMENT A

STATEMENT OF FACTS

The following Statement of Facts is incorporated by reference as part of the Deferred Prosecution Agreement (the "Agreement") between the United States Attorney's Office for the District of Massachusetts (the "Office"), and Veloxis Pharmaceuticals, Inc. ("Veloxis" or the "Company"). Veloxis hereby agrees and stipulates that the following information is true and accurate. Veloxis admits, accepts, and acknowledges that it is responsible for the acts of its current and former officers, directors, employees, and agents as set forth below. Should the Office pursue the prosecution that is deferred by the Agreement, Veloxis agrees that it will neither contest the admissibility of, nor contradict, this Statement of Facts in any such proceeding. The following facts establish beyond a reasonable doubt the charges set forth in the criminal Information attached to the Agreement.

Relevant Entities and Individuals

Beginning in or around October 2016 and continuing through in or around June 2023 (the "relevant period"):

1. Veloxis was a pharmaceutical company, incorporated in Delaware, with a principal place of business in Cary, North Carolina. Effective March 2020, Veloxis was acquired by Asahi Kasei Corporation, headquartered in Tokyo, Japan. Veloxis did 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 between July 2016 and June 1, 2022, and as Vice President of Sales between October 2021 and March 22, 2023.[1]

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 in Market Access who served 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.

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.

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

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 the generic form of tacrolimus drugs 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 it 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, protocol 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, and 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, extended *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 throughout 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

[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.

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 the sums it paid to transplant health care professionals, which further obscured its 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 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[]

[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.

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 Sunshine Act

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

(the "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 production, 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 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). The first reporting deadline was March 31, 2014, for the calendar year 2013. 42 C.F.R. § 403.908(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.

40. Veloxis is considered a manufacturer and Envarsus is considered a covered drug under the Sunshine Act.

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 of the Conspiracy

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 health care 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 Sunshine Act 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 in paragraph 48(a)-(g) 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. 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.

53. 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. 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).

54. 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.

55. 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.

56. 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.

57. 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.

ii. <u>February 2021: Scottsdale, Arizona</u>

58. 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 advisory board taking place over the course of a single day, Veloxis paid for a three-night stay at a Scottsdale resort for Nephrologist 1 and her husband, and for dinner costing approximately $276 for Nephrologist 1

and her husband. 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.

59. 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

60. 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.

61. 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.

62. 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 Sunshine Act reporting requirements. Employee 2 provided the names of seven nurses and pharmacists who did not attend the dinner.

63. Veloxis paid more than $605 per person for the July 16, 2021 hotel stays for Surgeons 2 and 3, Pharmacist 4, and Administrator 1. Employee 2 submitted an expense report for the hotel stays, and Employee 1 approved that expense report.

64. 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

65. 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 retreat was to hold a "Market Access and Payer Discussion."

66. 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.

67. 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.

68. 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.

69. Prior to this retreat, Employee 2 exchanged text messages with Surgeon 2, who resided in Colorado, about scheduling the "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

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

71. 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.

B. Dinners for Health Care Professionals

i. Philadelphia, Pennsylvania Dinners

72. 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.

73. Employee 2 submitted, and Employee 1 approved, an 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.

74. 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!"

75. 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."

76. Employee 1 submitted an expense report for the October 12, 2021 dinner that did not identify Surgeon 3 or Administrator 1 as attendees, in part to avoid Sunshine Act reporting requirements.

77. In addition, Employee 2 instructed Surgeon 3 and Administrator 1 to invoice Veloxis for three hours of purported consulting work in connection with the October 12, 2021 dinner.

ii. Other Dinners

78. 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—specifically, 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 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.

79. On or about January 13, 2022, after the May 5, 2021 dinner and the October 12, 2021 dinner (referenced in paragraph 75 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.

80. 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-health care professionals as purported attendees of the "introductory meeting" with Surgeon 1, in order to conceal the illegitimate nature of the dinner, artificially reduce the per attendee cost of the dinner, and avoid Sunshine Act reporting requirements.

C. Consulting Agreements

81. During the relevant period, Veloxis entered into consulting agreements with health care professionals, including kidney transplant surgeons, nephrologists, and pharmacists, pursuant to which Veloxis 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

82. 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.

83. On or about February 14, 2022, Veloxis amended its consulting agreement with Surgeon 1. Under the terms of the new agreement, Veloxis agreed to pay Surgeon 1 $750 per hour for a maximum of ten hours of consulting work per year.

84. 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 the consulting agreement. Veloxis, through Employee 1, approved and paid these invoices despite, as described below, acknowledging that they reflected "massive overbilling."

85. 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."

86. 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 a Market Access 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."

87. Veloxis also paid for personal travel for Surgeon 1 purportedly in connection with consulting work. 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 travel expenses for this trip, which totaled more than $3,700, including more than $1,700 for first class plane tickets, more than $1,500 for two nights of lodging, and more than $470 for ground transportation. Employee 1 also approved Veloxis's payment of approximately $5,250 in consulting fees to Surgeon 1 in connection with this trip. 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!"

88. 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

89. 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 agreements 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.

90. 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 per hour to $750 per hour.

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

D. Gifts

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

93. 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."

94. 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]

[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.

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

Net Value Conferred on Veloxis as a Result of the Kickbacks

95. Envarsus is typically prescribed to kidney transplant patients based on a ratio of milligrams of the drug per the patient's body weight. Medicare, Medicaid, and TRICARE reimbursement for Envarsus is based on its per-milligram price.

96. Based upon (i) the number of milligrams of Envarsus prescribed by physicians as a result of the unlawful payments made by Veloxis in connection with the conspiracy described above and (ii) Veloxis's net profit per milligram, the net benefit conferred on Veloxis as a result of kickback-tainted Envarsus sales was approximately $13,392,486.

Date: 7 Aug 2026

By: _____

Stacy G. Wheeler
Chief Executive Officer
Veloxis Pharmaceuticals, Inc.

ATTACHMENT B

CERTIFICATE OF CORPORATE RESOLUTIONS FOR VELOXIS PHARMACEUTICALS, INC.

WHEREAS, Veloxis Pharmaceuticals, Inc. (the "Company") has been engaged in discussions with the United States Attorney's Office for the District of Massachusetts (the "Office") regarding an ongoing investigation concerning violations of the Federal Anti-Kickback Statute, Title 42, United States Code, Section 1320a-7b; and

WHEREAS, in order to resolve such discussions, it is proposed that the Company enter into a certain agreement with the Office; and

WHEREAS, the Chief Executive Officer, Stacy G. Wheeler, together with outside counsel for the Company, have advised the Board of Directors of the Company of its rights, possible defenses, the Sentencing Guidelines' provisions, and the consequences of entering into such agreement with the Office;

Therefore, the Board of Directors has RESOLVED that:

1. The Company: (a) acknowledges the filing of an Information charging the Company with conspiracy to commit violations of the Federal Anti-Kickback Statute, contrary to Title 42, United States Code, Section 1320a-7b, in violation of Title 18, United States Code, Section 371; (b) waives indictment on such charges and enters into a deferred prosecution agreement with the Office (the "Agreement"); and (c) agrees to accept a monetary penalty against the Company in the amount of $10,044,364, and to pay such penalty to the Crime Victims Fund pursuant to 34 U.S.C. § 20101(b)(6)(A) with respect to the conduct described in the Information;

2. The Company accepts the terms and conditions of the Agreement, including, but not limited to: (a) a knowing waiver of its rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of

Criminal Procedure 48(b); (b) a knowing waiver for purposes of the Agreement and any charges by the United States arising out of the conduct described in the attached Statement of Facts of any objection with respect to venue and consent to the filing of the Information, as provided under the terms of the Agreement, in the United States District Court for the District of Massachusetts; and (c) a knowing waiver of any defenses based on the statute of limitations for any prosecution relating to the conduct described in the attached Statement of Facts or relating to conduct known to the Office prior to the date on which the Agreement was signed that is not time-barred by the applicable statute of limitations on the date of the signing of the Agreement;

3. The Chief Executive Officer is hereby authorized, empowered, and directed, on behalf of the Company, to execute the Agreement substantially in such form as reviewed by this Board of Directors at this meeting with such changes as the Chief Executive Officer may approve;

4. The Chief Executive Officer is hereby authorized, empowered, and directed to take any and all actions as may be necessary or appropriate and to approve the forms, terms, or provisions of any agreement or other documents as may be necessary or appropriate, to carry out and effectuate the purpose and intent of the foregoing resolutions; and to delegate in writing to one or more officers or employees of the Company the authority to approve the forms, terms, and provisions of, and to execute, any such agreements or documents; and

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5. All of the actions of the Chief Executive Officer, which actions would have been authorized by the foregoing resolutions except that such actions were taken prior to the adoption of such resolutions, are hereby severally ratified, confirmed, approved, and adopted as actions on behalf of the Company.

Date: 5 Aug 2026

By: _____

Stacy G. Wheeler
Chief Executive Officer
Veloxis Pharmaceuticals, Inc.

ATTACHMENT C

CORPORATE COMPLIANCE PROGRAM

In order to address any deficiencies in its internal controls, compliance code, policies, and procedures regarding compliance with the Federal Anti-Kickback Statute, Title 42, United States Code, Section 1320a-7b (the "Anti-Kickback Statute"), Veloxis Pharmaceuticals, Inc. (the "Company"), on behalf of itself and its subsidiaries, agrees to continue to conduct, in a manner consistent with all of its obligations under this Agreement, appropriate reviews of its existing internal controls, compliance code, policies, and procedures.

Where necessary and appropriate, the Company agrees to adopt a new or to modify its existing compliance program, including internal controls, compliance code, policies, and procedures, to ensure that it maintains an effective compliance program that is designed, implemented, and enforced to effectively deter and detect violations of the Anti-Kickback Statute. At a minimum, this should include, but not be limited to, the following elements to the extent they are not already part of the Company's existing internal controls, compliance code, policies, and procedures:

Commitment to Compliance

1. The Company will ensure that its directors and senior management provide strong, explicit, and visible support and commitment to its corporate policy against violations of the Anti-Kickback Statute and the Company's compliance code and demonstrate rigorous adherence by example. The Company will also ensure that all managers, in turn, reinforce those standards and encourage employees to abide by them. The Company will create and foster a culture of ethics and compliance with the law in its day-to-day operations at all levels of the Company.

Policies and Procedures

2. The Company will develop and promulgate a clearly articulated and visible corporate policy requiring adherence to the Anti-Kickback Statute, which policy shall be memorialized in a written compliance code or codes.

3. The Company will take appropriate measures to encourage and support the observance of ethics and compliance policies and procedures by personnel at all levels of the Company. These policies and procedures shall apply to all directors, officers, and employees and, where necessary and appropriate, outside parties acting on behalf of the Company, including, but not limited to, agents and intermediaries, consultants, representatives, distributors, teaming partners, contractors and suppliers, consortia, and joint venture partners. The Company shall notify all employees that compliance with the policies and procedures is the duty of individuals at all levels of the Company.

Periodic Risk-Based Review

4. The Company shall review its compliance policies and procedures regarding the Anti-Kickback Statute no less than annually and update them as appropriate to ensure their continued effectiveness, taking into account relevant developments in the field, evolving industry standards, and the risk profile of the Company.

Proper Oversight and Independence

5. The Company will assign responsibility to one or more senior corporate executives of the Company for the implementation and oversight of the Company's compliance code, policies, and procedures regarding the Anti-Kickback Statute. Such corporate official(s) shall have the authority to report directly to independent monitoring bodies, including the Company's Board of

Directors, and shall have an adequate level of stature and autonomy from management as well as sufficient resources and authority to maintain such autonomy.

Training and Guidance

6. The Company will implement mechanisms designed to ensure that its compliance code, policies, and procedures regarding the Anti-Kickback Statute are effectively communicated to all directors, officers, and employees. These mechanisms shall include: (a) periodic training for all directors and officers, and all employees in positions of leadership or trust or in positions that require such training; and (b) corresponding certifications by all such directors, officers, and employees certifying compliance with the training requirements. The Company will conduct training in a manner tailored to the audience's size, sophistication, or subject matter expertise and, where appropriate, will discuss prior compliance incidents.

7. The Company will maintain, or where necessary establish, an effective system for providing guidance and advice to directors, officers, and employees on complying with the Company's compliance code, policies, and procedures regarding the Anti-Kickback Statute.

Internal Reporting and Investigation

8. The Company will maintain, or where necessary establish, an effective system for internal and, where possible, confidential reporting by, and protection of, directors, officers, and employees concerning violations of the Anti-Kickback Statute or the Company's compliance code, policies, and procedures regarding the Anti-Kickback Statute.

9. The Company will maintain, or where necessary establish, an effective and reliable process with sufficient resources for responding to, investigating, and documenting allegations of violations of the Anti-Kickback Statute or the Company's compliance code, policies, and procedures regarding the Anti-Kickback Statute. The Company will handle the investigations of

such complaints in an effective manner, including routing the complaints to proper personnel, conducting timely and thorough investigations, and following up with appropriate discipline where necessary.

Enforcement and Discipline

10. The Company will implement mechanisms designed to effectively enforce its compliance code, policies, and procedures, including appropriately incentivizing compliance and disciplining violations. At a minimum, these mechanisms will include policies that incorporate adherence to compliance as one portion of employee and officer evaluations, that impose financial penalties for compliance-related misconduct, and that provide affirmative incentives for compliance-promoting behavior.

11. The Company will institute appropriate disciplinary procedures to address, among other things, violations of the Anti-Kickback Statute and the Company's compliance code, policies, and procedures regarding the Anti-Kickback Statute by the Company's directors, officers, and employees. Such procedures should be applied consistently, fairly, and in a manner commensurate with the violation, regardless of the position held by, or perceived importance of, the director, officer, or employee. The Company shall implement procedures to ensure that where misconduct is discovered, reasonable steps are taken to remedy the harm resulting from such misconduct, and to ensure that appropriate steps are taken to prevent further similar misconduct, including assessing the internal controls, compliance code, policies, and procedures and making modifications necessary to ensure the overall compliance program is effective.

Monitoring, Testing, and Remediation

12. In order to ensure that its compliance program does not become stale, the Company will conduct periodic reviews and testing of its compliance code, policies, and procedures

regarding the Anti-Kickback Statute designed to evaluate and improve their effectiveness in preventing and detecting violations of the Anti-Kickback Statute and the Company's compliance code, policies, and procedures regarding the Anti-Kickback Statute, taking into account relevant developments in the field, evolving industry standards, and the risk profile of the Company. The Company will ensure that compliance and control personnel have sufficient direct or indirect access to relevant sources of data to allow for timely and effective monitoring and/or testing. Based on such review and testing and its analysis of any prior misconduct, the Company will conduct a thoughtful root cause analysis and timely and appropriately remediate to address the root causes.

ATTACHMENT D

DISCLOSURE CERTIFICATION

To: Chief, Health Care Fraud Unit
United States Attorney's Office for the District of Massachusetts
John Joseph Moakley United States Federal Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210

Re: Veloxis Pharmaceuticals, Inc. Deferred Prosecution Agreement Disclosure Certification

The undersigned certify, pursuant to Paragraph 9 of the deferred prosecution agreement (the "Agreement") filed on August 10, 2026 in the United States District Court for the District of Massachusetts, by and between the United States Attorney's Office for the District of Massachusetts (the "Office") and Veloxis Pharmaceuticals, Inc., (the "Company"), that undersigned are aware of the Company's disclosure obligations under Paragraph 9 of the Agreement, and that the Company has disclosed to the Office any and all evidence or allegations of conduct as required by Paragraph 9 of the Agreement, which includes evidence or allegations of any violation of the Federal Anti-Kickback Statute, Title 42, United States Code, Section 1320a-7b ("Disclosable Information"). This obligation to disclose information extends to any and all Disclosable Information that has been identified through the Company's compliance policies and procedures or other processes.

The undersigned further acknowledge and agree that the reporting requirements contained in Paragraph 9 of the Agreement and the representations contained in this certification constitute a significant and important component of the Agreement and of the Office's determination whether the Company has satisfied its obligations under the Agreement.

The undersigned hereby certify that they are the Chief Executive Officer and the Chief Ethics and Compliance Officer of the Company, respectively, and that each has been duly authorized by the Company to sign this certification on behalf of the Company.

This certification shall constitute a material statement and representation by the undersigned by, on behalf of, and for the benefit of the Company to the executive branch of the United States for purposes of 18 U.S.C. § 1001, and such material statement and representation shall be deemed to have been made in the District of Massachusetts. This certification shall also constitute a record, document, or tangible object in connection with a matter within the jurisdiction of a department and agency of the United States for purposes of 18 U.S.C. § 1519, and such record, document, or tangible object shall be deemed to have been made in the District of Massachusetts.

Date: _____ Name (Printed): _____

Name (Signed): _____
Chief Executive Officer
Veloxis Pharmaceuticals, Inc.

Date: _____ Name (Printed): _____

Name (Signed): _____
Chief Ethics and Compliance Officer
Veloxis Pharmaceuticals, Inc.

ATTACHMENT E

COMPLIANCE CERTIFICATION

To: Chief, Health Care Fraud Unit
United States Attorney's Office for the District of Massachusetts
John Joseph Moakley United States Federal Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210

Re: Veloxis Pharmaceuticals, Inc. Deferred Prosecution Agreement Compliance Certification

The undersigned certify, pursuant to Paragraph 17 of the deferred prosecution agreement (the "Agreement") filed on August 10, 2026 in the United States District Court for the District of Massachusetts, by and between the United States Attorney's Office for the District of Massachusetts (the "Office") and Veloxis Pharmaceuticals, Inc. (the "Company"), that the undersigned are aware of the Company's compliance obligations under Paragraph 17 of the Agreement, and that, based on the undersigned's review and understanding of the Company's compliance policies and procedures related to the Federal Anti-Kickback Statute, Title 42, United States Code, Section 1320a-7b (the "Anti-Kickback Statute"), the Company has implemented a compliance program that meets the requirements set forth in Attachment C to the Agreement. The undersigned certify that such compliance program is reasonably designed to detect and prevent violations of the Anti-Kickback Statute throughout the Company's operations.

The undersigned hereby certify that they are the Chief Executive Officer and the Chief Ethics and Compliance Officer of the Company, respectively, and that each has been duly authorized by the Company to sign this certification on behalf of the Company.

This certification shall constitute a material statement and representation by the undersigned by, on behalf of, and for the benefit of the Company to the executive branch of the United States for purposes of 18 U.S.C. § 1001, and such material statement and representation

shall be deemed to have been made in the District of Massachusetts. This certification shall also constitute a record, document, or tangible object in connection with a matter within the jurisdiction of a department and agency of the United States for purposes of 18 U.S.C. § 1519, and such record, document, or tangible object shall be deemed to have been made in the District of Massachusetts.

Date: _____ Name (Printed): _____

Name (Signed): _____
Chief Executive Officer
Veloxis Pharmaceuticals, Inc.

Date: _____ Name (Printed): _____

Name (Signed): _____
Chief Ethics and Compliance Officer
Veloxis Pharmaceuticals, Inc.