

STATE SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into this day 14 of October, 2005. The parties to the Agreement are the State of Michigan (the "State"); Serono, Inc., a Delaware corporation with a principal place of business in Rockland, Massachusetts; Serono Laboratories, Inc., a Massachusetts corporation with a principal place of business in Rockland, Massachusetts (Serono, Inc. and Serono Laboratories, Inc. are hereinafter collectively referred to as "Serono"); Ares Trading S.A., a corporation duly organized under Swiss law with its registered offices in Aubonne, Switzerland; and Serono S.A., a corporation duly organized under Swiss law with its registered offices in Coisins (Vaud), Switzerland (Ares Trading S.A. and Serono S.A. are hereinafter collectively referred to as "Serono S.A."), through their authorized representatives. Collectively, all of the above will be referred to as "the Parties." The Parties now agree as follows:

PREAMBLE

A. WHEREAS, at all relevant times, Serono distributed, marketed and sold pharmaceutical products in the United States, including a drug they sold under the trade name Serostim for the treatment of AIDS wasting or cachexia;

B. WHEREAS, Serono S.A. and Serono are entering into a civil settlement agreement with the United States of America ("the Federal Settlement Agreement"), acting through its Department of Justice and the United States Attorney's Office for the Districts of Massachusetts, Maryland and Connecticut (collectively the "United States"); the Office of Inspector General of the United States Department of Health and Human Services ("HHS-OIG"); the United States Office of Personnel Management ("OPM"); the United States Department of Defense TRICARE Management Activity ("TMA"); and Relators in certain federal False Claims

Act lawsuits, as well as this Agreement and settlement agreements with the other states that will be receiving settlement funds as listed in Exhibit A (the "Medicaid Participating States"), all of which are intended to resolve civil claims against Serono for the Covered Conduct alleged in Paragraph E below;

C. WHEREAS, Serono Laboratories, Inc. has agreed to enter into a plea agreement with the United States Attorney for the District of Massachusetts (the "Plea Agreement"), under which, if the Plea Agreement is approved by the Court, Serono Laboratories, Inc. will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to an Information to be filed in United States of America v. Serono Laboratories, Inc., (District of Massachusetts) (the "Federal Criminal Action") that will allege that: (i) Serono Laboratories, Inc. violated 18 U.S.C. § 371 by conspiring to introduce and deliver for introduction into interstate commerce, with intent to defraud or mislead, adulterated medical devices; and (ii) Serono Laboratories, Inc. violated 18 U.S.C. § 371 by conspiring to knowingly and willfully pay illegal remuneration to health care providers to induce them to refer patients to pharmacies for the furnishing of the drug Serostim for which payments were made in whole or in part by the Medicaid Program;

D. WHEREAS, the State contends that Serono caused to be submitted claims for payment for Serostim to the State's Medical Assistance Program ("Medicaid"), established by Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v;

E. WHEREAS, the State contends that it has civil and administrative claims against Serono under various statutes and common law for engaging in the following alleged conduct involving the marketing, promotion and sale of Serostim (hereinafter referred to as the "Covered Conduct"):

(i) The State contends that, from as early as September 1996, Serono conspired with others to introduce and deliver for introduction into interstate commerce, with intent to defraud or mislead, adulterated medical devices in the form of computer software devices for use in conjunction with bioelectrical impedance analysis (“BIA”) devices, to be used as a tool for calculating body cell mass and/or diagnosing AIDS wasting. The State further contends that the software devices were adulterated because Serono and others had not obtained premarket approval from the United States Food and Drug Administration (“FDA”) to introduce these devices into interstate commerce for these uses. Furthermore, the State contends that, during this time period, Serono knowingly caused false and/or fraudulent claims to be submitted to Medicaid for Serostim that had been dispensed to patients based on testing using this adulterated medical device;

(ii) The State contends that, during the period of 1998 to 2004, Serono knowingly and willfully promoted the sale and use of Serostim for lipodystrophy and body cell mass (“BCM”) wasting (i.e., AIDS wasting defined as a purported loss of or deficient body cell mass), uses for which the FDA has not approved Serostim, i.e., Serono promoted Serostim for “unapproved” or “off-label” uses. The State further contends that Serono’s promotion of Serostim for these unapproved uses violated the Food Drug and Cosmetic Act, 21 U.S.C. §§ 331(a) & (d). Furthermore, the State contends that the uses of Serostim for lipodystrophy and BCM wasting under these circumstances were not medically accepted indications for which Medicaid may reimburse and that, during this time period, Serono knowingly caused false and/or fraudulent claims to be submitted to Medicaid for Serostim that had been dispensed to patients for these indications;

(iii) The State contends that, as part of Serono's marketing and sale of Serostim from 1997 to 2004, Serono knowingly and willfully offered and paid illegal remuneration (including, but not limited to, providing free BIA devices and software, free trips to Cannes, France and SeronAIDS and SALSA survey payments) to physicians in violation of federal and State anti-kickback statutes. Furthermore, the State contends that, during this time period, Serono knowingly caused false and/or fraudulent claims to be submitted to Medicaid for Serostim that had been dispensed to patients as a result of prescriptions by physicians who had been induced to order Serostim by this illegal remuneration;

(iv) The State contends that, during the period 1997 to 2004, Serono knowingly and willfully offered and paid illegal remuneration in the form of rebates and discounts to specialty pharmacies in violation of federal and State anti-kickback statutes. Furthermore, the State contends that, during this time period, Serono knowingly caused the submission of false and/or fraudulent claims to Medicaid by inducing these pharmacies to recommend Serostim or arrange for the use of Serostim by providing the rebates and discounts to them;

(v) The State contends that Serono engaged in misconduct relating to the accelerated approval of Serostim for AIDS wasting in 1996 by the FDA; and

(vi) The State contends that, during the period 1997 to 2004, Serono engaged in misconduct relating to the marketing and sale of Serostim in the United States, including conduct related to the \$36,000 cap; the Serostim Treatment Continuation Program; the unnecessary or unreasonable scripting and use of Serostim and/or the use of Serostim for conditions other than wasting; and any other matters alleged in any qui tam actions in which the State is a party.

F. WHEREAS, the State contends that it has certain authority for administrative and monetary penalties under state and federal law for the Covered Conduct;

G. WHEREAS, this Agreement is neither an admission of facts nor liability by Serono S.A. or Serono (with the exception of such admissions as Serono Laboratories, Inc. makes in connection with any guilty plea to the Information referenced in Paragraph C above and accepted by the Court) nor a concession by the State that its claims are not well founded; and

H. WHEREAS, to avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final settlement as set forth below.

TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. Serono S.A. and Serono shall pay to the United States and the Medicaid Participating States, collectively, the sum of \$567,065,000, plus interest thereon at the average trust fund rate of 4.375% per annum (\$67,970.12 per day) calculated from June 8, 2005 and continuing until and including the day before complete payment is made (the "Settlement Amount"). This sum shall constitute a debt immediately due and owing to the United States on the satisfaction of the conditions of set forth in the Federal Settlement Agreement and to the Medicaid Participating States on the satisfaction of the conditions of payment set forth in this Paragraph. This debt is to be discharged by payments to the Medicaid Participating States under the following terms and conditions:

A. Serono S.A. and Serono shall deposit into an interest bearing account they establish for this purpose ("the State Settlement Account") the sum of two hundred sixty one

million, nine hundred eighty eight thousand dollars (\$261,988,000), plus interest thereon at the average trust fund rate of 4.375% per annum (\$31,402.67 per day) calculated from June 8, 2005 and continuing until and including the day before transfer into the State Settlement Account is made (the "Medicaid State Settlement Amount"), which represents the state-funded portions of the claims settled with the Medicaid Participating States.

B. Serono S.A. shall make such deposit no later than seven (7) business days following the latest date on which either of the following occurs: (i) the Federal Settlement Agreement is fully executed by the Parties and delivered to Serono; and (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea in connection with the Federal Criminal Action as described in Preamble Paragraph C and imposes the agreed-upon sentence.

C. The total portion of the Settlement Amount paid in settlement for alleged injury to the State is \$312,721.69, consisting of a portion paid to the State under this Agreement and another portion paid to the federal government as part of the Federal Settlement Amount. The individual portion of the State Settlement Amount allocable to the State, which shall be paid to the State pursuant to this Agreement, is \$125,309.23 (the "Individual State Settlement Amount"), plus any accrued interest on that portion of the State Settlement Amount. The portion of the Federal Settlement Amount allocable to the State is \$187,412.46.

D. Upon the execution of state settlement agreements with all the Medicaid Participating States, or at any earlier date as otherwise agreed in writing between Serono and the National Association of Medicaid Fraud Control Units Settlement Team (the "NAMFCU Team"), Serono shall transfer the Individual State Settlement Amount and all accrued interest from the State Settlement Account to an account designated by the NAMFCU Team for distribution to the State. Any funds in the State Settlement Account not so disbursed to a state

within two hundred (200) days following deposit of the Medicaid State Settlement Amount into the State Settlement Account shall be disbursed to Serono S.A.

E. If Serono Laboratories, Inc.'s agreed upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the Federal Criminal Action described in Preamble Paragraph C is not accepted by the Court or the Court does not impose the agreed upon disposition for whatever reason, this Agreement shall be null and void at the option of either the State or Serono or Serono S.A. If either the State or Serono or Serono S.A. exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within ten (10) business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Serono and Serono S.A. will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any such civil or administrative claims, actions or proceeding which are brought by the State within 90 calendar days of notification to all other Parties of that rescission, except to the extent such defenses were available before October 6, 2005.

2. In consideration of the obligations of Serono S.A. and Serono set forth in this Agreement, conditioned upon Serono and Serono S.A.'s payment in full of the Settlement Amount, and subject to the exceptions from release set forth at Paragraph 3, below, the State, on behalf of itself, and its officers, agents, agencies, and departments, hereby fully and finally releases Serono S.A. and Serono, and their predecessors, subsidiaries, corporate parents and affiliates, successors and assigns, and their current and former officers, directors, employees and agents from any civil or administrative monetary claims, which the State may have, including without limitation, common law claims for fraud, payment by mistake, and unjust enrichment or disgorgement for the Covered Conduct.

3. Notwithstanding any term of this Agreement, the State specifically does not herein release any person or entity from any of the following claims or liabilities: (a) any potential criminal, civil, or administrative claims arising under State revenue codes; (b) any criminal liability other than as specified in Paragraph 5, below; (c) any liability to the State for any conduct other than the Covered Conduct; (d) any claims based upon obligations created by this Agreement; (e) except as explicitly stated in this Agreement, any administrative liability, including liability for mandatory exclusion from Federal health care programs; (f) any express or implied warranty claims or other claims for defective or deficient products and services; (g) any claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct; (h) any claim based on a failure to deliver items or services due; or (i) any civil or administrative claims against individuals, including current and former directors, officers, employees and agents of Serono S.A. and Serono, and their predecessors, subsidiaries, and their corporate parent and affiliates, who, related to the Covered Conduct, are criminally indicted or charged, or are convicted, or who enter into a criminal plea.

4. In consideration of the obligations of Serono S.A. and Serono in this Agreement, conditioned upon full payment of the Settlement Amount, and except as reserved in Paragraph 3 above, the State agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion or suspension from Medicaid against Serono S.A., Serono, Inc. and, except for Serono Laboratories, Inc., their predecessors, subsidiaries, corporate parents and affiliates, successors and assigns, based upon the Covered Conduct. Nothing in this Agreement precludes the State from taking action against any Serono entity in the event that such entity is excluded by the federal government, or for conduct and practices other than the Covered Conduct. Serono acknowledges that the State does not have the authority to release it

from any claims or actions that may be asserted by private payors or insurers, including those that are paid on a capitated basis for providing health care to Medicaid.

5. This Agreement is expressly conditioned upon resolution of the Federal Criminal Action. In consideration of that action, the State agrees that it shall not investigate, prosecute, or refer for prosecution or investigation to any agency, Serono S.A. and Serono, or their predecessors, subsidiaries, corporate parents and affiliates, successors and assigns for (i) the Covered Conduct or (ii) conduct relating to Serostim known to the State prior to the date hereof.

6. Serono S.A. and Serono, and their predecessors, subsidiaries, corporate parents and affiliates, successors and assigns, hereby fully and finally release the State, its agencies, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that they may have for the Covered Conduct.

7. Serono S.A. and Serono waive and will not assert any defenses they may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Provided, however, that nothing in this paragraph is intended to, or will operate to, limit the scope of Paragraph 5, in which the State agrees not to prosecute or investigate Serono and Serono S.A. for certain conduct.

8. The Settlement Amount to be paid pursuant to Paragraph 1 above will not be decreased as a result of the denial of any claims for payment now being withheld from payment by Medicaid related to the Covered Conduct; and, if applicable, Serono S.A. and Serono agree not to resubmit or cause anyone to resubmit to Medicaid any previously denied claims, which

denials were based on the Covered Conduct, and agree not to appeal or cause the appeal of any such denials of claims.

9. Except as otherwise set forth herein, this Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity, including but not limited to any individual or entity that purchased Serostim from Serono.

10. Nothing in any provision of this Agreement constitutes an agreement by the State concerning the characterization of the Settlement Amount for purposes of the state internal revenue laws.

11. In addition to all other payment and responsibilities under this Agreement, Serono S.A. shall pay all reasonable travel costs and expenses of the NAMFCU negotiating team. This amount shall be paid by separate check or wire transfer made payable to the NAMFCU, after all Medicaid Participating States execute this Agreement or as otherwise agreed in writing between Serono and the NAMFCU Team.

12. Serono and Serono S.A. agree to cooperate fully and truthfully with the State in any ongoing investigation or investigation commenced within five years of the execution of this Agreement of individuals and entities not specifically released by this Agreement (including any parties with whom Serono has or has had a business or professional relationship) relating to the Covered Conduct. More specifically, upon reasonable request from the State, Serono and Serono S.A. shall encourage and facilitate the cooperation of its current and former directors, officers and employees, consistent with the rights and privileges of such individuals. In connection with any investigations referenced herein, Serono and Serono S.A. agree, subject to any applicable privileges, to furnish to the State complete and unredacted copies of all documents, reports,

memoranda of interviews, computerized information and records in its possession, custody or control relating to the State's inquiry.

13. The making of this Agreement, and Serono's and Serono S.A.'s provision of information pursuant to it, shall not be construed by the State as a basis for the exclusion of Serono, Inc.'s products from the State's formulary.

14. The State agrees to dismiss with prejudice any lawsuit specifically as to Serono S.A. and Serono, or their predecessors, subsidiaries, corporate parents and affiliates, successors and assigns, or their current and former officers, directors, employees and agents relating to (i) the Covered Conduct or (ii) conduct relating to Serostim, including any state qui tam action in which the State has intervened and/or has not intervened and/or has the authority to dismiss, currently pending against these entities in the courts of the State, or any Federal Court.

15. If applicable, Serono and Serono S.A. agree that they will not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents or sponsors. Serono and Serono S.A. waive any causes of action against these beneficiaries or their parents or sponsors based upon the claims for payment covered by this Agreement.

16. Serono and Serono S.A. represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

17. Serono Holding, Inc. has entered into a Corporate Integrity Agreement ("CIA") with HHS-OIG. Serono Holding, Inc. and other Serono affiliates in the United States subject to the CIA acknowledge that the CIA does not preclude the State from taking any appropriate action against them for future conduct under the State's laws.

18. The undersigned Serono signatories represent and warrant that they are authorized by their Board of Directors to execute this Agreement. The undersigned State signatories represents that they are signing this Agreement in their official capacity and are authorized to execute this Agreement on behalf of the State.

19. This Agreement is governed by the laws of the State.

20. This Agreement is effective on the date of signature of the last signatory to the Agreement. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

21. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

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

23. Each party agrees to perform any further acts and to execute and deliver any further documents reasonably necessary to carry out this Agreement.

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

FOR THE STATE OF MICHIGAN

By: [Signature]

Dated: 10-11-05

Title: ASSISTANT ATTORNEY GENERAL

FOR THE STATE OF MICHIGAN MEDICAID PROGRAM:

By: [Signature]

Dated: 10-11-2005

Title: Director Bureau of Medicaid Financial Management
Medical Services Administration

SERONO, INC. AND SERONO LABORATORIES, INC.

By: _____

Dated:

Thomas G. Gunning
Vice President and General Counsel
Serono, Inc. and Serono Laboratories, Inc.

By: _____

Dated:

HENRY J. DEPIPPO
MELISSA BAYER TEARNEY
Nixon Peabody LLP
Counsel to Serono, Inc. and Serono Laboratories, Inc.

SERONO S.A. AND ARES TRADING S.A.

By: _____

Dated:

FRANCOIS NAEF
Counsel for Serono S A. and Ares Trading S.A.

FOR THE STATE OF MICHIGAN

By: _____

Dated: _____

Title: _____

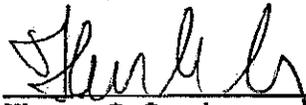
FOR THE STATE OF MICHIGAN MEDICAID PROGRAM:

By: _____

Dated: _____

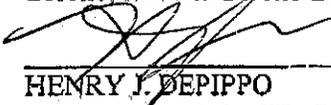
Title: _____

SERONO, INC. AND SERONO LABORATORIES, INC.

By:  _____

Dated: 10/14/05

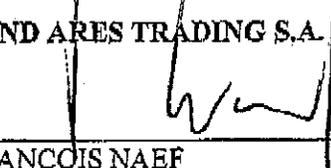
Thomas G. Gunning
Vice President and General Counsel
Serono, Inc. and Serono Laboratories, Inc.

By:  _____

Dated: 10/14/05

HENRY J. DEIPPO
MELISSA BAYER TEARNEY
Nixon Peabody LLP
Counsel to Serono, Inc. and Serono Laboratories, Inc.

SERONO S.A. AND ARES TRADING S.A.

By:  _____

Dated: 10/14/05

FRANCOIS NAEF
Counsel for Serono S.A. and Ares Trading S.A.

Exhibit A
to
State Settlement Agreement

AK
AL
AR
AZ
CA
CO
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DC
DE
FL
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